Momelotinib (Omjjara)

GlaxoSmithKline GmbH & Co. KG

Anhang 4-G zu Modul 4 A

Behandlung von krankheitsbedingter Splenomegalie oder Symptomen bei erwachsenen Patienten mit moderater bis schwerer Anämie, die an primärer Myelofibrose, Post-Polycythaemia Vera-Myelofibrose oder Post-Essentieller Thrombozythämie-Myelofibrose erkrankt sind, und die nicht mit einem Januskinase (JAK)-Inhibitor vorbehandelt sind oder die mit Ruxolitinib behandelt wurden

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Table 2.5502: Overall Survival Analysis by Age
Double-blind Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Subjects with Event					
Death, n(%)	2 (8.3%)	0	3 (4.8%)	1 (1.7%)	
Censor					
Subjects Censored, n(%)	22 (91.7%)	36 (100.0%)	59 (95.2%)	57 (98.3%)	
Kaplan-Meier Estimate of Overall Survival (Months)					
25-percentile (95% CI)	NE (2.14, NE)	NE (NE, NE)	NE (5.68, NE)	NE (NE, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (5.68, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (5.68, NE)	NE (NE, NE)	
Min, Max	1.18, 5.75	3.19, 6.01	0.72, 6.54	2.92, 6.54	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Death in the DB phase is death occurring on or after the 1st DB dose up to the earliest of the last DB dose + 30 days, or the 1st OL dose -1 day.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-os-sub.sas V.03.05 Output file: t-os-age.pdf 24AUG2023:11:04

Table 2.5504: Overall Survival Analysis by Region
Double-blind Treatment Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Subjects with Event					
Death, n(%)	3 (5.7%)	1 (2.0%)	2 (6.1%)	0	
Censor					
Subjects Censored, n(%)	50 (94.3%)	50 (98.0%)	31 (93.9%)	43 (100.0%)	
Kaplan-Meier Estimate of Overall Survival (Months)					
25-percentile (95% CI)	NE (5.68, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Median (95% CI)	NE (5.68, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (5.68, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	1.05, 6.54	2.92, 6.54	0.72, 5.78	4.67, 5.88	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Death in the DB phase is death occurring on or after the 1st DB dose up to the earliest of the last DB dose + 30 days, or the 1st OL dose -1 day.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-os-sub.sas V.03.05 Output file: t-os-geo.pdf 24AUG2023:11:04

Table 2.5507: Overall Survival Analysis by Baseline Hemoglobin Level
Double-blind Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Subjects with Event					
Death, n(%)	1 (3.6%)	1 (4.8%)	4 (6.9%)	0	
Censor					
Subjects Censored, n(%)	27 (96.4%)	20 (95.2%)	54 (93.1%)	73 (100.0%)	
Kaplan-Meier Estimate of Overall Survival (Months)					
25-percentile (95% CI)	NE (1.91, NE)	NE (2.92, NE)	NE (5.68, NE)	NE (NE, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (5.68, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	1.12, 6.54	2.92, 5.62	0.72, 5.78	3.45, 6.54	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Death in the DB phase is death occurring on or after the 1st DB dose up to the earliest of the last DB dose + 30 days, or the 1st OL dose -1 day.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-os-sub.sas V.03.05 Output file: t-os-hgb.pdf 24AUG2023:11:04

Table 2.5506: Overall Survival Analysis by Baseline IPSS Two-Level Risk
Double-blind Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Subjects with Event					
Death, n(%)	2 (7.1%)	0	3 (5.2%)	1 (1.4%)	
Censor					
Subjects Censored, n(%)	26 (92.9%)	24 (100.0%)	55 (94.8%)	69 (98.6%)	
Kaplan-Meier Estimate of Overall Survival (Months)					
25-percentile (95% CI)	NE (5.39, NE)	NE (NE, NE)	NE (5.68, NE)	NE (NE, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (5.68, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	1.08, 5.59	3.19, 6.54	0.72, 6.54	2.92, 6.24	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Death in the DB phase is death occurring on or after the 1st DB dose up to the earliest of the last DB dose + 30 days, or the 1st OL dose -1 day.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-os-sub.sas V.03.05 Output file: t-os-ipss2.pdf 24AUG2023:11:04

Table 2.5505: Overall Survival Analysis by Baseline IPSS Three-Level Risk
Double-blind Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Subjects with Event				
Death, n(%)	0	0	2 (7.7%)	0
Censor				
Subjects Censored, n(%)	2 (100.0%)	4 (100.0%)	24 (92.3%)	20 (100.0%)
Kaplan-Meier Estimate of Overall Survival (Months)				
25-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (2.14, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Min, Max	5.45, 5.55	5.45, 6.54	1.08, 5.59	3.19, 5.75
Stratified Log-Rank Test p-value	NA		NA	
Adjusted Hazard Ratio (95% CI)	NA		NA	
Unstratified Log-Rank Test p-value	NA		NA	
Unadjusted Hazard Ratio (95% CI)	NA		NA	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Death in the DB phase is death occurring on or after the 1st DB dose up to the earliest of the last DB dose + 30 days, or the 1st OL dose -1 day.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-os-sub.sas V.03.05 Output file: t-os-ipss3.pdf 24AUG2023:11:04

Table 2.5505: Overall Survival Analysis by Baseline IPSS Three-Level Risk
Double-blind Treatment Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=58)	High Risk RUX (N=70)	p-value
Subjects with Event			
Death, n(%)	3 (5.2%)	1 (1.4%)	
Censor			
Subjects Censored, n(%)	55 (94.8%)	69 (98.6%)	
Kaplan-Meier Estimate of Overall Survival (Months)			
25-percentile (95% CI)	NE (5.68, NE)	NE (NE, NE)	
Median (95% CI)	NE (5.68, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	
Min, Max	0.72, 6.54	2.92, 6.24	
Stratified Log-Rank Test p-value	NA		
Adjusted Hazard Ratio (95% CI)	NA		
Unstratified Log-Rank Test p-value	NA		
Unadjusted Hazard Ratio (95% CI)	NA		
P-value for interaction test			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Death in the DB phase is death occurring on or after the 1st DB dose up to the earliest of the last DB dose + 30 days, or the 1st OL dose -1 day.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-os-sub.sas V.03.05 Output file: t-os-ipss3.pdf 24AUG2023:11:04

Table 2.5508: Overall Survival Analysis by Baseline MF Disease Status
Double-blind Treatment Phase
ITT-Anemic Analysis Set

	Post-ET Myelofibrosis		Post-PV Myelofibrosis	
	MMB (N=16)	RUX (N=28)	MMB (N=11)	RUX (N=12)
Subjects with Event				
Death, n(%)	0	1 (3.6%)	2 (18.2%)	0
Censor				
Subjects Censored, n(%)	16 (100.0%)	27 (96.4%)	9 (81.8%)	12 (100.0%)
Kaplan-Meier Estimate of Overall Survival (Months)				
25-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (1.91, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (1.91, NE)	NE (NE, NE)
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Min, Max	1.05, 6.54	2.92, 6.24	1.12, 5.59	4.70, 5.75
Stratified Log-Rank Test p-value	NA		NA	
Adjusted Hazard Ratio (95% CI)	NA		NA	
Unstratified Log-Rank Test p-value	NA		NA	
Unadjusted Hazard Ratio (95% CI)	NA		NA	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Death in the DB phase is death occurring on or after the 1st DB dose up to the earliest of the last DB dose + 30 days, or the 1st OL dose -1 day.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-os-sub.sas V.03.05 Output file: t-os-mf.pdf 24AUG2023:11:04

Table 2.5508: Overall Survival Analysis by Baseline MF Disease Status
Double-blind Treatment Phase
ITT-Anemic Analysis Set

(Continued)	Primary Myelofibrosis MMB (N=59)	Primary Myelofibrosis RUX (N=54)	p-value
Subjects with Event			
Death, n(%)	3 (5.1%)	0	
Censor			
Subjects Censored, n(%)	56 (94.9%)	54 (100.0%)	
Kaplan-Meier Estimate of Overall Survival (Months)			
25-percentile (95% CI)	5.68 (5.68, NE)	NE (NE, NE)	
Median (95% CI)	NE (5.68, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (5.68, NE)	NE (NE, NE)	
Min, Max	0.72, 5.78	3.45, 6.54	
Stratified Log-Rank Test p-value	NA		
Adjusted Hazard Ratio (95% CI)	NA		
Unstratified Log-Rank Test p-value	NA		
Unadjusted Hazard Ratio (95% CI)	NA		
P-value for interaction test			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Death in the DB phase is death occurring on or after the 1st DB dose up to the earliest of the last DB dose + 30 days, or the 1st OL dose -1 day.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-os-sub.sas V.03.05 Output file: t-os-mf.pdf 24AUG2023:11:04

Table 2.5503: Overall Survival Analysis by Gender
Double-blind Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Subjects with Event					
Death, n(%)	2 (4.0%)	1 (1.8%)	3 (8.3%)	0	
Censor					
Subjects Censored, n(%)	48 (96.0%)	55 (98.2%)	33 (91.7%)	38 (100.0%)	
Kaplan-Meier Estimate of Overall Survival (Months)					
25-percentile (95% CI)	5.68 (5.68, NE)	NE (NE, NE)	NE (5.39, NE)	NE (NE, NE)	
Median (95% CI)	NE (5.68, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (5.68, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	1.51, 5.75	2.92, 6.54	0.72, 6.54	3.98, 6.24	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Death in the DB phase is death occurring on or after the 1st DB dose up to the earliest of the last DB dose + 30 days, or the 1st OL dose -1 day.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-os-sub.sas V.03.05 Output file: t-os-sex.pdf 24AUG2023:11:04

Table 2.5510: Overall Survival Analysis by Baseline Spleen Volume
Double-blind Treatment Phase
ITT-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Subjects with Event					
Death, n(%)	2 (4.3%)	0	3 (7.7%)	1 (2.0%)	
Censor					
Subjects Censored, n(%)	45 (95.7%)	43 (100.0%)	36 (92.3%)	50 (98.0%)	
Kaplan-Meier Estimate of Overall Survival (Months)					
25-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	5.68 (5.68, NE)	NE (NE, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (5.68, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (5.68, NE)	NE (NE, NE)	
Min, Max	0.72, 5.78	3.98, 6.24	1.08, 6.54	2.92, 6.54	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Death in the DB phase is death occurring on or after the 1st DB dose up to the earliest of the last DB dose + 30 days, or the 1st OL dose -1 day.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-os-sub.sas V.03.05 Output file: t-os-svb.pdf 24AUG2023:11:05

Table 2.5509: Overall Survival Analysis by Baseline TSS
Double-blind Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Subjects with Event					
Death, n(%)	0	0	5 (12.2%)	1 (2.6%)	
Censor					
Subjects Censored, n(%)	44 (100.0%)	55 (100.0%)	36 (87.8%)	37 (97.4%)	
Kaplan-Meier Estimate of Overall Survival (Months)					
25-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	5.68 (5.39, NE)	NE (NE, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (5.68, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (5.68, NE)	NE (NE, NE)	
Min, Max	1.12, 6.54	3.19, 6.01	0.72, 5.78	2.92, 6.54	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Death in the DB phase is death occurring on or after the 1st DB dose up to the earliest of the last DB dose + 30 days, or the 1st OL dose -1 day.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-os-sub.sas V.03.05 Output file: t-os-tss.pdf 24AUG2023:11:04

Table 2.5602: Analysis of Time to Leukemic Transformation by Age
Double-blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Subjects with Event					
Leukemic Transformation, n(%)	1 (4.2%)	0	0	0	
Censor					
Subjects Censored, n(%)	23 (95.8%)	36 (100.0%)	62 (100.0%)	58 (100.0%)	
Kaplan-Meier Estimate of Time to Leukemic Transformation (Months)					
25-percentile (95% CI)	NE (5.26, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	1.18, 5.75	3.22, 6.05	0.72, 6.54	2.92, 6.54	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-tte-lt-sub.sas V.03.05 Output file: t-tte-lt-age.pdf 24AUG2023:11:04

Table 2.5604: Analysis of Time to Leukemic Transformation by Region
Double-blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Subjects with Event					
Leukemic Transformation, n(%)	1 (1.9%)	0	0	0	
Censor					
Subjects Censored, n(%)	52 (98.1%)	51 (100.0%)	33 (100.0%)	43 (100.0%)	
Kaplan-Meier Estimate of Time to Leukemic Transformation (Months)					
25-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	1.08, 6.54	2.92, 6.54	0.72, 5.78	4.67, 5.88	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-tte-lt-sub.sas V.03.05 Output file: t-tte-lt-geo.pdf 24AUG2023:11:04

Table 2.5607: Analysis of Time to Leukemic Transformation by Baseline Hemoglobin Level
Double-blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Subjects with Event					
Leukemic Transformation, n(%)	0	0	1 (1.7%)	0	
Censor					
Subjects Censored, n(%)	28 (100.0%)	21 (100.0%)	57 (98.3%)	73 (100.0%)	
Kaplan-Meier Estimate of Time to Leukemic Transformation (Months)					
25-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	1.15, 6.54	2.92, 5.65	0.72, 5.78	3.45, 6.54	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-tte-lt-sub.sas V.03.05 Output file: t-tte-lt-hgb.pdf 24AUG2023:11:04

Table 2.5606: Analysis of Time to Leukemic Transformation by Baseline IPSS Two-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Subjects with Event					
Leukemic Transformation, n(%)	0	0	1 (1.7%)	0	
Censor					
Subjects Censored, n(%)	28 (100.0%)	24 (100.0%)	57 (98.3%)	70 (100.0%)	
Kaplan-Meier Estimate of Time to Leukemic Transformation (Months)					
25-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	1.28, 5.65	3.22, 6.54	0.72, 6.54	2.92, 6.28	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-tte-lt-sub.sas V.03.05 Output file: t-tte-lt-ipss2.pdf 24AUG2023:11:04

Table 2.5605: Analysis of Time to Leukemic Transformation by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Subjects with Event				
Leukemic Transformation, n(%)	0	0	0	0
Censor				
Subjects Censored, n(%)	2 (100.0%)	4 (100.0%)	26 (100.0%)	20 (100.0%)
Kaplan-Meier Estimate of Time to Leukemic Transformation (Months)				
25-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Min, Max	5.52, 5.55	5.45, 6.54	1.28, 5.65	3.22, 5.78
Stratified Log-Rank Test p-value	NA		NA	
Adjusted Hazard Ratio (95% CI)	NA		NA	
Unstratified Log-Rank Test p-value	NA		NA	
Unadjusted Hazard Ratio (95% CI)	NA		NA	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-tte-lt-sub.sas V.03.05 Output file: t-tte-lt-ipss3.pdf 24AUG2023:11:04

Table 2.5605: Analysis of Time to Leukemic Transformation by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=58)	High Risk RUX (N=70)	p-value
Subjects with Event			
Leukemic Transformation, n(%)	1 (1.7%)	0	
Censor			
Subjects Censored, n(%)	57 (98.3%)	70 (100.0%)	
Kaplan-Meier Estimate of Time to Leukemic Transformation (Months)			
25-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	
Min, Max	0.72, 6.54	2.92, 6.28	
Stratified Log-Rank Test p-value	NA		
Adjusted Hazard Ratio (95% CI)	NA		
Unstratified Log-Rank Test p-value	NA		
Unadjusted Hazard Ratio (95% CI)	NA		
P-value for interaction test			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-tte-lt-sub.sas V.03.05 Output file: t-tte-lt-ipss3.pdf 24AUG2023:11:04

Table 2.5608: Analysis of Time to Leukemic Transformation by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

	Post-ET Myelofibrosis		Post-PV Myelofibrosis	
	MMB (N=16)	RUX (N=28)	MMB (N=11)	RUX (N=12)
Subjects with Event				
Leukemic Transformation, n(%)	1 (6.3%)	0	0	0
Censor				
Subjects Censored, n(%)	15 (93.8%)	28 (100.0%)	11 (100.0%)	12 (100.0%)
Kaplan-Meier Estimate of Time to Leukemic Transformation (Months)				
25-percentile (95% CI)	NE (5.26, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Min, Max	1.08, 6.54	2.92, 6.28	1.15, 5.65	4.73, 5.75
Stratified Log-Rank Test p-value	NA		NA	
Adjusted Hazard Ratio (95% CI)	NA		NA	
Unstratified Log-Rank Test p-value	NA		NA	
Unadjusted Hazard Ratio (95% CI)	NA		NA	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-tte-lt-sub.sas V.03.05 Output file: t-tte-lt-mf.pdf 24AUG2023:11:04

Table 2.5608: Analysis of Time to Leukemic Transformation by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

(Continued)	Primary Myelofibrosis MMB (N=59)	Primary Myelofibrosis RUX (N=54)	p-value
Subjects with Event			
Leukemic Transformation, n(%)	0	0	
Censor			
Subjects Censored, n(%)	59 (100.0%)	54 (100.0%)	
Kaplan-Meier Estimate of Time to Leukemic Transformation (Months)			
25-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	
Min, Max	0.72, 5.78	3.45, 6.54	
Stratified Log-Rank Test p-value	NA		
Adjusted Hazard Ratio (95% CI)	NA		
Unstratified Log-Rank Test p-value	NA		
Unadjusted Hazard Ratio (95% CI)	NA		
P-value for interaction test			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-tte-lt-sub.sas V.03.05 Output file: t-tte-lt-mf.pdf 24AUG2023:11:04

Table 2.5603: Analysis of Time to Leukemic Transformation by Gender
Double-blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Subjects with Event					
Leukemic Transformation, n(%)	1 (2.0%)	0	0	0	
Censor					
Subjects Censored, n(%)	49 (98.0%)	56 (100.0%)	36 (100.0%)	38 (100.0%)	
Kaplan-Meier Estimate of Time to Leukemic Transformation (Months)					
25-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	1.51, 5.72	2.92, 6.54	0.72, 6.54	3.98, 6.28	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-tte-lt-sub.sas V.03.05 Output file: t-tte-lt-sex.pdf 24AUG2023:11:04

Table 2.5610: Analysis of Time to Leukemic Transformation by Baseline Spleen Volume
Double-blind Phase
ITT-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Subjects with Event					
Leukemic Transformation, n(%)	0	0	1 (2.6%)	0	
Censor					
Subjects Censored, n(%)	47 (100.0%)	43 (100.0%)	38 (97.4%)	51 (100.0%)	
Kaplan-Meier Estimate of Time to Leukemic Transformation (Months)					
25-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	0.72, 5.78	3.98, 6.28	1.15, 6.54	2.92, 6.54	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-tte-lt-sub.sas V.03.05 Output file: t-tte-lt-svb.pdf 24AUG2023:11:04

Table 2.5609: Analysis of Time to Leukemic Transformation by Baseline TSS
Double-blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Subjects with Event					
Leukemic Transformation, n(%)	0	0	1 (2.4%)	0	
Censor					
Subjects Censored, n(%)	44 (100.0%)	55 (100.0%)	40 (97.6%)	38 (100.0%)	
Kaplan-Meier Estimate of Time to Leukemic Transformation (Months)					
25-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	1.15, 6.54	3.22, 6.11	0.72, 5.78	2.92, 6.54	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no) baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-tte-lt-sub.sas V.03.05 Output file: t-tte-lt-tss.pdf 24AUG2023:11:04

Table 2.0102: Analysis of Splenic Response Rate at Week 24 by Age
Double-blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Splenic Response Rate at Week 24					
Responder, n(%)	6 (25.0%)	13 (36.1%)	21 (33.9%)	18 (31.0%)	
95% Exact CI	0.0977, 0.4671	0.2082, 0.5378	0.2233, 0.4701	0.1954, 0.4454	
Noninferior Proportion Difference - Stratified CMH Method (95% CI)	-0.01 (-0.24, 0.23)		0.13 (-0.01, 0.28)		
p-value	0.96		0.070		
Noninferior Proportion Difference - Unstratified CMH Method (95% CI)	0.03 (-0.17, 0.24)		0.15 (0.01, 0.29)		
p-value	0.75		0.032		
Superior Proportion Difference - Stratified CMH Method (95% CI)	-0.16 (-0.43, 0.11)		0.01 (-0.17, 0.19)		
p-value	0.25		0.92		
Superior Proportion Difference - Unstratified CMH Method (95% CI)	-0.11 (-0.35, 0.13)		0.03 (-0.14, 0.20)		
p-value	0.36		0.74		
Superior Proportion Difference - Unstratified Exact Method (95% CI)	-0.11 (-0.36, 0.15)		0.03 (-0.15, 0.20)		
p-value	0.41		0.85		
Unadjusted Inverse Relative Risk (95% CI)	1.44 (0.64, 3.27)		0.92 (0.55, 1.54)		
p-value [1]	0.38		0.74		
Unadjusted interaction test for Treatment*Age Group [3]					0.34

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-srr24-db-gba.sas V.03.05 Output file: t-sg-srr24-db-gba-age.pdf 29AUG2023: 9:01

Table 2.0102: Analysis of Splenic Response Rate at Week 24 by Age
Double-blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Unadjusted Inverse Odds Ratio (95% CI)	1.70 (0.54, 5.34)		0.88 (0.41, 1.89)		
p-value [1]	0.37		0.74		
Unadjusted Absolute Risk Difference (95% CI)	-0.11 (-0.34, 0.12)		0.03 (-0.14, 0.20)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Age Group [3]					0.40
Non-Responder, n(%)	18 (75.0%)	23 (63.9%)	41 (66.1%)	40 (69.0%)	
Baseline Spleen Volume not available	0	0	0	0	
Spleen Volume at Week 24 not available	4 (16.7%)	3 (8.3%)	12 (19.4%)	5 (8.6%)	
>0% Spleen Volume increase at Week 24	5 (20.8%)	4 (11.1%)	5 (8.1%)	4 (6.9%)	
<35% Spleen Volume reduction at Week 24	14 (58.3%)	20 (55.6%)	29 (46.8%)	35 (60.3%)	
Last participation date < Day 141 in DB phase	2 (8.3%)	2 (5.6%)	10 (16.1%)	2 (3.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-srr24-db-gba.sas V.03.05 Output file: t-sg-srr24-db-gba-age.pdf 29AUG2023: 9:01

Table 2.0107: Analysis of Splenic Response Rate at Week 24 by Baseline Hemoglobin Level
Double-blind Phase
ITT-Anemic Analysis Set

	HGB <8g/dL		HGB >=8g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Splenic Response Rate at Week 24					
Responder, n(%)	6 (21.4%)	7 (33.3%)	21 (36.2%)	24 (32.9%)	
95% Exact CI	0.0830, 0.4095	0.1459, 0.5697	0.2399, 0.4988	0.2233, 0.4487	
Noninferior Proportion Difference - Stratified CMH Method (95% CI)	0.02 (-0.17, 0.21)		0.18 (0.03, 0.32)		
p-value	0.83		0.018		
Noninferior Proportion Difference - Unstratified CMH Method (95% CI)	0.01 (-0.19, 0.21)		0.16 (0.02, 0.31)		
p-value	0.89		0.022		
Superior Proportion Difference - Stratified CMH Method (95% CI)	-0.11 (-0.35, 0.13)		0.05 (-0.12, 0.22)		
p-value	0.36		0.56		
Superior Proportion Difference - Unstratified CMH Method (95% CI)	-0.12 (-0.38, 0.14)		0.03 (-0.13, 0.20)		
p-value	0.37		0.69		
Superior Proportion Difference - Unstratified Exact Method (95% CI)	-0.12 (-0.39, 0.17)		0.03 (-0.14, 0.20)		
p-value	0.51		0.71		
Unadjusted Inverse Relative Risk (95% CI)	1.56 (0.61, 3.95)		0.91 (0.57, 1.46)		
p-value [1]	0.35		0.69		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.32

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-srr24-db-gba.sas V.03.05 Output file: t-sg-srr24-db-gba-hgb.pdf 29AUG2023: 9:01

Table 2.0107: Analysis of Splenic Response Rate at Week 24 by Baseline Hemoglobin Level
Double-blind Phase
ITT-Anemic Analysis Set

	HGB <8g/dL		HGB >=8g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Unadjusted Inverse Odds Ratio (95% CI)	1.83 (0.51, 6.59)		0.86 (0.42, 1.78)		
p-value [1]	0.35		0.69		
Unadjusted Absolute Risk Difference (95% CI)	-0.12 (-0.37, 0.13)		0.03 (-0.13, 0.20)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.51 (0.61, 3.72)		0.86 (0.54, 1.38)		
p-value [2]	0.37		0.54		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.29
Non-Responder, n(%)	22 (78.6%)	14 (66.7%)	37 (63.8%)	49 (67.1%)	
Baseline Spleen Volume not available	0	0	0	0	
Spleen Volume at Week 24 not available	5 (17.9%)	3 (14.3%)	11 (19.0%)	5 (6.8%)	
>0% Spleen Volume increase at Week 24	4 (14.3%)	3 (14.3%)	6 (10.3%)	5 (6.8%)	
<35% Spleen Volume reduction at Week 24	17 (60.7%)	11 (52.4%)	26 (44.8%)	44 (60.3%)	
Last participation date < Day 141 in DB phase	5 (17.9%)	2 (9.5%)	7 (12.1%)	2 (2.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-srr24-db-gba.sas V.03.05 Output file: t-sg-srr24-db-gba-hgb.pdf 29AUG2023: 9:01

Table 2.0106: Analysis of Splenic Response Rate at Week 24 by Baseline IPSS Two-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Splenic Response Rate at Week 24					
Responder, n(%)	8 (28.6%)	9 (37.5%)	19 (32.8%)	22 (31.4%)	
95% Exact CI	0.1322, 0.4867	0.1880, 0.5941	0.2101, 0.4634	0.2085, 0.4363	
Noninferior Proportion Difference - Stratified CMH Method (95% CI)	0.09 (-0.15, 0.33)		0.14 (0.00, 0.28)		
p-value	0.48		0.050		
Noninferior Proportion Difference - Unstratified CMH Method (95% CI)	0.06 (-0.15, 0.27)		0.14 (0.00, 0.28)		
p-value	0.57		0.050		
Superior Proportion Difference - Stratified CMH Method (95% CI)	-0.07 (-0.37, 0.23)		0.02 (-0.15, 0.19)		
p-value	0.65		0.82		
Superior Proportion Difference - Unstratified CMH Method (95% CI)	-0.09 (-0.35, 0.17)		0.01 (-0.15, 0.18)		
p-value	0.50		0.87		
Superior Proportion Difference - Unstratified Exact Method (95% CI)	-0.09 (-0.35, 0.18)		0.01 (-0.16, 0.19)		
p-value	0.56		1.00		
Unadjusted Inverse Relative Risk (95% CI)	1.31 (0.60, 2.87)		0.96 (0.58, 1.59)		
p-value [1]	0.49		0.87		
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.51

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-srr24-db-gba.sas V.03.05 Output file: t-sg-srr24-db-gba-ip2.pdf 29AUG2023: 9:01

Table 2.0106: Analysis of Splenic Response Rate at Week 24 by Baseline IPSS Two-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Unadjusted Inverse Odds Ratio (95% CI)	1.50 (0.47, 4.80)		0.94 (0.45, 1.98)		
p-value [1]	0.49		0.87		
Unadjusted Absolute Risk Difference (95% CI)	-0.09 (-0.35, 0.17)		0.01 (-0.15, 0.18)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.24 (0.54, 2.84)		NE		
p-value [2]	0.62		NE		
Adjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.61
Non-Responder, n(%)	20 (71.4%)	15 (62.5%)	39 (67.2%)	48 (68.6%)	
Baseline Spleen Volume not available	0	0	0	0	
Spleen Volume at Week 24 not available	5 (17.9%)	2 (8.3%)	11 (19.0%)	6 (8.6%)	
>0% Spleen Volume increase at Week 24	4 (14.3%)	3 (12.5%)	6 (10.3%)	5 (7.1%)	
<35% Spleen Volume reduction at Week 24	15 (53.6%)	13 (54.2%)	28 (48.3%)	42 (60.0%)	
Last participation date < Day 141 in DB phase	3 (10.7%)	2 (8.3%)	9 (15.5%)	2 (2.9%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-srr24-db-gba.sas V.03.05 Output file: t-sg-srr24-db-gba-ip2.pdf 29AUG2023: 9:01

Table 2.0105: Analysis of Splenic Response Rate at Week 24 by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Splenic Response Rate at Week 24				
Responder, n(%)	2 (100.0%)	2 (50.0%)	6 (23.1%)	7 (35.0%)
95% Exact CI	0.1581, 1.0000	0.0676, 0.9324	0.0897, 0.4365	0.1539, 0.5922
Noninferior Proportion Difference - Stratified CMH Method (95% CI)	0.70 (-0.24, 1.64)		0.04 (-0.19, 0.27)	
p-value	0.14		0.73	
Noninferior Proportion Difference - Unstratified CMH Method (95% CI)	0.70 (-0.11, 1.51)		0.02 (-0.19, 0.23)	
p-value	0.089		0.85	
Superior Proportion Difference - Stratified CMH Method (95% CI)	0.50 (-0.72, 1.72)		-0.11 (-0.40, 0.18)	
p-value	0.42		0.47	
Superior Proportion Difference - Unstratified CMH Method (95% CI)	0.50 (-0.42, 1.42)		-0.12 (-0.39, 0.15)	
p-value	0.29		0.39	
Superior Proportion Difference - Unstratified Exact Method (95% CI)	0.50 (-0.45, 0.99)		-0.12 (-0.40, 0.17)	
p-value	0.47		0.51	
Unadjusted Inverse Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.0105: Analysis of Splenic Response Rate at Week 24 by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=58)	High Risk RUX (N=70)	p-value
Splenic Response Rate at Week 24			
Responder, n(%)	19 (32.8%)	22 (31.4%)	
95% Exact CI	0.2101, 0.4634	0.2085, 0.4363	
Noninferior Proportion Difference - Stratified CMH Method (95% CI)	0.14 (0.00, 0.28)		
p-value	0.050		
Noninferior Proportion Difference - Unstratified CMH Method (95% CI)	0.14 (0.00, 0.28)		
p-value	0.050		
Superior Proportion Difference - Stratified CMH Method (95% CI)	0.02 (-0.15, 0.19)		
p-value	0.82		
Superior Proportion Difference - Unstratified CMH Method (95% CI)	0.01 (-0.15, 0.18)		
p-value	0.87		
Superior Proportion Difference - Unstratified Exact Method (95% CI)	0.01 (-0.16, 0.19)		
p-value	1.00		
Unadjusted Inverse Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.0105: Analysis of Splenic Response Rate at Week 24 by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Unadjusted Inverse Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Non-Responder, n(%)	0	2 (50.0%)	20 (76.9%)	13 (65.0%)
Baseline Spleen Volume not available	0	0	0	0
Spleen Volume at Week 24 not available	0	0	5 (19.2%)	2 (10.0%)
>0% Spleen Volume increase at Week 24	0	2 (50.0%)	4 (15.4%)	1 (5.0%)
<35% Spleen Volume reduction at Week 24	0	2 (50.0%)	15 (57.7%)	11 (55.0%)
Last participation date < Day 141 in DB phase	0	0	3 (11.5%)	2 (10.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.0105: Analysis of Splenic Response Rate at Week 24 by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=58)	High Risk RUX (N=70)	p-value
Unadjusted Inverse Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	39 (67.2%)	48 (68.6%)	
Baseline Spleen Volume not available	0	0	
Spleen Volume at Week 24 not available	11 (19.0%)	6 (8.6%)	
>0% Spleen Volume increase at Week 24	6 (10.3%)	5 (7.1%)	
<35% Spleen Volume reduction at Week 24	28 (48.3%)	42 (60.0%)	
Last participation date < Day 141 in DB phase	9 (15.5%)	2 (2.9%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.0108: Analysis of Splenic Response Rate at Week 24 by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
Splenic Response Rate at Week 24				
Responder, n(%)	21 (35.6%)	17 (31.5%)	2 (12.5%)	9 (32.1%)
95% Exact CI	0.2355, 0.4913	0.1952, 0.4555	0.0155, 0.3835	0.1588, 0.5235
Noninferior Proportion Difference - Stratified CMH Method (95% CI)	0.16 (0.02, 0.30)		-0.04 (-0.29, 0.22)	
p-value	0.027		0.78	
Noninferior Proportion Difference - Unstratified CMH Method (95% CI)	0.17 (0.02, 0.31)		-0.07 (-0.28, 0.14)	
p-value	0.023		0.52	
Superior Proportion Difference - Stratified CMH Method (95% CI)	0.03 (-0.15, 0.20)		-0.16 (-0.46, 0.13)	
p-value	0.76		0.28	
Superior Proportion Difference - Unstratified CMH Method (95% CI)	0.04 (-0.13, 0.22)		-0.20 (-0.45, 0.06)	
p-value	0.65		0.13	
Superior Proportion Difference - Unstratified Exact Method (95% CI)	0.04 (-0.14, 0.22)		-0.20 (-0.48, 0.12)	
p-value	0.69		0.28	
Unadjusted Inverse Relative Risk (95% CI)	0.88 (0.52, 1.49)		2.57 (0.63, 10.47)	
p-value [1]	0.64		0.19	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-srr24-db-gba.sas V.03.05 Output file: t-sg-srr24-db-gba-mf.pdf 29AUG2023: 9:01

Table 2.0108: Analysis of Splenic Response Rate at Week 24 by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

(Continued)	Post-PV Myelofibrosis MMB (N=11)	Post-PV Myelofibrosis RUX (N=12)	p-value
Splenic Response Rate at Week 24			
Responder, n(%)	4 (36.4%)	5 (41.7%)	
95% Exact CI	0.1093, 0.6921	0.1517, 0.7233	
Noninferior Proportion Difference - Stratified CMH Method (95% CI)	0.01 (-0.30, 0.31)		
p-value	0.97		
Noninferior Proportion Difference - Unstratified CMH Method (95% CI)	0.11 (-0.23, 0.46)		
p-value	0.52		
Superior Proportion Difference - Stratified CMH Method (95% CI)	-0.23 (-0.67, 0.21)		
p-value	0.31		
Superior Proportion Difference - Unstratified CMH Method (95% CI)	-0.05 (-0.47, 0.37)		
p-value	0.80		
Superior Proportion Difference - Unstratified Exact Method (95% CI)	-0.05 (-0.46, 0.35)		
p-value	1.00		
Unadjusted Inverse Relative Risk (95% CI)	1.15 (0.41, 3.21)		
p-value [1]	0.80		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.27

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-srr24-db-gba.sas V.03.05 Output file: t-sg-srr24-db-gba-mf.pdf 29AUG2023: 9:01

Table 2.0108: Analysis of Splenic Response Rate at Week 24 by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
Unadjusted Inverse Odds Ratio (95% CI)	0.83 (0.38, 1.82)		3.32 (0.62, 17.80)	
p-value [1]	0.64		0.16	
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.13, 0.22)		-0.20 (-0.43, 0.04)	
Adjusted Inverse Relative Risk (95% CI) [2]	0.92 (0.55, 1.55)		NE	
p-value [2]	0.76		NE	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	38 (64.4%)	37 (68.5%)	14 (87.5%)	19 (67.9%)
Baseline Spleen Volume not available	0	0	0	0
Spleen Volume at Week 24 not available	9 (15.3%)	5 (9.3%)	4 (25.0%)	2 (7.1%)
>0% Spleen Volume increase at Week 24	7 (11.9%)	4 (7.4%)	1 (6.3%)	3 (10.7%)
<35% Spleen Volume reduction at Week 24	29 (49.2%)	32 (59.3%)	10 (62.5%)	17 (60.7%)
Last participation date < Day 141 in DB phase	7 (11.9%)	2 (3.7%)	2 (12.5%)	2 (7.1%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-srr24-db-gba.sas V.03.05 Output file: t-sg-srr24-db-gba-mf.pdf 29AUG2023: 9:01

Table 2.0108: Analysis of Splenic Response Rate at Week 24 by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

(Continued)	Post-PV Myelofibrosis MMB (N=11)	Post-PV Myelofibrosis RUX (N=12)	p-value
Unadjusted Inverse Odds Ratio (95% CI)	1.25 (0.23, 6.71)		
p-value [1]	0.79		
Unadjusted Absolute Risk Difference (95% CI)	-0.05 (-0.45, 0.35)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.36
Non-Responder, n(%)	7 (63.6%)	7 (58.3%)	
Baseline Spleen Volume not available	0	0	
Spleen Volume at Week 24 not available	3 (27.3%)	1 (8.3%)	
>0% Spleen Volume increase at Week 24	2 (18.2%)	1 (8.3%)	
<35% Spleen Volume reduction at Week 24	4 (36.4%)	6 (50.0%)	
Last participation date < Day 141 in DB phase	3 (27.3%)	0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-srr24-db-gba.sas V.03.05 Output file: t-sg-srr24-db-gba-mf.pdf 29AUG2023: 9:01

Table 2.0104: Analysis of Splenic Response Rate at Week 24 by Region
Double-blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Splenic Response Rate at Week 24					
Responder, n(%)	17 (32.1%)	16 (31.4%)	10 (30.3%)	15 (34.9%)	
95% Exact CI	0.1992, 0.4632	0.1911, 0.4589	0.1559, 0.4871	0.2101, 0.5093	
Noninferior Proportion Difference - Stratified CMH Method (95% CI)	0.16 (0.01, 0.32)		0.08 (-0.10, 0.27)		
p-value	0.041		0.38		
Noninferior Proportion Difference - Unstratified CMH Method (95% CI)	0.13 (-0.02, 0.28)		0.09 (-0.09, 0.28)		
p-value	0.081		0.31		
Superior Proportion Difference - Stratified CMH Method (95% CI)	0.05 (-0.13, 0.24)		-0.06 (-0.28, 0.16)		
p-value	0.58		0.60		
Superior Proportion Difference - Unstratified CMH Method (95% CI)	0.01 (-0.17, 0.19)		-0.05 (-0.26, 0.17)		
p-value	0.94		0.68		
Superior Proportion Difference - Unstratified Exact Method (95% CI)	0.01 (-0.18, 0.20)		-0.05 (-0.27, 0.18)		
p-value	1.00		0.81		
Unadjusted Inverse Relative Risk (95% CI)	0.98 (0.56, 1.72)		1.15 (0.60, 2.23)		
p-value [1]	0.94		0.68		
Unadjusted interaction test for Treatment*Region [3]					0.71
Unadjusted Inverse Odds Ratio (95% CI)	0.97 (0.42, 2.21)		1.23 (0.47, 3.26)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-srr24-db-gba.sas V.03.05 Output file: t-sg-srr24-db-gba-reg.pdf 29AUG2023: 9:01

Table 2.0104: Analysis of Splenic Response Rate at Week 24 by Region
Double-blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
p-value [1]	0.94		0.67		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.17, 0.19)		-0.05 (-0.26, 0.17)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.84 (0.48, 1.48)		NE		
p-value [2]	0.55		NE		
Adjusted interaction test for Treatment*Region [3]					0.49
Non-Responder, n(%)	36 (67.9%)	35 (68.6%)	23 (69.7%)	28 (65.1%)	
Baseline Spleen Volume not available	0	0	0	0	
Spleen Volume at Week 24 not available	9 (17.0%)	4 (7.8%)	7 (21.2%)	4 (9.3%)	
>0% Spleen Volume increase at Week 24	5 (9.4%)	6 (11.8%)	5 (15.2%)	2 (4.7%)	
<35% Spleen Volume reduction at Week 24	27 (50.9%)	31 (60.8%)	16 (48.5%)	24 (55.8%)	
Last participation date < Day 141 in DB phase	8 (15.1%)	4 (7.8%)	4 (12.1%)	0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-srr24-db-gba.sas V.03.05 Output file: t-sg-srr24-db-gba-reg.pdf 29AUG2023: 9:01

Table 2.0103: Analysis of Splenic Response Rate at Week 24 by Gender
Double-blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Splenic Response Rate at Week 24					
Responder, n(%)	14 (28.0%)	14 (25.0%)	13 (36.1%)	17 (44.7%)	
95% Exact CI	0.1623, 0.4249	0.1439, 0.3837	0.2082, 0.5378	0.2862, 0.6170	
Noninferior Proportion Difference - Stratified CMH Method (95% CI)	0.15 (0.00, 0.30)		0.09 (-0.10, 0.28)		
p-value	0.054		0.36		
Noninferior Proportion Difference - Unstratified CMH Method (95% CI)	0.13 (-0.01, 0.27)		0.09 (-0.09, 0.28)		
p-value	0.077		0.33		
Superior Proportion Difference - Stratified CMH Method (95% CI)	0.06 (-0.12, 0.24)		-0.09 (-0.32, 0.15)		
p-value	0.54		0.47		
Superior Proportion Difference - Unstratified CMH Method (95% CI)	0.03 (-0.14, 0.20)		-0.09 (-0.31, 0.14)		
p-value	0.73		0.45		
Superior Proportion Difference - Unstratified Exact Method (95% CI)	0.03 (-0.16, 0.22)		-0.09 (-0.31, 0.14)		
p-value	0.83		0.49		
Unadjusted Inverse Relative Risk (95% CI)	0.89 (0.47, 1.69)		1.24 (0.71, 2.17)		
p-value [1]	0.73		0.45		
Unadjusted interaction test for Treatment*Gender [3]					0.45
Unadjusted Inverse Odds Ratio (95% CI)	0.86 (0.36, 2.03)		1.43 (0.56, 3.64)		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-srr24-db-gba.sas V.03.05 Output file: t-sg-srr24-db-gba-sex.pdf 29AUG2023: 9:01

Table 2.0103: Analysis of Splenic Response Rate at Week 24 by Gender
Double-blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
p-value [1]	0.73		0.45		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.14, 0.20)		-0.09 (-0.31, 0.14)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.81 (0.42, 1.56)		NE		
p-value [2]	0.53		NE		
Adjusted interaction test for Treatment*Gender [3]					0.34
Non-Responder, n(%)	36 (72.0%)	42 (75.0%)	23 (63.9%)	21 (55.3%)	
Baseline Spleen Volume not available	0	0	0	0	
Spleen Volume at Week 24 not available	7 (14.0%)	6 (10.7%)	9 (25.0%)	2 (5.3%)	
>0% Spleen Volume increase at Week 24	6 (12.0%)	6 (10.7%)	4 (11.1%)	2 (5.3%)	
<35% Spleen Volume reduction at Week 24	29 (58.0%)	36 (64.3%)	14 (38.9%)	19 (50.0%)	
Last participation date < Day 141 in DB phase	4 (8.0%)	4 (7.1%)	8 (22.2%)	0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-srr24-db-gba.sas V.03.05 Output file: t-sg-srr24-db-gba-sex.pdf 29AUG2023: 9:01

Table 2.0110: Analysis of Splenic Response Rate at Week 24 by Baseline Spleen Volume
Double-blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Splenic Response Rate at Week 24					
Responder, n(%)	20 (42.6%)	17 (39.5%)	7 (17.9%)	14 (27.5%)	
95% Exact CI	0.2826, 0.5782	0.2498, 0.5559	0.0754, 0.3353	0.1589, 0.4174	
Noninferior Proportion Difference - Stratified CMH Method (95% CI)	0.17 (0.00, 0.35)		0.01 (-0.16, 0.19)		
p-value	0.051		0.89		
Noninferior Proportion Difference - Unstratified CMH Method (95% CI)	0.19 (0.02, 0.36)		0.01 (-0.13, 0.16)		
p-value	0.028		0.84		
Superior Proportion Difference - Stratified CMH Method (95% CI)	0.02 (-0.19, 0.24)		-0.10 (-0.32, 0.11)		
p-value	0.83		0.33		
Superior Proportion Difference - Unstratified CMH Method (95% CI)	0.03 (-0.18, 0.24)		-0.10 (-0.27, 0.08)		
p-value	0.77		0.29		
Superior Proportion Difference - Unstratified Exact Method (95% CI)	0.03 (-0.17, 0.24)		-0.10 (-0.30, 0.11)		
p-value	0.83		0.33		
Unadjusted Inverse Relative Risk (95% CI)	0.93 (0.57, 1.53)		1.53 (0.68, 3.42)		
p-value [1]	0.77		0.30		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.29

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-srr24-db-gba.sas V.03.05 Output file: t-sg-srr24-db-gba-spv.pdf 29AUG2023: 9:02

Table 2.0110: Analysis of Splenic Response Rate at Week 24 by Baseline Spleen Volume
Double-blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Unadjusted Inverse Odds Ratio (95% CI)	0.88 (0.38, 2.05)		1.73 (0.62, 4.81)		
p-value [1]	0.77		0.29		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.17, 0.23)		-0.10 (-0.27, 0.08)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		1.59 (0.66, 3.85)		
p-value [2]	NE		0.31		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.28
Non-Responder, n(%)	27 (57.4%)	26 (60.5%)	32 (82.1%)	37 (72.5%)	
Baseline Spleen Volume not available	0	0	0	0	
Spleen Volume at Week 24 not available	7 (14.9%)	4 (9.3%)	9 (23.1%)	4 (7.8%)	
>0% Spleen Volume increase at Week 24	5 (10.6%)	1 (2.3%)	5 (12.8%)	7 (13.7%)	
<35% Spleen Volume reduction at Week 24	20 (42.6%)	22 (51.2%)	23 (59.0%)	33 (64.7%)	
Last participation date < Day 141 in DB phase	7 (14.9%)	1 (2.3%)	5 (12.8%)	3 (5.9%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-srr24-db-gba.sas V.03.05 Output file: t-sg-srr24-db-gba-spv.pdf 29AUG2023: 9:02

Table 2.0109: Analysis of Splenic Response Rate at Week 24 by Baseline TSS
Double-blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Splenic Response Rate at Week 24					
Responder, n(%)	17 (38.6%)	16 (29.1%)	9 (22.0%)	15 (39.5%)	
95% Exact CI	0.2436, 0.5450	0.1763, 0.4290	0.1056, 0.3761	0.2404, 0.5661	
Noninferior Proportion Difference - Stratified CMH Method (95% CI)	0.24 (0.07, 0.41)		-0.02 (-0.19, 0.15)		
p-value	0.005		0.83		
Noninferior Proportion Difference - Unstratified CMH Method (95% CI)	0.21 (0.05, 0.37)		-0.02 (-0.18, 0.14)		
p-value	0.011		0.83		
Superior Proportion Difference - Stratified CMH Method (95% CI)	0.13 (-0.07, 0.32)		-0.18 (-0.39, 0.03)		
p-value	0.20		0.10		
Superior Proportion Difference - Unstratified CMH Method (95% CI)	0.10 (-0.09, 0.29)		-0.18 (-0.38, 0.03)		
p-value	0.32		0.093		
Superior Proportion Difference - Unstratified Exact Method (95% CI)	0.10 (-0.10, 0.29)		-0.18 (-0.39, 0.05)		
p-value	0.39		0.14		
Unadjusted Inverse Relative Risk (95% CI)	0.75 (0.43, 1.31)		1.80 (0.89, 3.62)		
p-value [1]	0.32		0.100		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.053

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.0109: Analysis of Splenic Response Rate at Week 24 by Baseline TSS
Double-blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Unadjusted Inverse Odds Ratio (95% CI)	0.65 (0.28, 1.51)		2.32 (0.87, 6.21)		
p-value [1]	0.32		0.094		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.09, 0.28)		-0.18 (-0.38, 0.03)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		1.81 (0.90, 3.62)		
p-value [2]	NE		0.095		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					0.041
Non-Responder, n(%)	27 (61.4%)	39 (70.9%)	32 (78.0%)	23 (60.5%)	
Baseline Spleen Volume not available	0	0	0	0	
Spleen Volume at Week 24 not available	4 (9.1%)	5 (9.1%)	12 (29.3%)	3 (7.9%)	
>0% Spleen Volume increase at Week 24	4 (9.1%)	5 (9.1%)	6 (14.6%)	3 (7.9%)	
<35% Spleen Volume reduction at Week 24	23 (52.3%)	34 (61.8%)	20 (48.8%)	20 (52.6%)	
Last participation date < Day 141 in DB phase	3 (6.8%)	2 (3.6%)	9 (22.0%)	2 (5.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-srr24-db-gba.sas V.03.05 Output file: t-sg-srr24-db-gba-tss.pdf 29AUG2023: 9:01

Table 2.6202: Analysis of Response Rate (improvement, 15% criterion) in Mean Symptom Score at Week 24 by Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	RUX (N = 36)	MMB (N = 62)	RUX (N = 58)	p-value
MPN-SAF at Week 24					
Responder, n(%)	4 (16.7%)	7 (19.4%)	14 (22.6%)	12 (20.7%)	
Unadjusted Inverse Relative Risk (95% CI)	1.17 (0.38, 3.56)		0.92 (0.46, 1.81)		
p-value [1]	0.79		0.80		
Unadjusted interaction test for Treatment*Age Group [3]					0.71
Unadjusted Inverse Odds Ratio (95% CI)	1.21 (0.31, 4.67)		0.89 (0.37, 2.14)		
p-value [1]	0.79		0.80		
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.23, 0.17)		0.02 (-0.13, 0.17)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		1.05 (0.54, 2.05)		
p-value [2]	NE		0.88		
Adjusted interaction test for Treatment*Age Group [3]					0.73
Non-Responder, n(%)	20 (83.3%)	29 (80.6%)	48 (77.4%)	46 (79.3%)	
Non-missing	12 (50.0%)	18 (50.0%)	29 (46.8%)	31 (53.4%)	
Missing	8 (33.3%)	11 (30.6%)	19 (30.6%)	15 (25.9%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-mpnsaf-gba-improv.sas V.03.05 Output file: t-sgp-mpnsaf-gba-imp-age.pdf 29AUG2023: 9:41

Table 2.6204: Analysis of Response Rate (improvement, 15% criterion) in Mean Symptom Score at Week 24 by Region
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N = 53)	RUX (N = 51)	MMB (N = 33)	RUX (N = 43)	p-value
MPN-SAF at Week 24					
Responder, n(%)	11 (20.8%)	9 (17.6%)	7 (21.2%)	10 (23.3%)	
Unadjusted Inverse Relative Risk (95% CI)	0.85 (0.38, 1.88)		1.10 (0.47, 2.57)		
p-value [1]	0.69		0.83		
Unadjusted interaction test for Treatment*Region [3]					0.67
Unadjusted Inverse Odds Ratio (95% CI)	0.82 (0.31, 2.18)		1.13 (0.38, 3.36)		
p-value [1]	0.69		0.83		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.12, 0.18)		-0.02 (-0.21, 0.17)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.83 (0.40, 1.73)		NE		
p-value [2]	0.61		NE		
Adjusted interaction test for Treatment*Region [3]					0.58
Non-Responder, n(%)	42 (79.2%)	42 (82.4%)	26 (78.8%)	33 (76.7%)	
Non-missing	21 (39.6%)	24 (47.1%)	20 (60.6%)	25 (58.1%)	
Missing	21 (39.6%)	18 (35.3%)	6 (18.2%)	8 (18.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-mpnsaf-gba-improv.sas V.03.05 Output file: t-sgp-mpnsaf-gba-imp-geo.pdf 29AUG2023: 9:41

Table 2.6207: Analysis of Response Rate (improvement, 15% criterion) in Mean Symptom Score at Week 24 by Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 28)	RUX (N = 21)	MMB (N = 58)	RUX (N = 73)	p-value
MPN-SAF at Week 24					
Responder, n(%)	7 (25.0%)	4 (19.0%)	11 (19.0%)	15 (20.5%)	
Unadjusted Inverse Relative Risk (95% CI)	0.76 (0.26, 2.27)		1.08 (0.54, 2.18)		
p-value [1]	0.62		0.82		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.59
Unadjusted Inverse Odds Ratio (95% CI)	0.71 (0.18, 2.82)		1.11 (0.46, 2.63)		
p-value [1]	0.62		0.82		
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.17, 0.29)		-0.02 (-0.15, 0.12)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.74 (0.25, 2.19)		1.20 (0.63, 2.29)		
p-value [2]	0.59		0.59		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.45
Non-Responder, n(%)	21 (75.0%)	17 (81.0%)	47 (81.0%)	58 (79.5%)	
Non-missing	11 (39.3%)	12 (57.1%)	30 (51.7%)	37 (50.7%)	
Missing	10 (35.7%)	5 (23.8%)	17 (29.3%)	21 (28.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-mpnsaf-gba-improv.sas V.03.05 Output file: t-sgp-mpnsaf-gba-imp-hgb.pdf 29AUG2023: 9:42

Table 2.6206: Analysis of Response Rate (improvement, 15% criterion) in Mean Symptom Score at Week 24 by Baseline IPSS Two-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 28)	RUX (N = 24)	MMB (N = 58)	RUX (N = 70)	p-value
MPN-SAF at Week 24					
Responder, n(%)	4 (14.3%)	5 (20.8%)	14 (24.1%)	14 (20.0%)	
Unadjusted Inverse Relative Risk (95% CI)	1.46 (0.44, 4.82)		0.83 (0.43, 1.59)		
p-value [1]	0.54		0.57		
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.42
Unadjusted Inverse Odds Ratio (95% CI)	1.58 (0.37, 6.70)		0.79 (0.34, 1.82)		
p-value [1]	0.54		0.57		
Unadjusted Absolute Risk Difference (95% CI)	-0.07 (-0.27, 0.14)		0.04 (-0.10, 0.19)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.87 (0.46, 1.62)		
p-value [2]	NE		0.65		
Adjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.48
Non-Responder, n(%)	24 (85.7%)	19 (79.2%)	44 (75.9%)	56 (80.0%)	
Non-missing	14 (50.0%)	12 (50.0%)	27 (46.6%)	37 (52.9%)	
Missing	10 (35.7%)	7 (29.2%)	17 (29.3%)	19 (27.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.6205: Analysis of Response Rate (improvement, 15% criterion) in Mean Symptom Score at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 2)	RUX (N = 4)	MMB (N = 26)	RUX (N = 20)
MPN-SAF at Week 24				
Responder, n(%)	0	1 (25.0%)	4 (15.4%)	4 (20.0%)
Unadjusted Inverse Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Non-Responder, n(%)	2 (100.0%)	3 (75.0%)	22 (84.6%)	16 (80.0%)
Non-missing	1 (50.0%)	2 (50.0%)	13 (50.0%)	10 (50.0%)
Missing	1 (50.0%)	1 (25.0%)	9 (34.6%)	6 (30.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-mpnsaf-gba-improv.sas V.03.05 Output file: t-sgp-mpnsaf-gba-imp-ip3.pdf 29AUG2023: 9:41

Table 2.6205: Analysis of Response Rate (improvement, 15% criterion) in Mean Symptom Score at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 58)	RUX (N = 70)	p-value
MPN-SAF at Week 24			
Responder, n(%)	14 (24.1%)	14 (20.0%)	
Unadjusted Inverse Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	44 (75.9%)	56 (80.0%)	
Non-missing	27 (46.6%)	37 (52.9%)	
Missing	17 (29.3%)	19 (27.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-mpnsaf-gba-improv.sas V.03.05 Output file: t-sgp-mpnsaf-gba-imp-ip3.pdf 29AUG2023: 9:41

Table 2.6208: Analysis of Response Rate (improvement, 15% criterion) in Mean Symptom Score at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 59)	RUX (N = 54)	MMB (N = 16)	RUX (N = 28)
MPN-SAF at Week 24				
Responder, n(%)	14 (23.7%)	13 (24.1%)	1 (6.3%)	4 (14.3%)
Unadjusted Inverse Relative Risk (95% CI)	1.01 (0.53, 1.96)		2.29 (0.28, 18.73)	
p-value [1]	0.97		0.44	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	1.02 (0.43, 2.42)		2.50 (0.25, 24.55)	
p-value [1]	0.97		0.43	
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.16, 0.15)		-0.08 (-0.26, 0.10)	
Adjusted Inverse Relative Risk (95% CI) [2]	1.18 (0.63, 2.19)		NE	
p-value [2]	0.61		NE	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	45 (76.3%)	41 (75.9%)	15 (93.8%)	24 (85.7%)
Non-missing	28 (47.5%)	31 (57.4%)	9 (56.3%)	13 (46.4%)
Missing	17 (28.8%)	10 (18.5%)	6 (37.5%)	11 (39.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-mpnsaf-gba-improv.sas V.03.05 Output file: t-sgp-mpnsaf-gba-imp-mf.pdf 29AUG2023: 9:42

Table 2.6208: Analysis of Response Rate (improvement, 15% criterion) in Mean Symptom Score at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 11)	RUX (N = 12)	p-value
MPN-SAF at Week 24			
Responder, n(%)	3 (27.3%)	2 (16.7%)	
Unadjusted Inverse Relative Risk (95% CI)	0.61 (0.12, 3.00)		
p-value [1]	0.54		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.56
Unadjusted Inverse Odds Ratio (95% CI)	0.53 (0.07, 4.01)		
p-value [1]	0.54		
Unadjusted Absolute Risk Difference (95% CI)	0.11 (-0.23, 0.44)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.58
Non-Responder, n(%)	8 (72.7%)	10 (83.3%)	
Non-missing	4 (36.4%)	5 (41.7%)	
Missing	4 (36.4%)	5 (41.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-mpnsaf-gba-improv.sas V.03.05 Output file: t-sgp-mpnsaf-gba-imp-mf.pdf 29AUG2023: 9:42

Table 2.6203: Analysis of Response Rate (improvement, 15% criterion) in Mean Symptom Score at Week 24 by Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 50)	RUX (N = 56)	MMB (N = 36)	RUX (N = 38)	p-value
MPN-SAF at Week 24					
Responder, n(%)	10 (20.0%)	8 (14.3%)	8 (22.2%)	11 (28.9%)	
Unadjusted Inverse Relative Risk (95% CI)	0.71 (0.31, 1.67)		1.30 (0.59, 2.87)		
p-value [1]	0.44		0.51		
Unadjusted interaction test for Treatment*Gender [3]					0.31
Unadjusted Inverse Odds Ratio (95% CI)	0.67 (0.24, 1.85)		1.43 (0.50, 4.09)		
p-value [1]	0.44		0.51		
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.09, 0.20)		-0.07 (-0.27, 0.13)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		1.25 (0.59, 2.64)		
p-value [2]	NE		0.57		
Adjusted interaction test for Treatment*Gender [3]					0.43
Non-Responder, n(%)	40 (80.0%)	48 (85.7%)	28 (77.8%)	27 (71.1%)	
Non-missing	25 (50.0%)	34 (60.7%)	16 (44.4%)	15 (39.5%)	
Missing	15 (30.0%)	14 (25.0%)	12 (33.3%)	12 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-mpnsaf-gba-improv.sas V.03.05 Output file: t-sgp-mpnsaf-gba-imp-sex.pdf 29AUG2023: 9:41

Table 2.6210: Analysis of Response Rate (improvement, 15% criterion) in Mean Symptom Score at Week 24 by Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N = 47)	RUX (N = 43)	MMB (N = 39)	RUX (N = 51)	p-value
MPN-SAF at Week 24					
Responder, n(%)	11 (23.4%)	11 (25.6%)	7 (17.9%)	8 (15.7%)	
Unadjusted Inverse Relative Risk (95% CI)	1.09 (0.53, 2.26)		0.87 (0.35, 2.20)		
p-value [1]	0.81		0.78		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.71
Unadjusted Inverse Odds Ratio (95% CI)	1.13 (0.43, 2.94)		0.85 (0.28, 2.59)		
p-value [1]	0.81		0.78		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.20, 0.16)		0.02 (-0.13, 0.18)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.93 (0.35, 2.48)		
p-value [2]	NE		0.88		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.66
Non-Responder, n(%)	36 (76.6%)	32 (74.4%)	32 (82.1%)	43 (84.3%)	
Non-missing	24 (51.1%)	20 (46.5%)	17 (43.6%)	29 (56.9%)	
Missing	12 (25.5%)	12 (27.9%)	15 (38.5%)	14 (27.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-mpnsaf-gba-improv.sas V.03.05 Output file: t-sgp-mpnsaf-gba-imp-svb.pdf 29AUG2023: 9:42

Table 2.6209: Analysis of Response Rate (improvement, 15% criterion) in Mean Symptom Score at Week 24 by Baseline TSS
Double-Blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 44)	RUX (N = 55)	MMB (N = 41)	RUX (N = 38)	p-value
MPN-SAF at Week 24					
Responder, n(%)	6 (13.6%)	4 (7.3%)	11 (26.8%)	14 (36.8%)	
Unadjusted Inverse Relative Risk (95% CI)	0.53 (0.16, 1.77)		1.37 (0.71, 2.64)		
p-value [1]	0.31		0.34		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.18
Unadjusted Inverse Odds Ratio (95% CI)	0.50 (0.13, 1.88)		1.59 (0.61, 4.13)		
p-value [1]	0.30		0.34		
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.06, 0.19)		-0.10 (-0.30, 0.10)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		1.46 (0.80, 2.68)		
p-value [2]	NE		0.22		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					0.18
Non-Responder, n(%)	38 (86.4%)	51 (92.7%)	30 (73.2%)	24 (63.2%)	
Non-missing	29 (65.9%)	38 (69.1%)	12 (29.3%)	11 (28.9%)	
Missing	9 (20.5%)	13 (23.6%)	18 (43.9%)	13 (34.2%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.0702: Analysis of Response Rate (improvement, 50% criterion) in TSS at Week 24 by Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Total Symptom Score Status					
Missing TSS at baseline (excluded from rate calculation)	0	0	1 (1.6%)	1 (1.7%)	
TSS = 0 at baseline	0	0	2 (3.2%)	0	
TSS > 0 at baseline	24 (100.0%)	36 (100.0%)	59 (95.2%)	57 (98.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates. [3] Interaction test p-value was obtained for treatment by subgroup interaction term from the corresponding modified Poisson regression which also includes subgroup as covariate and treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-tss24-subgrp.sas V.03.05 Output file: t-subgrp-tss24-gba-db-age.pdf 29AUG2023: 9:49

Table 2.0702: Analysis of Response Rate (improvement, 50% criterion) in TSS at Week 24 by Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Response Rate of Total Symptom Score at Week 24					
Subjects Evaluable at Week 24, n	24	36	60	57	
TSS = 0 at baseline and TSS > 0 or missing at Week 24	0	0	1 (1.7%)	0	
Responder, n(%)	8 (33.3%)	13 (36.1%)	13 (21.7%)	20 (35.1%)	
95% Exact CI	0.1563, 0.5532	0.2082, 0.5378	0.1207, 0.3420	0.2291, 0.4887	
Proportion Difference - Stratified CMH Method (95% CI)	-0.11 (-0.40, 0.19)		-0.14 (-0.32, 0.03)		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.03 (-0.28, 0.22)		-0.13 (-0.30, 0.03)		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.03 (-0.29, 0.23)		-0.13 (-0.31, 0.05)		
Unadjusted Inverse Relative Risk (95% CI)	1.08 (0.53, 2.21)		1.62 (0.89, 2.94)		
p-value [1]	0.83		0.11		
Unadjusted interaction test for Treatment*Age Group [3]					0.41
Unadjusted Inverse Odds Ratio (95% CI)	1.13 (0.38, 3.35)		1.95 (0.86, 4.44)		
p-value [1]	0.83		0.11		
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.27, 0.22)		-0.13 (-0.30, 0.03)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.39 (0.63, 3.08)		1.70 (0.92, 3.13)		
p-value [2]	0.41		0.091		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates. [3] Interaction test p-value was obtained for treatment by subgroup interaction term from the corresponding modified Poisson regression which also includes subgroup as covariate and treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.0702: Analysis of Response Rate (improvement, 50% criterion) in TSS at Week 24 by Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Adjusted interaction test for Treatment*Age Group [3]					0.67
Non-Responder, n(%)	16 (66.7%)	23 (63.9%)	47 (78.3%)	37 (64.9%)	
Last participation date < Day 162 in DB Phase	4 (16.7%)	3 (8.3%)	12 (20.0%)	5 (8.8%)	
Last participation date >= Day 162 and TSS at Week 24 not available	1 (4.2%)	2 (5.6%)	2 (3.3%)	4 (7.0%)	
>0% increase from baseline at Week 24	4 (16.7%)	4 (11.1%)	13 (21.7%)	9 (15.8%)	
<50% reduction from baseline at Week 24	11 (45.8%)	18 (50.0%)	32 (53.3%)	28 (49.1%)	
Return Rate (%)	79%	86%	77%	84%	
Number of Subjects in Risk	20	33	50	53	
Return Rate in Risk (%)	95%	94%	96%	92%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates. [3] Interaction test p-value was obtained for treatment by subgroup interaction term from the corresponding modified Poisson regression which also includes subgroup as covariate and treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-tss24-subgrp.sas V.03.05 Output file: t-subgrp-tss24-gba-db-age.pdf 29AUG2023: 9:49

Table 2.0704: Analysis of Response Rate (improvement, 50% criterion) in TSS at Week 24 by Region
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Total Symptom Score Status					
Missing TSS at baseline (excluded from rate calculation)	0	1 (2.0%)	1 (3.0%)	0	
TSS = 0 at baseline	2 (3.8%)	0	0	0	
TSS > 0 at baseline	51 (96.2%)	50 (98.0%)	32 (97.0%)	43 (100.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates. [3] Interaction test p-value was obtained for treatment by subgroup interaction term from the corresponding modified Poisson regression which also includes subgroup as covariate and treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 01JUL2019

Table 2.0704: Analysis of Response Rate (improvement, 50% criterion) in TSS at Week 24 by Region
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Response Rate of Total Symptom Score at Week 24					
Subjects Evaluable at Week 24, n	52	50	32	43	
TSS = 0 at baseline and TSS > 0 or missing at Week 24	1 (1.9%)	0	0	0	
Responder, n(%)	15 (28.8%)	17 (34.0%)	6 (18.8%)	16 (37.2%)	
95% Exact CI	0.1713, 0.4308	0.2121, 0.4877	0.0721, 0.3644	0.2298, 0.5327	
Proportion Difference - Stratified CMH Method (95% CI)	-0.05 (-0.25, 0.15)		-0.19 (-0.41, 0.03)		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.05 (-0.23, 0.13)		-0.18 (-0.39, 0.02)		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.05 (-0.24, 0.14)		-0.18 (-0.40, 0.04)		
Unadjusted Inverse Relative Risk (95% CI)	1.18 (0.66, 2.10)		1.98 (0.87, 4.50)		
p-value [1]	0.58		0.10		
Unadjusted interaction test for Treatment*Region [3]					0.29
Unadjusted Inverse Odds Ratio (95% CI)	1.27 (0.55, 2.94)		2.57 (0.87, 7.58)		
p-value [1]	0.58		0.088		
Unadjusted Absolute Risk Difference (95% CI)	-0.05 (-0.23, 0.13)		-0.18 (-0.38, 0.01)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.19 (0.66, 2.14)		NE		
p-value [2]	0.57		NE		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates. [3] Interaction test p-value was obtained for treatment by subgroup interaction term from the corresponding modified Poisson regression which also includes subgroup as covariate and treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 01JUL2019

Table 2.0704: Analysis of Response Rate (improvement, 50% criterion) in TSS at Week 24 by Region
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Adjusted interaction test for Treatment*Region [3]					0.37
Non-Responder, n(%)	37 (71.2%)	33 (66.0%)	26 (81.3%)	27 (62.8%)	
Last participation date < Day 162 in DB Phase	10 (19.2%)	5 (10.0%)	6 (18.8%)	3 (7.0%)	
Last participation date >= Day 162 and TSS at Week 24 not available	3 (5.8%)	5 (10.0%)	0	1 (2.3%)	
>0% increase from baseline at Week 24	11 (21.2%)	10 (20.0%)	6 (18.8%)	3 (7.0%)	
<50% reduction from baseline at Week 24	23 (44.2%)	23 (46.0%)	20 (62.5%)	23 (53.5%)	
Return Rate (%)	75%	80%	82%	91%	
Number of Subjects in Risk	43	46	27	40	
Return Rate in Risk (%)	93%	89%	100%	98%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates. [3] Interaction test p-value was obtained for treatment by subgroup interaction term from the corresponding modified Poisson regression which also includes subgroup as covariate and treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 01JUL2019

Table 2.0707: Analysis of Response Rate (improvement, 50% criterion) in TSS at Week 24 by Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Total Symptom Score Status					
Missing TSS at baseline (excluded from rate calculation)	0	1 (4.8%)	1 (1.7%)	0	
TSS = 0 at baseline	1 (3.6%)	0	1 (1.7%)	0	
TSS > 0 at baseline	27 (96.4%)	20 (95.2%)	56 (96.6%)	73 (100.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates. [3] Interaction test p-value was obtained for treatment by subgroup interaction term from the corresponding modified Poisson regression which also includes subgroup as covariate and treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-tss24-subgrp.sas V.03.05 Output file: t-subgrp-tss24-gba-db-hgb.pdf 29AUG2023: 9:54

Table 2.0707: Analysis of Response Rate (improvement, 50% criterion) in TSS at Week 24 by Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Response Rate of Total Symptom Score at Week 24					
Subjects Evaluable at Week 24, n	27	20	57	73	
TSS = 0 at baseline and TSS > 0 or missing at Week 24	0	0	1 (1.8%)	0	
Responder, n(%)	5 (18.5%)	7 (35.0%)	16 (28.1%)	26 (35.6%)	
95% Exact CI	0.0630, 0.3808	0.1539, 0.5922	0.1697, 0.4154	0.2475, 0.4769	
Proportion Difference - Stratified CMH Method (95% CI)	-0.16 (-0.45, 0.12)		-0.09 (-0.26, 0.08)		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.16 (-0.43, 0.10)		-0.08 (-0.24, 0.09)		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.16 (-0.43, 0.13)		-0.08 (-0.25, 0.10)		
Unadjusted Inverse Relative Risk (95% CI)	1.89 (0.70, 5.09)		1.27 (0.76, 2.13)		
p-value [1]	0.21		0.37		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.48
Unadjusted Inverse Odds Ratio (95% CI)	2.37 (0.62, 9.02)		1.42 (0.67, 3.00)		
p-value [1]	0.21		0.36		
Unadjusted Absolute Risk Difference (95% CI)	-0.16 (-0.42, 0.09)		-0.08 (-0.24, 0.08)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.89 (0.70, 5.07)		1.33 (0.80, 2.21)		
p-value [2]	0.21		0.27		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates. [3] Interaction test p-value was obtained for treatment by subgroup interaction term from the corresponding modified Poisson regression which also includes subgroup as covariate and treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.0707: Analysis of Response Rate (improvement, 50% criterion) in TSS at Week 24 by Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.53
Non-Responder, n(%)	22 (81.5%)	13 (65.0%)	41 (71.9%)	47 (64.4%)	
Last participation date < Day 162 in DB Phase	6 (22.2%)	4 (20.0%)	10 (17.5%)	4 (5.5%)	
Last participation date >= Day 162 and TSS at Week 24 not available	1 (3.7%)	2 (10.0%)	2 (3.5%)	4 (5.5%)	
>0% increase from baseline at Week 24	6 (22.2%)	2 (10.0%)	11 (19.3%)	11 (15.1%)	
<50% reduction from baseline at Week 24	15 (55.6%)	7 (35.0%)	28 (49.1%)	39 (53.4%)	
Return Rate (%)	75%	71%	79%	89%	
Number of Subjects in Risk	22	17	48	69	
Return Rate in Risk (%)	95%	88%	96%	94%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates. [3] Interaction test p-value was obtained for treatment by subgroup interaction term from the corresponding modified Poisson regression which also includes subgroup as covariate and treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-tss24-subgrp.sas V.03.05 Output file: t-subgrp-tss24-gba-db-hgb.pdf 29AUG2023: 9:54

Table 2.0706: Analysis of Response Rate (improvement, 50% criterion) in TSS at Week 24 by Baseline IPSS Two-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Total Symptom Score Status					
Missing TSS at baseline (excluded from rate calculation)	0	0	1 (1.7%)	1 (1.4%)	
TSS = 0 at baseline	1 (3.6%)	0	1 (1.7%)	0	
TSS > 0 at baseline	27 (96.4%)	24 (100.0%)	56 (96.6%)	69 (98.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates. [3] Interaction test p-value was obtained for treatment by subgroup interaction term from the corresponding modified Poisson regression which also includes subgroup as covariate and treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-tss24-subgrp.sas V.03.05 Output file: t-subgrp-tss24-gba-db-ipss2.pdf 29AUG2023: 9:53

Table 2.0706: Analysis of Response Rate (improvement, 50% criterion) in TSS at Week 24 by Baseline IPSS Two-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Response Rate of Total Symptom Score at Week 24					
Subjects Evaluable at Week 24, n	28	24	56	69	
TSS = 0 at baseline and TSS > 0 or missing at Week 24	1 (3.6%)	0	0	0	
Responder, n(%)	11 (39.3%)	8 (33.3%)	10 (17.9%)	25 (36.2%)	
95% Exact CI	0.2150, 0.5942	0.1563, 0.5532	0.0891, 0.3040	0.2499, 0.4869	
Proportion Difference - Stratified CMH Method (95% CI)	0.04 (-0.28, 0.36)		-0.19 (-0.36, -0.03)		
Proportion Difference - Unstratified CMH Method (95% CI)	0.06 (-0.21, 0.33)		-0.18 (-0.34, -0.03)		
Proportion Difference - Unstratified Exact Method (95% CI)	0.06 (-0.21, 0.32)		-0.18 (-0.35, -0.01)		
Unadjusted Inverse Relative Risk (95% CI)	0.85 (0.41, 1.76)		2.03 (1.07, 3.86)		
p-value [1]	0.66		0.031		
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.075
Unadjusted Inverse Odds Ratio (95% CI)	0.77 (0.25, 2.41)		2.61 (1.13, 6.07)		
p-value [1]	0.66		0.025		
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.20, 0.32)		-0.18 (-0.34, -0.03)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.90 (0.43, 1.90)		2.10 (1.10, 3.98)		
p-value [2]	0.78		0.024		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates. [3] Interaction test p-value was obtained for treatment by subgroup interaction term from the corresponding modified Poisson regression which also includes subgroup as covariate and treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-tss24-subgrp.sas V.03.05 Output file: t-subgrp-tss24-gba-db-ipss2.pdf 29AUG2023: 9:53

Table 2.0706: Analysis of Response Rate (improvement, 50% criterion) in TSS at Week 24 by Baseline IPSS Two-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Adjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.10
Non-Responder, n(%)	17 (60.7%)	16 (66.7%)	46 (82.1%)	44 (63.8%)	
Last participation date < Day 162 in DB Phase	4 (14.3%)	2 (8.3%)	12 (21.4%)	6 (8.7%)	
Last participation date >= Day 162 and TSS at Week 24 not available	1 (3.6%)	1 (4.2%)	2 (3.6%)	5 (7.2%)	
>0% increase from baseline at Week 24	5 (17.9%)	6 (25.0%)	12 (21.4%)	7 (10.1%)	
<50% reduction from baseline at Week 24	11 (39.3%)	13 (54.2%)	32 (57.1%)	33 (47.8%)	
Return Rate (%)	82%	88%	76%	84%	
Number of Subjects in Risk	24	22	46	64	
Return Rate in Risk (%)	96%	95%	96%	92%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates. [3] Interaction test p-value was obtained for treatment by subgroup interaction term from the corresponding modified Poisson regression which also includes subgroup as covariate and treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-tss24-subgrp.sas V.03.05 Output file: t-subgrp-tss24-gba-db-ipss2.pdf 29AUG2023: 9:53

Table 2.0705: Analysis of Response Rate (improvement, 50% criterion) in TSS at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Total Symptom Score Status				
Missing TSS at baseline (excluded from rate calculation)	0	0	0	0
TSS = 0 at baseline	0	0	1 (3.8%)	0
TSS > 0 at baseline	2 (100.0%)	4 (100.0%)	25 (96.2%)	20 (100.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates. [3] Interaction test p-value was obtained for treatment by subgroup interaction term from the corresponding modified Poisson regression which also includes subgroup as covariate and treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-tss24-subgrp.sas V.03.05 Output file: t-subgrp-tss24-gba-db-ipss3.pdf 29AUG2023: 9:55

Table 2.0705: Analysis of Response Rate (improvement, 50% criterion) in TSS at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=58)	High Risk RUX (N=70)	p-value
Total Symptom Score Status			
Missing TSS at baseline (excluded from rate calculation)	1 (1.7%)	1 (1.4%)	
TSS = 0 at baseline	1 (1.7%)	0	
TSS > 0 at baseline	56 (96.6%)	69 (98.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates. [3] Interaction test p-value was obtained for treatment by subgroup interaction term from the corresponding modified Poisson regression which also includes subgroup as covariate and treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.0705: Analysis of Response Rate (improvement, 50% criterion) in TSS at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Response Rate of Total Symptom Score at Week 24				
Subjects Evaluable at Week 24, n	2	4	26	20
TSS = 0 at baseline and TSS > 0 or missing at Week 24	0	0	1 (3.8%)	0
Responder, n(%)	2 (100.0%)	2 (50.0%)	9 (34.6%)	6 (30.0%)
95% Exact CI	0.1581, 1.0000	0.0676, 0.9324	0.1721, 0.5567	0.1189, 0.5428
Proportion Difference - Stratified CMH Method (95% CI)	0.50 (-0.72, 1.72)		-0.02 (-0.31, 0.27)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.50 (-0.42, 1.42)		0.05 (-0.23, 0.33)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.50 (-0.45, 0.99)		0.05 (-0.24, 0.33)	
Unadjusted Inverse Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates. [3] Interaction test p-value was obtained for treatment by subgroup interaction term from the corresponding modified Poisson regression which also includes subgroup as covariate and treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-tss24-subgrp.sas V.03.05 Output file: t-subgrp-tss24-gba-db-ipss3.pdf 29AUG2023: 9:55

Table 2.0705: Analysis of Response Rate (improvement, 50% criterion) in TSS at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=58)	High Risk RUX (N=70)	p-value
Response Rate of Total Symptom Score at Week 24			
Subjects Evaluable at Week 24, n	56	69	
TSS = 0 at baseline and TSS > 0 or missing at Week 24	0	0	
Responder, n(%)	10 (17.9%)	25 (36.2%)	
95% Exact CI	0.0891, 0.3040	0.2499, 0.4869	
Proportion Difference - Stratified CMH Method (95% CI)	-0.19 (-0.36, -0.03)		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.18 (-0.34, -0.03)		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.18 (-0.35, -0.01)		
Unadjusted Inverse Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates. [3] Interaction test p-value was obtained for treatment by subgroup interaction term from the corresponding modified Poisson regression which also includes subgroup as covariate and treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.0705: Analysis of Response Rate (improvement, 50% criterion) in TSS at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Non-Responder, n(%)	0	2 (50.0%)	17 (65.4%)	14 (70.0%)
Last participation date < Day 162 in DB Phase	0	0	4 (15.4%)	2 (10.0%)
Last participation date >= Day 162 and TSS at Week 24 not available	0	0	1 (3.8%)	1 (5.0%)
>0% increase from baseline at Week 24	0	0	5 (19.2%)	6 (30.0%)
<50% reduction from baseline at Week 24	0	2 (50.0%)	11 (42.3%)	11 (55.0%)
Return Rate (%)	100%	100%	81%	85%
Number of Subjects in Risk	2	4	22	18
Return Rate in Risk (%)	100%	100%	95%	94%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates. [3] Interaction test p-value was obtained for treatment by subgroup interaction term from the corresponding modified Poisson regression which also includes subgroup as covariate and treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-tss24-subgrp.sas V.03.05 Output file: t-subgrp-tss24-gba-db-ipss3.pdf 29AUG2023: 9:55

Table 2.0705: Analysis of Response Rate (improvement, 50% criterion) in TSS at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=58)	High Risk RUX (N=70)	p-value
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	46 (82.1%)	44 (63.8%)	
Last participation date < Day 162 in DB Phase	12 (21.4%)	6 (8.7%)	
Last participation date >= Day 162 and TSS at Week 24 not available	2 (3.6%)	5 (7.2%)	
>0% increase from baseline at Week 24	12 (21.4%)	7 (10.1%)	
<50% reduction from baseline at Week 24	32 (57.1%)	33 (47.8%)	
Return Rate (%)	76%	84%	
Number of Subjects in Risk	46	64	
Return Rate in Risk (%)	96%	92%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates. [3] Interaction test p-value was obtained for treatment by subgroup interaction term from the corresponding modified Poisson regression which also includes subgroup as covariate and treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.0708: Analysis of Response Rate (improvement, 50% criterion) in TSS at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-OL Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
Total Symptom Score Status				
Missing TSS at baseline (excluded from rate calculation)	1 (1.7%)	0	0	1 (3.6%)
TSS = 0 at baseline	1 (1.7%)	0	0	0
TSS > 0 at baseline	57 (96.6%)	54 (100.0%)	16 (100.0%)	27 (96.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates. [3] Interaction test p-value was obtained for treatment by subgroup interaction term from the corresponding modified Poisson regression which also includes subgroup as covariate and treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-tss24-subgrp.sas V.03.05 Output file: t-subgrp-tss24-gba-db-mf.pdf 29AUG2023: 9:56

Table 2.0708: Analysis of Response Rate (improvement, 50% criterion) in TSS at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

(Continued)	Post-PV Myelofibrosis MMB (N=11)	Post-PV Myelofibrosis RUX (N=12)	p-value
Total Symptom Score Status			
Missing TSS at baseline (excluded from rate calculation)	0	0	
TSS = 0 at baseline	1 (9.1%)	0	
TSS > 0 at baseline	10 (90.9%)	12 (100.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates. [3] Interaction test p-value was obtained for treatment by subgroup interaction term from the corresponding modified Poisson regression which also includes subgroup as covariate and treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 01JUL2019

Table 2.0708: Analysis of Response Rate (improvement, 50% criterion) in TSS at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-OL Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
Response Rate of Total Symptom Score at Week 24				
Subjects Evaluable at Week 24, n	58	54	16	27
TSS = 0 at baseline and TSS > 0 or missing at Week 24	1 (1.7%)	0	0	0
Responder, n(%)	14 (24.1%)	25 (46.3%)	4 (25.0%)	4 (14.8%)
95% Exact CI	0.1387, 0.3717	0.3262, 0.6039	0.0727, 0.5238	0.0419, 0.3373
Proportion Difference - Stratified CMH Method (95% CI)	-0.22 (-0.40, -0.04)		0.08 (-0.22, 0.38)	
Proportion Difference - Unstratified CMH Method (95% CI)	-0.22 (-0.40, -0.05)		0.10 (-0.16, 0.37)	
Proportion Difference - Unstratified Exact Method (95% CI)	-0.22 (-0.40, -0.04)		0.10 (-0.21, 0.39)	
Unadjusted Inverse Relative Risk (95% CI)	1.92 (1.12, 3.29)		0.59 (0.17, 2.05)	
p-value [1]	0.018		0.41	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	2.71 (1.21, 6.06)		0.52 (0.11, 2.46)	
p-value [1]	0.015		0.41	
Unadjusted Absolute Risk Difference (95% CI)	-0.22 (-0.39, -0.05)		0.10 (-0.15, 0.35)	
Adjusted Inverse Relative Risk (95% CI) [2]	1.92 (1.11, 3.30)		NE	
p-value [2]	0.019		NE	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates. [3] Interaction test p-value was obtained for treatment by subgroup interaction term from the corresponding modified Poisson regression which also includes subgroup as covariate and treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-tss24-subgrp.sas V.03.05 Output file: t-subgrp-tss24-gba-db-mf.pdf 29AUG2023: 9:56

Table 2.0708: Analysis of Response Rate (improvement, 50% criterion) in TSS at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

(Continued)	Post-PV Myelofibrosis MMB (N=11)	Post-PV Myelofibrosis RUX (N=12)	p-value
Response Rate of Total Symptom Score at Week 24			
Subjects Evaluable at Week 24, n	10	12	
TSS = 0 at baseline and TSS > 0 or missing at Week 24	0	0	
Responder, n(%)	3 (30.0%)	4 (33.3%)	
95% Exact CI	0.0667, 0.6525	0.0992, 0.6511	
Proportion Difference - Stratified CMH Method (95% CI)	-0.10 (-0.56, 0.37)		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.03 (-0.45, 0.38)		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.03 (-0.44, 0.37)		
Unadjusted Inverse Relative Risk (95% CI)	1.11 (0.32, 3.84)		
p-value [1]	0.87		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.28
Unadjusted Inverse Odds Ratio (95% CI)	1.17 (0.19, 7.12)		
p-value [1]	0.87		
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.42, 0.36)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates. [3] Interaction test p-value was obtained for treatment by subgroup interaction term from the corresponding modified Poisson regression which also includes subgroup as covariate and treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 01JUL2019

Table 2.0708: Analysis of Response Rate (improvement, 50% criterion) in TSS at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-OL Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	44 (75.9%)	29 (53.7%)	12 (75.0%)	23 (85.2%)
Last participation date < Day 162 in DB Phase	10 (17.2%)	4 (7.4%)	3 (18.8%)	2 (7.4%)
Last participation date >= Day 162 and TSS at Week 24 not available	0	2 (3.7%)	2 (12.5%)	2 (7.4%)
>0% increase from baseline at Week 24	10 (17.2%)	6 (11.1%)	5 (31.3%)	6 (22.2%)
<50% reduction from baseline at Week 24	33 (56.9%)	23 (42.6%)	7 (43.8%)	19 (70.4%)
Return Rate (%)	83%	89%	69%	86%
Number of Subjects in Risk	49	50	13	26
Return Rate in Risk (%)	100%	96%	85%	92%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates. [3] Interaction test p-value was obtained for treatment by subgroup interaction term from the corresponding modified Poisson regression which also includes subgroup as covariate and treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-tss24-subgrp.sas V.03.05 Output file: t-subgrp-tss24-gba-db-mf.pdf 29AUG2023: 9:56

Table 2.0708: Analysis of Response Rate (improvement, 50% criterion) in TSS at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

(Continued)	Post-PV Myelofibrosis MMB (N=11)	Post-PV Myelofibrosis RUX (N=12)	p-value
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.36
Non-Responder, n(%)	7 (70.0%)	8 (66.7%)	
Last participation date < Day 162 in DB Phase	3 (30.0%)	2 (16.7%)	
Last participation date >= Day 162 and TSS at Week 24 not available	1 (10.0%)	2 (16.7%)	
>0% increase from baseline at Week 24	2 (20.0%)	1 (8.3%)	
<50% reduction from baseline at Week 24	3 (30.0%)	4 (33.3%)	
Return Rate (%)	64%	67%	
Number of Subjects in Risk	8	10	
Return Rate in Risk (%)	88%	80%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates. [3] Interaction test p-value was obtained for treatment by subgroup interaction term from the corresponding modified Poisson regression which also includes subgroup as covariate and treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 01JUL2019

Table 2.0703: Analysis of Response Rate (improvement, 50% criterion) in TSS at Week 24 by Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Total Symptom Score Status					
Missing TSS at baseline (excluded from rate calculation)	0	0	1 (2.8%)	1 (2.6%)	
TSS = 0 at baseline	2 (4.0%)	0	0	0	
TSS > 0 at baseline	48 (96.0%)	56 (100.0%)	35 (97.2%)	37 (97.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates. [3] Interaction test p-value was obtained for treatment by subgroup interaction term from the corresponding modified Poisson regression which also includes subgroup as covariate and treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-tss24-subgrp.sas V.03.05 Output file: t-subgrp-tss24-gba-db-sex.pdf 29AUG2023: 9:50

Table 2.0703: Analysis of Response Rate (improvement, 50% criterion) in TSS at Week 24 by Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Response Rate of Total Symptom Score at Week 24					
Subjects Evaluable at Week 24, n	49	56	35	37	
TSS = 0 at baseline and TSS > 0 or missing at Week 24	1 (2.0%)	0	0	0	
Responder, n(%)	14 (28.6%)	18 (32.1%)	7 (20.0%)	15 (40.5%)	
95% Exact CI	0.1658, 0.4326	0.2029, 0.4596	0.0844, 0.3694	0.2475, 0.5790	
Proportion Difference - Stratified CMH Method (95% CI)	-0.05 (-0.24, 0.15)		-0.21 (-0.45, 0.02)		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.04 (-0.21, 0.14)		-0.21 (-0.42, 0.01)		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.04 (-0.23, 0.16)		-0.21 (-0.42, 0.02)		
Unadjusted Inverse Relative Risk (95% CI)	1.13 (0.63, 2.02)		2.03 (0.94, 4.37)		
p-value [1]	0.69		0.072		
Unadjusted interaction test for Treatment*Gender [3]					0.22
Unadjusted Inverse Odds Ratio (95% CI)	1.18 (0.51, 2.73)		2.73 (0.95, 7.85)		
p-value [1]	0.69		0.063		
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.21, 0.14)		-0.21 (-0.41, 0.00)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.18 (0.64, 2.15)		2.08 (0.98, 4.39)		
p-value [2]	0.60		0.055		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates. [3] Interaction test p-value was obtained for treatment by subgroup interaction term from the corresponding modified Poisson regression which also includes subgroup as covariate and treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.0703: Analysis of Response Rate (improvement, 50% criterion) in TSS at Week 24 by Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Adjusted interaction test for Treatment*Gender [3]					0.25
Non-Responder, n(%)	35 (71.4%)	38 (67.9%)	28 (80.0%)	22 (59.5%)	
Last participation date < Day 162 in DB Phase	6 (12.2%)	6 (10.7%)	10 (28.6%)	2 (5.4%)	
Last participation date >= Day 162 and TSS at Week 24 not available	2 (4.1%)	1 (1.8%)	1 (2.9%)	5 (13.5%)	
>0% increase from baseline at Week 24	10 (20.4%)	11 (19.6%)	7 (20.0%)	2 (5.4%)	
<50% reduction from baseline at Week 24	26 (53.1%)	31 (55.4%)	17 (48.6%)	15 (40.5%)	
Return Rate (%)	84%	88%	69%	82%	
Number of Subjects in Risk	44	50	26	36	
Return Rate in Risk (%)	95%	98%	96%	86%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates. [3] Interaction test p-value was obtained for treatment by subgroup interaction term from the corresponding modified Poisson regression which also includes subgroup as covariate and treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-tss24-subgrp.sas V.03.05 Output file: t-subgrp-tss24-gba-db-sex.pdf 29AUG2023: 9:50

Table 2.0710: Analysis of Response Rate (improvement, 50% criterion) in TSS at Week 24 by Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Total Symptom Score Status					
Missing TSS at baseline (excluded from rate calculation)	0	1 (2.3%)	1 (2.6%)	0	
TSS = 0 at baseline	2 (4.3%)	0	0	0	
TSS > 0 at baseline	45 (95.7%)	42 (97.7%)	38 (97.4%)	51 (100.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates. [3] Interaction test p-value was obtained for treatment by subgroup interaction term from the corresponding modified Poisson regression which also includes subgroup as covariate and treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-tss24-subgrp.sas V.03.05 Output file: t-subgrp-tss24-gba-db-svb.pdf 29AUG2023: 9:55

Table 2.0710: Analysis of Response Rate (improvement, 50% criterion) in TSS at Week 24 by Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Response Rate of Total Symptom Score at Week 24					
Subjects Evaluable at Week 24, n	46	42	38	51	
TSS = 0 at baseline and TSS > 0 or missing at Week 24	1 (2.2%)	0	0	0	
Responder, n(%)	13 (28.3%)	14 (33.3%)	8 (21.1%)	19 (37.3%)	
95% Exact CI	0.1599, 0.4346	0.1957, 0.4955	0.0955, 0.3732	0.2413, 0.5192	
Proportion Difference - Stratified CMH Method (95% CI)	-0.06 (-0.27, 0.16)		-0.22 (-0.42, -0.01)		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.05 (-0.25, 0.15)		-0.16 (-0.35, 0.03)		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.05 (-0.26, 0.16)		-0.16 (-0.36, 0.05)		
Unadjusted Inverse Relative Risk (95% CI)	1.18 (0.63, 2.21)		1.77 (0.87, 3.60)		
p-value [1]	0.61		0.12		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.39
Unadjusted Inverse Odds Ratio (95% CI)	1.27 (0.51, 3.15)		2.23 (0.85, 5.84)		
p-value [1]	0.61		0.10		
Unadjusted Absolute Risk Difference (95% CI)	-0.05 (-0.24, 0.14)		-0.16 (-0.35, 0.02)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.20 (0.62, 2.31)		2.09 (1.05, 4.15)		
p-value [2]	0.59		0.035		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates. [3] Interaction test p-value was obtained for treatment by subgroup interaction term from the corresponding modified Poisson regression which also includes subgroup as covariate and treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-tss24-subgrp.sas V.03.05 Output file: t-subgrp-tss24-gba-db-svb.pdf 29AUG2023: 9:55

Table 2.0710: Analysis of Response Rate (improvement, 50% criterion) in TSS at Week 24 by Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.30
Non-Responder, n(%)	33 (71.7%)	28 (66.7%)	30 (78.9%)	32 (62.7%)	
Last participation date < Day 162 in DB Phase	7 (15.2%)	4 (9.5%)	9 (23.7%)	4 (7.8%)	
Last participation date >= Day 162 and TSS at Week 24 not available	1 (2.2%)	4 (9.5%)	2 (5.3%)	2 (3.9%)	
>0% increase from baseline at Week 24	10 (21.7%)	8 (19.0%)	7 (18.4%)	5 (9.8%)	
<50% reduction from baseline at Week 24	24 (52.2%)	20 (47.6%)	19 (50.0%)	26 (51.0%)	
Return Rate (%)	83%	81%	72%	88%	
Number of Subjects in Risk	40	39	30	47	
Return Rate in Risk (%)	98%	90%	93%	96%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates. [3] Interaction test p-value was obtained for treatment by subgroup interaction term from the corresponding modified Poisson regression which also includes subgroup as covariate and treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-tss24-subgrp.sas V.03.05 Output file: t-subgrp-tss24-gba-db-svb.pdf 29AUG2023: 9:55

Table 2.0709: Analysis of Response Rate (improvement, 50% criterion) in TSS at Week 24 by Baseline TSS
Double-Blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Total Symptom Score Status					
Missing TSS at baseline (excluded from rate calculation)	0	0	0	0	
TSS = 0 at baseline	2 (4.5%)	0	0	0	
TSS > 0 at baseline	42 (95.5%)	55 (100.0%)	41 (100.0%)	38 (100.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates. [3] Interaction test p-value was obtained for treatment by subgroup interaction term from the corresponding modified Poisson regression which also includes subgroup as covariate and treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 01JUL2019

Table 2.0709: Analysis of Response Rate (improvement, 50% criterion) in TSS at Week 24 by Baseline TSS
Double-Blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Response Rate of Total Symptom Score at Week 24					
Subjects Evaluable at Week 24, n	43	55	41	38	
TSS = 0 at baseline and TSS > 0 or missing at Week 24	1 (2.3%)	0	0	0	
Responder, n(%)	13 (30.2%)	19 (34.5%)	8 (19.5%)	14 (36.8%)	
95% Exact CI	0.1718, 0.4613	0.2224, 0.4858	0.0882, 0.3487	0.2181, 0.5401	
Proportion Difference - Stratified CMH Method (95% CI)	-0.05 (-0.26, 0.15)		-0.19 (-0.40, 0.02)		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.04 (-0.23, 0.15)		-0.17 (-0.37, 0.03)		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.04 (-0.24, 0.16)		-0.17 (-0.38, 0.05)		
Unadjusted Inverse Relative Risk (95% CI)	1.14 (0.64, 2.04)		1.89 (0.89, 3.99)		
p-value [1]	0.65		0.096		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.29
Unadjusted Inverse Odds Ratio (95% CI)	1.22 (0.52, 2.87)		2.41 (0.87, 6.64)		
p-value [1]	0.65		0.090		
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.23, 0.14)		-0.17 (-0.37, 0.02)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		1.99 (1.00, 3.97)		
p-value [2]	NE		0.051		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates. [3] Interaction test p-value was obtained for treatment by subgroup interaction term from the corresponding modified Poisson regression which also includes subgroup as covariate and treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 01JUL2019

Table 2.0709: Analysis of Response Rate (improvement, 50% criterion) in TSS at Week 24 by Baseline TSS
Double-Blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Adjusted interaction test for Treatment*Baseline TSS Group [3]					0.28
Non-Responder, n(%)	30 (69.8%)	36 (65.5%)	33 (80.5%)	24 (63.2%)	
Last participation date < Day 162 in DB Phase	3 (7.0%)	4 (7.3%)	13 (31.7%)	4 (10.5%)	
Last participation date >= Day 162 and TSS at Week 24 not available	1 (2.3%)	1 (1.8%)	2 (4.9%)	5 (13.2%)	
>0% increase from baseline at Week 24	12 (27.9%)	12 (21.8%)	5 (12.2%)	1 (2.6%)	
<50% reduction from baseline at Week 24	25 (58.1%)	31 (56.4%)	18 (43.9%)	15 (39.5%)	
Return Rate (%)	91%	91%	63%	76%	
Number of Subjects in Risk	41	51	28	34	
Return Rate in Risk (%)	98%	98%	93%	85%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates. [3] Interaction test p-value was obtained for treatment by subgroup interaction term from the corresponding modified Poisson regression which also includes subgroup as covariate and treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 01JUL2019

Table 2.1402: Analysis of Time to First Response (50% criterion) in TSS by Age
Double-blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Subjects with Event					
Response (50% criterion) in TSS, n(%)	11 (45.8%)	14 (38.9%)	21 (33.9%)	25 (43.1%)	
Censor					
Subjects Censored, n(%)	13 (54.2%)	22 (61.1%)	41 (66.1%)	33 (56.9%)	
Non-Responder: Censored at Last Daily mMPN-SAF TSS Assessment Date on or before Day 176	13 (100.0%)	22 (100.0%)	41 (100.0%)	33 (100.0%)	
No Post-Baseline TSS data: Censored at Randomization Date	0	0	0	0	
Kaplan-Meier Estimate of Time to First Response (50% criterion) in TSS (Weeks)					
25-percentile (95% CI)	8.14 (4.14, 12.14)	8.14 (4.14, 23.86)	12.14 (8.14, 20.14)	8.14 (4.14, 16.14)	
Median (95% CI)	NE (8.14, NE)	NE (23.29, NE)	NE (20.14, NE)	NE (16.14, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	4.14, 25.14	4.14, 25.14	1.14, 25.14	4.00, 25.14	
Stratified Log-Rank Test p-value	0.94		0.42		
Adjusted Inverse Hazard Ratio (95% CI)	1.03 (0.43, 2.49)		1.30 (0.71, 2.38)		
Unstratified Log-Rank Test p-value	0.73		0.52		
Unadjusted Inverse Hazard Ratio (95% CI)	0.87 (0.40, 1.92)		1.20 (0.67, 2.15)		
P-value for interaction test					0.64

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Response is defined as >=50% reduction in TSS from baseline.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-tte-tss50-sub.sas V.03.05 Output file: t-tte-tss50-age.pdf 24AUG2023:12:41

Table 2.1404: Analysis of Time to First Response (50% criterion) in TSS by Region
Double-blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Subjects with Event					
Response (50% criterion) in TSS, n(%)	24 (45.3%)	21 (41.2%)	8 (24.2%)	18 (41.9%)	
Censor					
Subjects Censored, n(%)	29 (54.7%)	30 (58.8%)	25 (75.8%)	25 (58.1%)	
Non-Responder: Censored at Last Daily mMPN-SAF TSS Assessment Date on or before Day 176	29 (100.0%)	30 (100.0%)	25 (100.0%)	25 (100.0%)	
No Post-Baseline TSS data: Censored at Randomization Date	0	0	0	0	
Kaplan-Meier Estimate of Time to First Response (50% criterion) in TSS (Weeks)					
25-percentile (95% CI)	8.14 (8.14, 12.14)	8.14 (4.14, 16.14)	16.14 (8.14, NE)	8.14 (4.14, 23.71)	
Median (95% CI)	20.14 (12.14, NE)	NE (12.14, NE)	NE (NE, NE)	25.00 (20.14, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	1.14, 25.14	4.00, 25.14	3.29, 25.14	4.14, 25.14	
Stratified Log-Rank Test p-value	0.72		0.20		
Adjusted Inverse Hazard Ratio (95% CI)	0.92 (0.50, 1.69)		1.77 (0.76, 4.14)		
Unstratified Log-Rank Test p-value	0.56		0.15		
Unadjusted Inverse Hazard Ratio (95% CI)	0.84 (0.47, 1.50)		1.81 (0.79, 4.16)		
P-value for interaction test					0.22

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Response is defined as >=50% reduction in TSS from baseline.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-tte-tss50-sub.sas V.03.05 Output file: t-tte-tss50-geo.pdf 24AUG2023:12:41

Table 2.1407: Analysis of Time to First Response (50% criterion) in TSS by Baseline Hemoglobin Level
Double-blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Subjects with Event					
Response (50% criterion) in TSS, n(%)	9 (32.1%)	9 (42.9%)	23 (39.7%)	30 (41.1%)	
Censor					
Subjects Censored, n(%)	19 (67.9%)	12 (57.1%)	35 (60.3%)	43 (58.9%)	
Non-Responder: Censored at Last Daily mMPN-SAF TSS Assessment Date on or before Day 176	19 (100.0%)	12 (100.0%)	35 (100.0%)	43 (100.0%)	
No Post-Baseline TSS data: Censored at Randomization Date	0	0	0	0	
Kaplan-Meier Estimate of Time to First Response (50% criterion) in TSS (Weeks)					
25-percentile (95% CI)	8.14 (8.14, NE)	8.14 (4.14, 23.71)	12.14 (8.14, 16.14)	8.14 (4.14, 16.14)	
Median (95% CI)	NE (12.14, NE)	NE (8.14, NE)	NE (16.14, NE)	NE (23.29, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	1.14, 25.14	4.14, 25.14	1.14, 25.14	4.00, 25.14	
Stratified Log-Rank Test p-value	0.59		0.95		
Adjusted Inverse Hazard Ratio (95% CI)	1.32 (0.53, 3.34)		1.02 (0.58, 1.77)		
Unstratified Log-Rank Test p-value	0.50		0.96		
Unadjusted Inverse Hazard Ratio (95% CI)	1.33 (0.53, 3.36)		0.99 (0.57, 1.70)		
P-value for interaction test					0.64

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Response is defined as >=50% reduction in TSS from baseline.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-tte-tss50-sub.sas V.03.05 Output file: t-tte-tss50-hgb.pdf 24AUG2023:12:41

Table 2.1406: Analysis of Time to First Response (50% criterion) in TSS by Baseline IPSS Two-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Subjects with Event					
Response (50% criterion) in TSS, n(%)	14 (50.0%)	9 (37.5%)	18 (31.0%)	30 (42.9%)	
Censor					
Subjects Censored, n(%)	14 (50.0%)	15 (62.5%)	40 (69.0%)	40 (57.1%)	
Non-Responder: Censored at Last Daily mMPN-SAF TSS Assessment Date on or before Day 176	14 (100.0%)	15 (100.0%)	40 (100.0%)	40 (100.0%)	
No Post-Baseline TSS data: Censored at Randomization Date	0	0	0	0	
Kaplan-Meier Estimate of Time to First Response (50% criterion) in TSS (Weeks)					
25-percentile (95% CI)	8.14 (4.14, 12.14)	8.14 (4.14, NE)	12.14 (8.14, NE)	8.14 (4.14, 20.14)	
Median (95% CI)	20.14 (8.14, NE)	NE (8.14, NE)	NE (NE, NE)	NE (23.29, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	4.14, 25.14	4.14, 25.14	1.14, 25.14	4.00, 25.14	
Stratified Log-Rank Test p-value	0.59		0.24		
Adjusted Inverse Hazard Ratio (95% CI)	0.87 (0.35, 2.17)		1.43 (0.79, 2.58)		
Unstratified Log-Rank Test p-value	0.41		0.29		
Unadjusted Inverse Hazard Ratio (95% CI)	0.71 (0.31, 1.64)		1.36 (0.76, 2.45)		
P-value for interaction test					0.28

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Response is defined as >=50% reduction in TSS from baseline.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-tte-tss50-sub.sas V.03.05 Output file: t-tte-tss50-ipss2.pdf 24AUG2023:12:41

Table 2.1405: Analysis of Time to First Response (50% criterion) in TSS by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Subjects with Event				
Response (50% criterion) in TSS, n(%)	2 (100.0%)	2 (50.0%)	12 (46.2%)	7 (35.0%)
Censor				
Subjects Censored, n(%)	0	2 (50.0%)	14 (53.8%)	13 (65.0%)
Non-Responder: Censored at Last Daily mMPN-SAF TSS Assessment Date on or before Day 176	0	2 (100.0%)	14 (100.0%)	13 (100.0%)
No Post-Baseline TSS data: Censored at Randomization Date	0	0	0	0
Kaplan-Meier Estimate of Time to First Response (50% criterion) in TSS (Weeks)				
25-percentile (95% CI)	8.14 (8.14, NE)	6.14 (4.14, NE)	8.14 (4.14, 12.14)	8.14 (4.14, NE)
Median (95% CI)	14.14 (8.14, NE)	NE (4.14, NE)	NE (8.14, NE)	NE (8.14, NE)
75-percentile (95% CI)	20.14 (8.14, NE)	NE (4.14, NE)	NE (NE, NE)	NE (NE, NE)
Min, Max	8.14, 20.14	4.14, 25.14	4.14, 25.14	4.14, 25.14
Stratified Log-Rank Test p-value	NA		NA	
Adjusted Inverse Hazard Ratio (95% CI)	NA		NA	
Unstratified Log-Rank Test p-value	NA		NA	
Unadjusted Inverse Hazard Ratio (95% CI)	NA		NA	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Response is defined as >=50% reduction in TSS from baseline.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-tte-tss50-sub.sas V.03.05 Output file: t-tte-tss50-ipss3.pdf 24AUG2023:12:41

Table 2.1405: Analysis of Time to First Response (50% criterion) in TSS by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=58)	High Risk RUX (N=70)	p-value
Subjects with Event			
Response (50% criterion) in TSS, n(%)	18 (31.0%)	30 (42.9%)	
Censor			
Subjects Censored, n(%)	40 (69.0%)	40 (57.1%)	
Non-Responder: Censored at Last Daily mMPN-SAF TSS Assessment Date on or before Day 176	40 (100.0%)	40 (100.0%)	
No Post-Baseline TSS data: Censored at Randomization Date	0	0	
Kaplan-Meier Estimate of Time to First Response (50% criterion) in TSS (Weeks)			
25-percentile (95% CI)	12.14 (8.14, NE)	8.14 (4.14, 20.14)	
Median (95% CI)	NE (NE, NE)	NE (23.29, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	
Min, Max	1.14, 25.14	4.00, 25.14	
Stratified Log-Rank Test p-value	NA		
Adjusted Inverse Hazard Ratio (95% CI)	NA		
Unstratified Log-Rank Test p-value	NA		
Unadjusted Inverse Hazard Ratio (95% CI)	NA		
P-value for interaction test			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Response is defined as >=50% reduction in TSS from baseline.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-tte-tss50-sub.sas V.03.05 Output file: t-tte-tss50-ipss3.pdf 24AUG2023:12:41

Table 2.1408: Analysis of Time to First Response (50% criterion) in TSS by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

	Post-ET Myelofibrosis		Post-PV Myelofibrosis	
	MMB (N=16)	RUX (N=28)	MMB (N=11)	RUX (N=12)
Subjects with Event				
Response (50% criterion) in TSS, n(%)	5 (31.3%)	7 (25.0%)	4 (36.4%)	5 (41.7%)
Censor				
Subjects Censored, n(%)	11 (68.8%)	21 (75.0%)	7 (63.6%)	7 (58.3%)
Non-Responder: Censored at Last Daily mMPN-SAF TSS Assessment Date on or before Day 176	11 (100.0%)	21 (100.0%)	7 (100.0%)	7 (100.0%)
No Post-Baseline TSS data: Censored at Randomization Date	0	0	0	0
Kaplan-Meier Estimate of Time to First Response (50% criterion) in TSS (Weeks)				
25-percentile (95% CI)	12.14 (4.14, NE)	20.14 (4.14, NE)	10.14 (8.14, NE)	10.14 (4.14, NE)
Median (95% CI)	NE (8.14, NE)	NE (NE, NE)	NE (8.14, NE)	NE (8.14, NE)
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (12.14, NE)	NE (23.29, NE)
Min, Max	1.14, 25.14	4.14, 25.14	1.14, 25.14	4.14, 25.14
Stratified Log-Rank Test p-value	0.42		0.49	
Adjusted Inverse Hazard Ratio (95% CI)	0.62 (0.16, 2.35)		2.33 (0.39, 13.91)	
Unstratified Log-Rank Test p-value	0.58		0.88	
Unadjusted Inverse Hazard Ratio (95% CI)	0.73 (0.23, 2.31)		0.87 (0.23, 3.25)	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Response is defined as >=50% reduction in TSS from baseline.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-tte-tss50-sub.sas V.03.05 Output file: t-tte-tss50-mf.pdf 24AUG2023:12:41

Table 2.1408: Analysis of Time to First Response (50% criterion) in TSS by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

(Continued)	Primary Myelofibrosis MMB (N=59)	Primary Myelofibrosis RUX (N=54)	p-value
Subjects with Event			
Response (50% criterion) in TSS, n(%)	23 (39.0%)	27 (50.0%)	
Censor			
Subjects Censored, n(%)	36 (61.0%)	27 (50.0%)	
Non-Responder: Censored at Last Daily mMPN-SAF TSS Assessment Date on or before Day 176	36 (100.0%)	27 (100.0%)	
No Post-Baseline TSS data: Censored at Randomization Date	0	0	
Kaplan-Meier Estimate of Time to First Response (50% criterion) in TSS (Weeks)			
25-percentile (95% CI)	12.14 (8.14, 16.14)	8.14 (4.14, 12.14)	
Median (95% CI)	NE (16.14, NE)	25.00 (12.14, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (25.00, NE)	
Min, Max	2.43, 25.14	4.00, 25.14	
Stratified Log-Rank Test p-value	0.54		
Adjusted Inverse Hazard Ratio (95% CI)	1.29 (0.72, 2.29)		
Unstratified Log-Rank Test p-value	0.25		
Unadjusted Inverse Hazard Ratio (95% CI)	1.38 (0.79, 2.40)		
P-value for interaction test			0.77

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Response is defined as >=50% reduction in TSS from baseline.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019

Table 2.1403: Analysis of Time to First Response (50% criterion) in TSS by Gender
Double-blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Subjects with Event					
Response (50% criterion) in TSS, n(%)	19 (38.0%)	23 (41.1%)	13 (36.1%)	16 (42.1%)	
Censor					
Subjects Censored, n(%)	31 (62.0%)	33 (58.9%)	23 (63.9%)	22 (57.9%)	
Non-Responder: Censored at Last Daily mMPN-SAF TSS Assessment Date on or before Day 176	31 (100.0%)	33 (100.0%)	23 (100.0%)	22 (100.0%)	
No Post-Baseline TSS data: Censored at Randomization Date	0	0	0	0	
Kaplan-Meier Estimate of Time to First Response (50% criterion) in TSS (Weeks)					
25-percentile (95% CI)	12.14 (8.14, 16.14)	8.14 (4.14, 20.14)	12.14 (4.14, 20.14)	8.14 (4.14, 16.14)	
Median (95% CI)	NE (12.14, NE)	NE (20.14, NE)	NE (12.14, NE)	25.00 (12.14, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (25.00, NE)	
Min, Max	2.43, 25.14	4.00, 25.14	1.14, 25.14	4.14, 25.14	
Stratified Log-Rank Test p-value	0.53		0.62		
Adjusted Inverse Hazard Ratio (95% CI)	1.25 (0.66, 2.37)		1.19 (0.57, 2.52)		
Unstratified Log-Rank Test p-value	0.74		0.92		
Unadjusted Inverse Hazard Ratio (95% CI)	1.09 (0.60, 2.01)		1.05 (0.50, 2.18)		
P-value for interaction test					0.89

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Response is defined as >=50% reduction in TSS from baseline.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-tte-tss50-sub.sas V.03.05 Output file: t-tte-tss50-sex.pdf 24AUG2023:12:41

Table 2.1410: Analysis of Time to First Response (50% criterion) in TSS by Baseline Spleen Volume
Double-blind Phase
ITT-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Subjects with Event					
Response (50% criterion) in TSS, n(%)	20 (42.6%)	17 (39.5%)	12 (30.8%)	22 (43.1%)	
Censor					
Subjects Censored, n(%)	27 (57.4%)	26 (60.5%)	27 (69.2%)	29 (56.9%)	
Non-Responder: Censored at Last Daily mMPN-SAF TSS Assessment Date on or before Day 176	27 (100.0%)	26 (100.0%)	27 (100.0%)	29 (100.0%)	
No Post-Baseline TSS data: Censored at Randomization Date	0	0	0	0	
Kaplan-Meier Estimate of Time to First Response (50% criterion) in TSS (Weeks)					
25-percentile (95% CI)	12.14 (4.14, 16.14)	8.14 (4.14, 25.00)	12.14 (8.14, NE)	8.14 (4.14, 16.14)	
Median (95% CI)	NE (12.14, NE)	NE (20.14, NE)	NE (12.14, NE)	NE (12.14, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	1.14, 25.14	4.00, 25.14	1.14, 25.14	4.14, 25.14	
Stratified Log-Rank Test p-value	0.75		0.083		
Adjusted Inverse Hazard Ratio (95% CI)	0.86 (0.44, 1.71)		2.01 (0.95, 4.27)		
Unstratified Log-Rank Test p-value	0.57		0.27		
Unadjusted Inverse Hazard Ratio (95% CI)	0.83 (0.43, 1.59)		1.46 (0.72, 2.94)		
P-value for interaction test					0.15

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Response is defined as >=50% reduction in TSS from baseline.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-tte-tss50-sub.sas V.03.05 Output file: t-tte-tss50-svb.pdf 24AUG2023:12:41

Table 2.1409: Analysis of Time to First Response (50% criterion) in TSS by Baseline TSS
Double-blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Subjects with Event					
Response (50% criterion) in TSS, n(%)	17 (38.6%)	23 (41.8%)	15 (36.6%)	16 (42.1%)	
Censor					
Subjects Censored, n(%)	27 (61.4%)	32 (58.2%)	26 (63.4%)	22 (57.9%)	
Non-Responder: Censored at Last Daily mMPN-SAF TSS Assessment Date on or before Day 176	27 (100.0%)	32 (100.0%)	26 (100.0%)	22 (100.0%)	
No Post-Baseline TSS data: Censored at Randomization Date	0	0	0	0	
Kaplan-Meier Estimate of Time to First Response (50% criterion) in TSS (Weeks)					
25-percentile (95% CI)	12.14 (8.14, 20.14)	4.14 (4.14, 12.14)	12.14 (8.14, 16.14)	12.14 (8.14, 23.71)	
Median (95% CI)	NE (12.14, NE)	NE (12.14, NE)	NE (12.14, NE)	25.00 (16.14, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (25.00, NE)	
Min, Max	1.14, 25.14	4.00, 25.14	1.14, 25.14	4.14, 25.14	
Stratified Log-Rank Test p-value	0.57		0.94		
Adjusted Inverse Hazard Ratio (95% CI)	1.24 (0.66, 2.36)		1.09 (0.53, 2.22)		
Unstratified Log-Rank Test p-value	0.75		0.94		
Unadjusted Inverse Hazard Ratio (95% CI)	1.12 (0.60, 2.10)		1.01 (0.50, 2.05)		
P-value for interaction test					0.85

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Response is defined as >=50% reduction in TSS from baseline.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-tte-tss50-sub.sas V.03.05 Output file: t-tte-tss50-tss.pdf 24AUG2023:12:41

Table 2.6402: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Age
Double-blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	RUX (N = 36)	MMB (N = 62)	RUX (N = 58)	p-value
BFI Total Score at Week 24					
Responder, n(%)	3 (12.5%)	2 (5.6%)	4 (6.5%)	2 (3.4%)	
Unadjusted Relative Risk (95% CI)	2.25 (0.41, 12.48)		1.87 (0.36, 9.83)		
p-value [1]	0.35		0.46		
Unadjusted interaction test for Treatment*Age Group [3]					NA
Unadjusted Odds Ratio (95% CI)	2.43 (0.37, 15.76)		1.93 (0.34, 10.97)		
p-value [1]	0.35		0.46		
Unadjusted Absolute Risk Difference (95% CI)	0.07 (-0.08, 0.22)		0.03 (-0.05, 0.11)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Age Group [3]					NA
Non-Responder, n(%)	21 (87.5%)	34 (94.4%)	58 (93.5%)	56 (96.6%)	
Non-missing	13 (54.2%)	23 (63.9%)	39 (62.9%)	41 (70.7%)	
Missing	8 (33.3%)	11 (30.6%)	19 (30.6%)	15 (25.9%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-bfi-gba-improv.sas V.03.05 Output file: t-sgp-bfi-gba-det-age.pdf 29AUG2023: 9:39

Table 2.6402: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Age
Double-blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	RUX (N = 36)	MMB (N = 62)	RUX (N = 58)	p-value
BFI Fatigue Score at Week 24					
Responder, n(%)	4 (16.7%)	2 (5.6%)	6 (9.7%)	2 (3.4%)	
Unadjusted Relative Risk (95% CI)	3.00 (0.60, 15.11)		2.81 (0.59, 13.35)		
p-value [1]	0.18		0.19		
Unadjusted interaction test for Treatment*Age Group [3]					NA
Unadjusted Odds Ratio (95% CI)	3.40 (0.57, 20.26)		3.00 (0.58, 15.51)		
p-value [1]	0.18		0.19		
Unadjusted Absolute Risk Difference (95% CI)	0.11 (-0.06, 0.28)		0.06 (-0.03, 0.15)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Age Group [3]					NA
Non-Responder, n(%)	20 (83.3%)	34 (94.4%)	56 (90.3%)	56 (96.6%)	
Non-missing	12 (50.0%)	23 (63.9%)	37 (59.7%)	41 (70.7%)	
Missing	8 (33.3%)	11 (30.6%)	19 (30.6%)	15 (25.9%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-bfi-gba-improv.sas V.03.05 Output file: t-sgp-bfi-gba-det-age.pdf 29AUG2023: 9:39

Table 2.6402: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Age
Double-blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	RUX (N = 36)	MMB (N = 62)	RUX (N = 58)	p-value
BFI Interference Score at Week 24					
Responder, n(%)	3 (12.5%)	1 (2.8%)	3 (4.8%)	1 (1.7%)	
Unadjusted Relative Risk (95% CI)	4.50 (0.50, 40.75)		2.81 (0.30, 26.22)		
p-value [1]	0.18		0.37		
Unadjusted interaction test for Treatment*Age Group [3]					NA
Unadjusted Odds Ratio (95% CI)	5.00 (0.49, 51.23)		2.90 (0.29, 28.69)		
p-value [1]	0.18		0.36		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.05, 0.24)		0.03 (-0.03, 0.09)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Age Group [3]					NA
Non-Responder, n(%)	21 (87.5%)	35 (97.2%)	59 (95.2%)	57 (98.3%)	
Non-missing	13 (54.2%)	24 (66.7%)	40 (64.5%)	42 (72.4%)	
Missing	8 (33.3%)	11 (30.6%)	19 (30.6%)	15 (25.9%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.6404: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Region
Double-blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N = 53)	RUX (N = 51)	MMB (N = 33)	RUX (N = 43)	p-value
BFI Total Score at Week 24					
Responder, n(%)	5 (9.4%)	3 (5.9%)	2 (6.1%)	1 (2.3%)	
Unadjusted Relative Risk (95% CI)	1.60 (0.40, 6.37)		2.61 (0.25, 27.52)		
p-value [1]	0.50		0.43		
Unadjusted interaction test for Treatment*Region [3]					NA
Unadjusted Odds Ratio (95% CI)	1.67 (0.38, 7.37)		2.71 (0.24, 31.24)		
p-value [1]	0.50		0.42		
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.07, 0.14)		0.04 (-0.06, 0.13)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Region [3]					NA
Non-Responder, n(%)	48 (90.6%)	48 (94.1%)	31 (93.9%)	42 (97.7%)	
Non-missing	27 (50.9%)	30 (58.8%)	25 (75.8%)	34 (79.1%)	
Missing	21 (39.6%)	18 (35.3%)	6 (18.2%)	8 (18.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-bfi-gba-improv.sas V.03.05 Output file: t-sgp-bfi-gba-det-geo.pdf 29AUG2023: 9:39

Table 2.6404: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Region
Double-blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N = 53)	RUX (N = 51)	MMB (N = 33)	RUX (N = 43)	p-value
BFI Fatigue Score at Week 24					
Responder, n(%)	4 (7.5%)	4 (7.8%)	6 (18.2%)	0	
Unadjusted Relative Risk (95% CI)	0.96 (0.25, 3.64)		16.82 (0.98, 288.37)		
p-value [1]	0.95		0.052		
Unadjusted interaction test for Treatment*Region [3]					NA
Unadjusted Odds Ratio (95% CI)	0.96 (0.23, 4.06)		20.56 (1.11, 379.70)		
p-value [1]	0.95		0.042		
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.11, 0.10)		0.18 (0.04, 0.32)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Region [3]					NA
Non-Responder, n(%)	49 (92.5%)	47 (92.2%)	27 (81.8%)	43 (100.0%)	
Non-missing	28 (52.8%)	29 (56.9%)	21 (63.6%)	35 (81.4%)	
Missing	21 (39.6%)	18 (35.3%)	6 (18.2%)	8 (18.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-bfi-gba-improv.sas V.03.05 Output file: t-sgp-bfi-gba-det-geo.pdf 29AUG2023: 9:39

Table 2.6404: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Region
Double-blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N = 53)	RUX (N = 51)	MMB (N = 33)	RUX (N = 43)	p-value
BFI Interference Score at Week 24					
Responder, n(%)	5 (9.4%)	1 (2.0%)	1 (3.0%)	1 (2.3%)	
Unadjusted Relative Risk (95% CI)	4.81 (0.58, 39.78)		1.30 (0.08, 20.07)		
p-value [1]	0.14		0.85		
Unadjusted interaction test for Treatment*Region [3]					NA
Unadjusted Odds Ratio (95% CI)	5.21 (0.59, 46.23)		1.31 (0.08, 21.80)		
p-value [1]	0.14		0.85		
Unadjusted Absolute Risk Difference (95% CI)	0.07 (-0.01, 0.16)		0.01 (-0.07, 0.08)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Region [3]					NA
Non-Responder, n(%)	48 (90.6%)	50 (98.0%)	32 (97.0%)	42 (97.7%)	
Non-missing	27 (50.9%)	32 (62.7%)	26 (78.8%)	34 (79.1%)	
Missing	21 (39.6%)	18 (35.3%)	6 (18.2%)	8 (18.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
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Table 2.6407: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline Hemoglobin Level
Double-blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 28)	RUX (N = 21)	MMB (N = 58)	RUX (N = 73)	p-value
BFI Total Score at Week 24					
Responder, n(%)	2 (7.1%)	2 (9.5%)	5 (8.6%)	2 (2.7%)	
Unadjusted Relative Risk (95% CI)	0.75 (0.11, 4.90)		3.15 (0.63, 15.63)		
p-value [1]	0.76		0.16		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Unadjusted Odds Ratio (95% CI)	0.73 (0.09, 5.66)		3.35 (0.63, 17.93)		
p-value [1]	0.76		0.16		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.18, 0.13)		0.06 (-0.02, 0.14)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Non-Responder, n(%)	26 (92.9%)	19 (90.5%)	53 (91.4%)	71 (97.3%)	
Non-missing	16 (57.1%)	14 (66.7%)	36 (62.1%)	50 (68.5%)	
Missing	10 (35.7%)	5 (23.8%)	17 (29.3%)	21 (28.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-bfi-gba-improv.sas V.03.05 Output file: t-sgp-bfi-gba-det-hgb.pdf 29AUG2023: 9:40

Table 2.6407: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline Hemoglobin Level
Double-blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 28)	RUX (N = 21)	MMB (N = 58)	RUX (N = 73)	p-value
BFI Fatigue Score at Week 24					
Responder, n(%)	2 (7.1%)	2 (9.5%)	8 (13.8%)	2 (2.7%)	
Unadjusted Relative Risk (95% CI)	0.75 (0.11, 4.90)		5.03 (1.11, 22.81)		
p-value [1]	0.76		0.036		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.21
Unadjusted Odds Ratio (95% CI)	0.73 (0.09, 5.66)		5.68 (1.16, 27.89)		
p-value [1]	0.76		0.032		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.18, 0.13)		0.11 (0.01, 0.21)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.21
Non-Responder, n(%)	26 (92.9%)	19 (90.5%)	50 (86.2%)	71 (97.3%)	
Non-missing	16 (57.1%)	14 (66.7%)	33 (56.9%)	50 (68.5%)	
Missing	10 (35.7%)	5 (23.8%)	17 (29.3%)	21 (28.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-bfi-gba-improv.sas V.03.05 Output file: t-sgp-bfi-gba-det-hgb.pdf 29AUG2023: 9:40

Table 2.6407: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline Hemoglobin Level
Double-blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 28)	RUX (N = 21)	MMB (N = 58)	RUX (N = 73)	p-value
BFI Interference Score at Week 24					
Responder, n(%)	2 (7.1%)	2 (9.5%)	4 (6.9%)	0	
Unadjusted Relative Risk (95% CI)	0.75 (0.11, 4.90)		11.29 (0.62, 205.50)		
p-value [1]	0.76		0.10		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Unadjusted Odds Ratio (95% CI)	0.73 (0.09, 5.66)		12.14 (0.64, 230.22)		
p-value [1]	0.76		0.096		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.18, 0.13)		0.07 (0.00, 0.14)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Non-Responder, n(%)	26 (92.9%)	19 (90.5%)	54 (93.1%)	73 (100.0%)	
Non-missing	16 (57.1%)	14 (66.7%)	37 (63.8%)	52 (71.2%)	
Missing	10 (35.7%)	5 (23.8%)	17 (29.3%)	21 (28.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-bfi-gba-improv.sas V.03.05 Output file: t-sgp-bfi-gba-det-hgb.pdf 29AUG2023: 9:40

Table 2.6406: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline IPSS Two-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 28)	RUX (N = 24)	MMB (N = 58)	RUX (N = 70)	p-value
BFI Total Score at Week 24					
Responder, n(%)	2 (7.1%)	1 (4.2%)	5 (8.6%)	3 (4.3%)	
Unadjusted Relative Risk (95% CI)	1.71 (0.17, 17.76)		2.01 (0.50, 8.06)		
p-value [1]	0.65		0.32		
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [3]					NA
Unadjusted Odds Ratio (95% CI)	1.77 (0.15, 20.82)		2.11 (0.48, 9.22)		
p-value [1]	0.65		0.32		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.09, 0.15)		0.04 (-0.04, 0.13)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*IPSS 2-Level Risk [3]					NA
Non-Responder, n(%)	26 (92.9%)	23 (95.8%)	53 (91.4%)	67 (95.7%)	
Non-missing	16 (57.1%)	16 (66.7%)	36 (62.1%)	48 (68.6%)	
Missing	10 (35.7%)	7 (29.2%)	17 (29.3%)	19 (27.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-bfi-gba-improv.sas V.03.05 Output file: t-sgp-bfi-gba-det-ip2.pdf 29AUG2023: 9:40

Table 2.6406: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline IPSS Two-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 28)	RUX (N = 24)	MMB (N = 58)	RUX (N = 70)	p-value
BFI Fatigue Score at Week 24					
Responder, n(%)	4 (14.3%)	1 (4.2%)	6 (10.3%)	3 (4.3%)	
Unadjusted Relative Risk (95% CI)	3.43 (0.41, 28.63)		2.41 (0.63, 9.23)		
p-value [1]	0.26		0.20		
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [3]					NA
Unadjusted Odds Ratio (95% CI)	3.83 (0.40, 36.91)		2.58 (0.62, 10.79)		
p-value [1]	0.24		0.20		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.05, 0.25)		0.06 (-0.03, 0.15)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*IPSS 2-Level Risk [3]					NA
Non-Responder, n(%)	24 (85.7%)	23 (95.8%)	52 (89.7%)	67 (95.7%)	
Non-missing	14 (50.0%)	16 (66.7%)	35 (60.3%)	48 (68.6%)	
Missing	10 (35.7%)	7 (29.2%)	17 (29.3%)	19 (27.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-bfi-gba-improv.sas V.03.05 Output file: t-sgp-bfi-gba-det-ip2.pdf 29AUG2023: 9:40

Table 2.6406: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline IPSS Two-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 28)	RUX (N = 24)	MMB (N = 58)	RUX (N = 70)	p-value
BFI Interference Score at Week 24					
Responder, n(%)	2 (7.1%)	0	4 (6.9%)	2 (2.9%)	
Unadjusted Relative Risk (95% CI)	4.31 (0.22, 85.62)		2.41 (0.46, 12.71)		
p-value [1]	0.34		0.30		
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [3]					NA
Unadjusted Odds Ratio (95% CI)	4.62 (0.21, 101.16)		2.52 (0.44, 14.27)		
p-value [1]	0.33		0.30		
Unadjusted Absolute Risk Difference (95% CI)	0.07 (-0.05, 0.18)		0.04 (-0.04, 0.12)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*IPSS 2-Level Risk [3]					NA
Non-Responder, n(%)	26 (92.9%)	24 (100.0%)	54 (93.1%)	68 (97.1%)	
Non-missing	16 (57.1%)	17 (70.8%)	37 (63.8%)	49 (70.0%)	
Missing	10 (35.7%)	7 (29.2%)	17 (29.3%)	19 (27.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-bfi-gba-improv.sas V.03.05 Output file: t-sgp-bfi-gba-det-ip2.pdf 29AUG2023: 9:40

Table 2.6405: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 2)	RUX (N = 4)	MMB (N = 26)	RUX (N = 20)
BFI Total Score at Week 24				
Responder, n(%)	0	1 (25.0%)	2 (7.7%)	0
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Non-Responder, n(%)	2 (100.0%)	3 (75.0%)	24 (92.3%)	20 (100.0%)
Non-missing	1 (50.0%)	2 (50.0%)	15 (57.7%)	14 (70.0%)
Missing	1 (50.0%)	1 (25.0%)	9 (34.6%)	6 (30.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-bfi-gba-improv.sas V.03.05 Output file: t-sgp-bfi-gba-det-ip3.pdf 29AUG2023: 9:40

Table 2.6405: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 58)	RUX (N = 70)	p-value
BFI Total Score at Week 24			
Responder, n(%)	5 (8.6%)	3 (4.3%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	53 (91.4%)	67 (95.7%)	
Non-missing	36 (62.1%)	48 (68.6%)	
Missing	17 (29.3%)	19 (27.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-bfi-gba-improv.sas V.03.05 Output file: t-sgp-bfi-gba-det-ip3.pdf 29AUG2023: 9:40

Table 2.6405: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 2)	RUX (N = 4)	MMB (N = 26)	RUX (N = 20)
BFI Fatigue Score at Week 24				
Responder, n(%)	0	1 (25.0%)	4 (15.4%)	0
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Non-Responder, n(%)	2 (100.0%)	3 (75.0%)	22 (84.6%)	20 (100.0%)
Non-missing	1 (50.0%)	2 (50.0%)	13 (50.0%)	14 (70.0%)
Missing	1 (50.0%)	1 (25.0%)	9 (34.6%)	6 (30.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-bfi-gba-improv.sas V.03.05 Output file: t-sgp-bfi-gba-det-ip3.pdf 29AUG2023: 9:40

Table 2.6405: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 58)	RUX (N = 70)	p-value
BFI Fatigue Score at Week 24			
Responder, n(%)	6 (10.3%)	3 (4.3%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	52 (89.7%)	67 (95.7%)	
Non-missing	35 (60.3%)	48 (68.6%)	
Missing	17 (29.3%)	19 (27.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-bfi-gba-improv.sas V.03.05 Output file: t-sgp-bfi-gba-det-ip3.pdf 29AUG2023: 9:40

Table 2.6405: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 2)	RUX (N = 4)	MMB (N = 26)	RUX (N = 20)
BFI Interference Score at Week 24				
Responder, n(%)	0	0	2 (7.7%)	0
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Non-Responder, n(%)	2 (100.0%)	4 (100.0%)	24 (92.3%)	20 (100.0%)
Non-missing	1 (50.0%)	3 (75.0%)	15 (57.7%)	14 (70.0%)
Missing	1 (50.0%)	1 (25.0%)	9 (34.6%)	6 (30.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-bfi-gba-improv.sas V.03.05 Output file: t-sgp-bfi-gba-det-ip3.pdf 29AUG2023: 9:40

Table 2.6405: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 58)	RUX (N = 70)	p-value
BFI Interference Score at Week 24			
Responder, n(%)	4 (6.9%)	2 (2.9%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	54 (93.1%)	68 (97.1%)	
Non-missing	37 (63.8%)	49 (70.0%)	
Missing	17 (29.3%)	19 (27.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-bfi-gba-improv.sas V.03.05 Output file: t-sgp-bfi-gba-det-ip3.pdf 29AUG2023: 9:40

Table 2.6408: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 59)	RUX (N = 54)	MMB (N = 16)	RUX (N = 28)
BFI Total Score at Week 24				
Responder, n(%)	4 (6.8%)	3 (5.6%)	3 (18.8%)	0
Unadjusted Relative Risk (95% CI)	1.22 (0.29, 5.21)		11.94 (0.66, 217.48	
p-value [1]	0.79		0.094	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Odds Ratio (95% CI)	1.24 (0.26, 5.79)		14.78 (0.71, 306.83	
p-value [1]	0.79		0.082	
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.08, 0.10)		0.19 (-0.01, 0.39)	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	55 (93.2%)	51 (94.4%)	13 (81.3%)	28 (100.0%)
Non-missing	38 (64.4%)	41 (75.9%)	7 (43.8%)	17 (60.7%)
Missing	17 (28.8%)	10 (18.5%)	6 (37.5%)	11 (39.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-bfi-gba-improv.sas V.03.05 Output file: t-sgp-bfi-gba-det-mf.pdf 29AUG2023: 9:40

Table 2.6408: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 11)	RUX (N = 12)	p-value
BFI Total Score at Week 24			
Responder, n(%)	0	1 (8.3%)	
Unadjusted Relative Risk (95% CI)	0.36 (0.02, 8.04)		
p-value [1]	0.52		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Unadjusted Odds Ratio (95% CI)	0.33 (0.01, 9.07)		
p-value [1]	0.51		
Unadjusted Absolute Risk Difference (95% CI)	-0.07 (-0.28, 0.13)		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Non-Responder, n(%)	11 (100.0%)	11 (91.7%)	
Non-missing	7 (63.6%)	6 (50.0%)	
Missing	4 (36.4%)	5 (41.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.6408: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 59)	RUX (N = 54)	MMB (N = 16)	RUX (N = 28)
BFI Fatigue Score at Week 24				
Responder, n(%)	7 (11.9%)	2 (3.7%)	3 (18.8%)	0
Unadjusted Relative Risk (95% CI)	3.20 (0.70, 14.76)		11.94 (0.66, 217.48	
p-value [1]	0.14		0.094	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Odds Ratio (95% CI)	3.50 (0.69, 17.65)		14.78 (0.71, 306.83	
p-value [1]	0.13		0.082	
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.02, 0.18)		0.19 (-0.01, 0.39)	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	52 (88.1%)	52 (96.3%)	13 (81.3%)	28 (100.0%)
Non-missing	35 (59.3%)	42 (77.8%)	7 (43.8%)	17 (60.7%)
Missing	17 (28.8%)	10 (18.5%)	6 (37.5%)	11 (39.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.6408: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 11)	RUX (N = 12)	p-value
BFI Fatigue Score at Week 24			
Responder, n(%)	0	2 (16.7%)	
Unadjusted Relative Risk (95% CI)	0.22 (0.01, 4.07)		
p-value [1]	0.31		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Unadjusted Odds Ratio (95% CI)	0.18 (0.01, 4.26)		
p-value [1]	0.29		
Unadjusted Absolute Risk Difference (95% CI)	-0.15 (-0.39, 0.09)		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Non-Responder, n(%)	11 (100.0%)	10 (83.3%)	
Non-missing	7 (63.6%)	5 (41.7%)	
Missing	4 (36.4%)	5 (41.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.6408: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 59)	RUX (N = 54)	MMB (N = 16)	RUX (N = 28)
BFI Interference Score at Week 24				
Responder, n(%)	3 (5.1%)	1 (1.9%)	3 (18.8%)	0
Unadjusted Relative Risk (95% CI)	2.75 (0.29, 25.61)		11.94 (0.66, 217.48	
p-value [1]	0.38		0.094	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Odds Ratio (95% CI)	2.84 (0.29, 28.15)		14.78 (0.71, 306.83	
p-value [1]	0.37		0.082	
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.03, 0.10)		0.19 (-0.01, 0.39)	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	56 (94.9%)	53 (98.1%)	13 (81.3%)	28 (100.0%)
Non-missing	39 (66.1%)	43 (79.6%)	7 (43.8%)	17 (60.7%)
Missing	17 (28.8%)	10 (18.5%)	6 (37.5%)	11 (39.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
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Table 2.6408: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 11)	RUX (N = 12)	p-value
BFI Interference Score at Week 24			
Responder, n(%)	0	1 (8.3%)	
Unadjusted Relative Risk (95% CI)	0.36 (0.02, 8.04)		
p-value [1]	0.52		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Unadjusted Odds Ratio (95% CI)	0.33 (0.01, 9.07)		
p-value [1]	0.51		
Unadjusted Absolute Risk Difference (95% CI)	-0.07 (-0.28, 0.13)		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Non-Responder, n(%)	11 (100.0%)	11 (91.7%)	
Non-missing	7 (63.6%)	6 (50.0%)	
Missing	4 (36.4%)	5 (41.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.6403: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Gender
Double-blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 50)	RUX (N = 56)	MMB (N = 36)	RUX (N = 38)	p-value
BFI Total Score at Week 24					
Responder, n(%)	4 (8.0%)	2 (3.6%)	3 (8.3%)	2 (5.3%)	
Unadjusted Relative Risk (95% CI)	2.24 (0.43, 11.71)		1.58 (0.28, 8.93)		
p-value [1]	0.34		0.60		
Unadjusted interaction test for Treatment*Gender [3]					NA
Unadjusted Odds Ratio (95% CI)	2.35 (0.41, 13.41)		1.64 (0.26, 10.41)		
p-value [1]	0.34		0.60		
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.05, 0.13)		0.03 (-0.08, 0.15)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Gender [3]					NA
Non-Responder, n(%)	46 (92.0%)	54 (96.4%)	33 (91.7%)	36 (94.7%)	
Non-missing	31 (62.0%)	40 (71.4%)	21 (58.3%)	24 (63.2%)	
Missing	15 (30.0%)	14 (25.0%)	12 (33.3%)	12 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-bfi-gba-improv.sas V.03.05 Output file: t-sgp-bfi-gba-det-sex.pdf 29AUG2023: 9:39

Table 2.6403: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Gender
Double-blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 50)	RUX (N = 56)	MMB (N = 36)	RUX (N = 38)	p-value
BFI Fatigue Score at Week 24					
Responder, n(%)	6 (12.0%)	3 (5.4%)	4 (11.1%)	1 (2.6%)	
Unadjusted Relative Risk (95% CI)	2.24 (0.59, 8.49)		4.22 (0.50, 36.01)		
p-value [1]	0.24		0.19		
Unadjusted interaction test for Treatment*Gender [3]					NA
Unadjusted Odds Ratio (95% CI)	2.41 (0.57, 10.19)		4.63 (0.49, 43.52)		
p-value [1]	0.23		0.18		
Unadjusted Absolute Risk Difference (95% CI)	0.07 (-0.04, 0.17)		0.08 (-0.03, 0.20)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Gender [3]					NA
Non-Responder, n(%)	44 (88.0%)	53 (94.6%)	32 (88.9%)	37 (97.4%)	
Non-missing	29 (58.0%)	39 (69.6%)	20 (55.6%)	25 (65.8%)	
Missing	15 (30.0%)	14 (25.0%)	12 (33.3%)	12 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-bfi-gba-improv.sas V.03.05 Output file: t-sgp-bfi-gba-det-sex.pdf 29AUG2023: 9:39

Table 2.6403: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Gender
Double-blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 50)	RUX (N = 56)	MMB (N = 36)	RUX (N = 38)	p-value
BFI Interference Score at Week 24					
Responder, n(%)	3 (6.0%)	1 (1.8%)	3 (8.3%)	1 (2.6%)	
Unadjusted Relative Risk (95% CI)	3.36 (0.36, 31.27)		3.17 (0.35, 29.06)		
p-value [1]	0.29		0.31		
Unadjusted interaction test for Treatment*Gender [3]					NA
Unadjusted Odds Ratio (95% CI)	3.51 (0.35, 34.89)		3.36 (0.33, 33.93)		
p-value [1]	0.28		0.30		
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.03, 0.12)		0.06 (-0.05, 0.16)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Gender [3]					NA
Non-Responder, n(%)	47 (94.0%)	55 (98.2%)	33 (91.7%)	37 (97.4%)	
Non-missing	32 (64.0%)	41 (73.2%)	21 (58.3%)	25 (65.8%)	
Missing	15 (30.0%)	14 (25.0%)	12 (33.3%)	12 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-bfi-gba-improv.sas V.03.05 Output file: t-sgp-bfi-gba-det-sex.pdf 29AUG2023: 9:39

Table 2.6410: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline Spleen Volume
Double-blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N = 47)	RUX (N = 43)	MMB (N = 39)	RUX (N = 51)	p-value
BFI Total Score at Week 24					
Responder, n(%)	4 (8.5%)	1 (2.3%)	3 (7.7%)	3 (5.9%)	
Unadjusted Relative Risk (95% CI)	3.66 (0.43, 31.48)		1.31 (0.28, 6.13)		
p-value [1]	0.24		0.73		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Odds Ratio (95% CI)	3.91 (0.42, 36.42)		1.33 (0.25, 7.00)		
p-value [1]	0.23		0.73		
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.03, 0.15)		0.02 (-0.09, 0.12)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Non-Responder, n(%)	43 (91.5%)	42 (97.7%)	36 (92.3%)	48 (94.1%)	
Non-missing	31 (66.0%)	30 (69.8%)	21 (53.8%)	34 (66.7%)	
Missing	12 (25.5%)	12 (27.9%)	15 (38.5%)	14 (27.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
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Table 2.6410: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline Spleen Volume
Double-blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N = 47)	RUX (N = 43)	MMB (N = 39)	RUX (N = 51)	p-value
BFI Fatigue Score at Week 24					
Responder, n(%)	6 (12.8%)	2 (4.7%)	4 (10.3%)	2 (3.9%)	
Unadjusted Relative Risk (95% CI)	2.74 (0.58, 12.88)		2.62 (0.50, 13.56)		
p-value [1]	0.20		0.25		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Odds Ratio (95% CI)	3.00 (0.57, 15.74)		2.80 (0.49, 16.14)		
p-value [1]	0.19		0.25		
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.03, 0.20)		0.06 (-0.05, 0.17)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Non-Responder, n(%)	41 (87.2%)	41 (95.3%)	35 (89.7%)	49 (96.1%)	
Non-missing	29 (61.7%)	29 (67.4%)	20 (51.3%)	35 (68.6%)	
Missing	12 (25.5%)	12 (27.9%)	15 (38.5%)	14 (27.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-bfi-gba-improv.sas V.03.05 Output file: t-sgp-bfi-gba-det-svb.pdf 29AUG2023: 9:41

Table 2.6410: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline Spleen Volume
Double-blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N = 47)	RUX (N = 43)	MMB (N = 39)	RUX (N = 51)	p-value
BFI Interference Score at Week 24					
Responder, n(%)	4 (8.5%)	0	2 (5.1%)	2 (3.9%)	
Unadjusted Relative Risk (95% CI)	8.25 (0.46, 148.89)		1.31 (0.19, 8.88)		
p-value [1]	0.15		0.78		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Odds Ratio (95% CI)	9.00 (0.47, 172.27)		1.32 (0.18, 9.84)		
p-value [1]	0.14		0.78		
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.01, 0.17)		0.01 (-0.08, 0.10)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Non-Responder, n(%)	43 (91.5%)	43 (100.0%)	37 (94.9%)	49 (96.1%)	
Non-missing	31 (66.0%)	31 (72.1%)	22 (56.4%)	35 (68.6%)	
Missing	12 (25.5%)	12 (27.9%)	15 (38.5%)	14 (27.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
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Table 2.6409: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline TSS
Double-blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 44)	RUX (N = 55)	MMB (N = 41)	RUX (N = 38)	p-value
BFI Total Score at Week 24					
Responder, n(%)	4 (9.1%)	2 (3.6%)	3 (7.3%)	2 (5.3%)	
Unadjusted Relative Risk (95% CI)	2.50 (0.48, 13.02)		1.39 (0.25, 7.87)		
p-value [1]	0.28		0.71		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Unadjusted Odds Ratio (95% CI)	2.65 (0.46, 15.19)		1.42 (0.22, 9.01)		
p-value [1]	0.27		0.71		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.04, 0.15)		0.02 (-0.09, 0.13)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Non-Responder, n(%)	40 (90.9%)	53 (96.4%)	38 (92.7%)	36 (94.7%)	
Non-missing	31 (70.5%)	40 (72.7%)	20 (48.8%)	23 (60.5%)	
Missing	9 (20.5%)	13 (23.6%)	18 (43.9%)	13 (34.2%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
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Table 2.6409: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline TSS
Double-blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 44)	RUX (N = 55)	MMB (N = 41)	RUX (N = 38)	p-value
BFI Fatigue Score at Week 24					
Responder, n(%)	5 (11.4%)	1 (1.8%)	5 (12.2%)	3 (7.9%)	
Unadjusted Relative Risk (95% CI)	6.25 (0.76, 51.56)		1.54 (0.40, 6.03)		
p-value [1]	0.089		0.53		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Unadjusted Odds Ratio (95% CI)	6.92 (0.78, 61.63)		1.62 (0.36, 7.30)		
p-value [1]	0.083		0.53		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (0.00, 0.20)		0.04 (-0.09, 0.17)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Non-Responder, n(%)	39 (88.6%)	54 (98.2%)	36 (87.8%)	35 (92.1%)	
Non-missing	30 (68.2%)	41 (74.5%)	18 (43.9%)	22 (57.9%)	
Missing	9 (20.5%)	13 (23.6%)	18 (43.9%)	13 (34.2%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
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Table 2.6409: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline TSS
Double-blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 44)	RUX (N = 55)	MMB (N = 41)	RUX (N = 38)	p-value
BFI Interference Score at Week 24					
Responder, n(%)	4 (9.1%)	1 (1.8%)	2 (4.9%)	1 (2.6%)	
Unadjusted Relative Risk (95% CI)	5.00 (0.58, 43.15)		1.85 (0.18, 19.62)		
p-value [1]	0.14		0.61		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Unadjusted Odds Ratio (95% CI)	5.40 (0.58, 50.18)		1.90 (0.17, 21.82)		
p-value [1]	0.14		0.61		
Unadjusted Absolute Risk Difference (95% CI)	0.07 (-0.02, 0.16)		0.02 (-0.06, 0.11)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Non-Responder, n(%)	40 (90.9%)	54 (98.2%)	39 (95.1%)	37 (97.4%)	
Non-missing	31 (70.5%)	41 (74.5%)	21 (51.2%)	24 (63.2%)	
Missing	9 (20.5%)	13 (23.6%)	18 (43.9%)	13 (34.2%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
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Table 2.6302: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Age
Double-blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	RUX (N = 36)	MMB (N = 62)	RUX (N = 58)	p-value
BFI Total Score at Week 24					
Responder, n(%)	3 (12.5%)	9 (25.0%)	18 (29.0%)	17 (29.3%)	
Unadjusted Inverse Relative Risk (95% CI)	2.00 (0.60, 6.64)		1.01 (0.58, 1.76)		
p-value [1]	0.26		0.97		
Unadjusted interaction test for Treatment*Age Group [3]					0.28
Unadjusted Inverse Odds Ratio (95% CI)	2.33 (0.56, 9.71)		1.01 (0.46, 2.23)		
p-value [1]	0.24		0.97		
Unadjusted Absolute Risk Difference (95% CI)	-0.13 (-0.32, 0.07)		0.00 (-0.17, 0.16)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Age Group [3]					NE
Non-Responder, n(%)	21 (87.5%)	27 (75.0%)	44 (71.0%)	41 (70.7%)	
Non-missing	13 (54.2%)	16 (44.4%)	25 (40.3%)	26 (44.8%)	
Missing	8 (33.3%)	11 (30.6%)	19 (30.6%)	15 (25.9%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.6302: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Age
Double-blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	RUX (N = 36)	MMB (N = 62)	RUX (N = 58)	p-value
BFI Fatigue Score at Week 24					
Responder, n(%)	4 (16.7%)	5 (13.9%)	19 (30.6%)	18 (31.0%)	
Unadjusted Inverse Relative Risk (95% CI)	0.83 (0.25, 2.79)		1.01 (0.59, 1.73)		
p-value [1]	0.77		0.96		
Unadjusted interaction test for Treatment*Age Group [3]					0.78
Unadjusted Inverse Odds Ratio (95% CI)	0.81 (0.19, 3.37)		1.02 (0.47, 2.21)		
p-value [1]	0.77		0.96		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.16, 0.21)		0.00 (-0.17, 0.16)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		1.16 (0.68, 1.96)		
p-value [2]	NE		0.59		
Adjusted interaction test for Treatment*Age Group [3]					0.62
Non-Responder, n(%)	20 (83.3%)	31 (86.1%)	43 (69.4%)	40 (69.0%)	
Non-missing	12 (50.0%)	20 (55.6%)	24 (38.7%)	25 (43.1%)	
Missing	8 (33.3%)	11 (30.6%)	19 (30.6%)	15 (25.9%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
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Table 2.6302: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Age
Double-blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	RUX (N = 36)	MMB (N = 62)	RUX (N = 58)	p-value
BFI Interference Score at Week 24					
Responder, n(%)	4 (16.7%)	9 (25.0%)	16 (25.8%)	18 (31.0%)	
Unadjusted Inverse Relative Risk (95% CI)	1.50 (0.52, 4.32)		1.20 (0.68, 2.13)		
p-value [1]	0.45		0.53		
Unadjusted interaction test for Treatment*Age Group [3]					0.71
Unadjusted Inverse Odds Ratio (95% CI)	1.67 (0.45, 6.19)		1.29 (0.58, 2.87)		
p-value [1]	0.45		0.53		
Unadjusted Absolute Risk Difference (95% CI)	-0.08 (-0.29, 0.12)		-0.05 (-0.21, 0.11)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Age Group [3]					NE
Non-Responder, n(%)	20 (83.3%)	27 (75.0%)	46 (74.2%)	40 (69.0%)	
Non-missing	12 (50.0%)	16 (44.4%)	27 (43.5%)	25 (43.1%)	
Missing	8 (33.3%)	11 (30.6%)	19 (30.6%)	15 (25.9%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.6304: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Region
Double-blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N = 53)	RUX (N = 51)	MMB (N = 33)	RUX (N = 43)	p-value
BFI Total Score at Week 24					
Responder, n(%)	14 (26.4%)	12 (23.5%)	7 (21.2%)	14 (32.6%)	
Unadjusted Inverse Relative Risk (95% CI)	0.89 (0.46, 1.74)		1.53 (0.70, 3.37)		
p-value [1]	0.73		0.29		
Unadjusted interaction test for Treatment*Region [3]					0.29
Unadjusted Inverse Odds Ratio (95% CI)	0.86 (0.35, 2.09)		1.79 (0.63, 5.13)		
p-value [1]	0.73		0.28		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.14, 0.20)		-0.11 (-0.31, 0.08)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Region [3]					NE
Non-Responder, n(%)	39 (73.6%)	39 (76.5%)	26 (78.8%)	29 (67.4%)	
Non-missing	18 (34.0%)	21 (41.2%)	20 (60.6%)	21 (48.8%)	
Missing	21 (39.6%)	18 (35.3%)	6 (18.2%)	8 (18.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
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Table 2.6304: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Region
Double-blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N = 53)	RUX (N = 51)	MMB (N = 33)	RUX (N = 43)	p-value
BFI Fatigue Score at Week 24					
Responder, n(%)	13 (24.5%)	12 (23.5%)	10 (30.3%)	11 (25.6%)	
Unadjusted Inverse Relative Risk (95% CI)	0.96 (0.48, 1.90)		0.84 (0.41, 1.75)		
p-value [1]	0.91		0.65		
Unadjusted interaction test for Treatment*Region [3]					0.80
Unadjusted Inverse Odds Ratio (95% CI)	0.95 (0.38, 2.33)		0.79 (0.29, 2.17)		
p-value [1]	0.91		0.65		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.15, 0.17)		0.05 (-0.16, 0.25)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.90 (0.47, 1.75)		NE		
p-value [2]	0.76		NE		
Adjusted interaction test for Treatment*Region [3]					0.78
Non-Responder, n(%)	40 (75.5%)	39 (76.5%)	23 (69.7%)	32 (74.4%)	
Non-missing	19 (35.8%)	21 (41.2%)	17 (51.5%)	24 (55.8%)	
Missing	21 (39.6%)	18 (35.3%)	6 (18.2%)	8 (18.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
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Table 2.6304: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Region
Double-blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N = 53)	RUX (N = 51)	MMB (N = 33)	RUX (N = 43)	p-value
BFI Interference Score at Week 24					
Responder, n(%)	13 (24.5%)	11 (21.6%)	7 (21.2%)	16 (37.2%)	
Unadjusted Inverse Relative Risk (95% CI)	0.88 (0.43, 1.78)		1.75 (0.82, 3.76)		
p-value [1]	0.72		0.15		
Unadjusted interaction test for Treatment*Region [3]					0.18
Unadjusted Inverse Odds Ratio (95% CI)	0.85 (0.34, 2.11)		2.20 (0.78, 6.22)		
p-value [1]	0.72		0.14		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.13, 0.19)		-0.16 (-0.36, 0.04)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Region [3]					NE
Non-Responder, n(%)	40 (75.5%)	40 (78.4%)	26 (78.8%)	27 (62.8%)	
Non-missing	19 (35.8%)	22 (43.1%)	20 (60.6%)	19 (44.2%)	
Missing	21 (39.6%)	18 (35.3%)	6 (18.2%)	8 (18.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
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Table 2.6307: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline Hemoglobin Level
Double-blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 28)	RUX (N = 21)	MMB (N = 58)	RUX (N = 73)	p-value
BFI Total Score at Week 24					
Responder, n(%)	8 (28.6%)	6 (28.6%)	13 (22.4%)	20 (27.4%)	
Unadjusted Inverse Relative Risk (95% CI)	1.00 (0.41, 2.45)		1.22 (0.67, 2.24)		
p-value [1]	1.00		0.52		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.71
Unadjusted Inverse Odds Ratio (95% CI)	1.00 (0.29, 3.50)		1.31 (0.58, 2.92)		
p-value [1]	1.00		0.51		
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.26, 0.26)		-0.05 (-0.20, 0.10)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.98 (0.41, 2.32)		NE		
p-value [2]	0.96		NE		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE
Non-Responder, n(%)	20 (71.4%)	15 (71.4%)	45 (77.6%)	53 (72.6%)	
Non-missing	10 (35.7%)	10 (47.6%)	28 (48.3%)	32 (43.8%)	
Missing	10 (35.7%)	5 (23.8%)	17 (29.3%)	21 (28.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-bfi-gba-improv.sas V.03.05 Output file: t-sgp-bfi-gba-imp-hgb.pdf 29AUG2023: 9:39

Table 2.6307: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline Hemoglobin Level
Double-blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 28)	RUX (N = 21)	MMB (N = 58)	RUX (N = 73)	p-value
BFI Fatigue Score at Week 24					
Responder, n(%)	10 (35.7%)	6 (28.6%)	13 (22.4%)	17 (23.3%)	
Unadjusted Inverse Relative Risk (95% CI)	0.80 (0.35, 1.85)		1.04 (0.55, 1.96)		
p-value [1]	0.60		0.91		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.62
Unadjusted Inverse Odds Ratio (95% CI)	0.72 (0.21, 2.44)		1.05 (0.46, 2.39)		
p-value [1]	0.60		0.91		
Unadjusted Absolute Risk Difference (95% CI)	0.07 (-0.19, 0.33)		-0.01 (-0.15, 0.14)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.79 (0.35, 1.78)		1.11 (0.60, 2.03)		
p-value [2]	0.56		0.75		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.50
Non-Responder, n(%)	18 (64.3%)	15 (71.4%)	45 (77.6%)	56 (76.7%)	
Non-missing	8 (28.6%)	10 (47.6%)	28 (48.3%)	35 (47.9%)	
Missing	10 (35.7%)	5 (23.8%)	17 (29.3%)	21 (28.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-bfi-gba-improv.sas V.03.05 Output file: t-sgp-bfi-gba-imp-hgb.pdf 29AUG2023: 9:39

Table 2.6307: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline Hemoglobin Level
Double-blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 28)	RUX (N = 21)	MMB (N = 58)	RUX (N = 73)	p-value
BFI Interference Score at Week 24					
Responder, n(%)	7 (25.0%)	5 (23.8%)	13 (22.4%)	22 (30.1%)	
Unadjusted Inverse Relative Risk (95% CI)	0.95 (0.35, 2.58)		1.34 (0.74, 2.43)		
p-value [1]	0.92		0.33		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.56
Unadjusted Inverse Odds Ratio (95% CI)	0.94 (0.25, 3.51)		1.49 (0.67, 3.30)		
p-value [1]	0.92		0.32		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.23, 0.25)		-0.08 (-0.23, 0.07)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.92 (0.35, 2.45)		NE		
p-value [2]	0.87		NE		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE
Non-Responder, n(%)	21 (75.0%)	16 (76.2%)	45 (77.6%)	51 (69.9%)	
Non-missing	11 (39.3%)	11 (52.4%)	28 (48.3%)	30 (41.1%)	
Missing	10 (35.7%)	5 (23.8%)	17 (29.3%)	21 (28.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-bfi-gba-improv.sas V.03.05 Output file: t-sgp-bfi-gba-imp-hgb.pdf 29AUG2023: 9:39

Table 2.6306: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline IPSS Two-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 28)	RUX (N = 24)	MMB (N = 58)	RUX (N = 70)	p-value
BFI Total Score at Week 24					
Responder, n(%)	4 (14.3%)	7 (29.2%)	17 (29.3%)	19 (27.1%)	
Unadjusted Inverse Relative Risk (95% CI)	2.04 (0.68, 6.14)		0.93 (0.53, 1.61)		
p-value [1]	0.20		0.79		
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.20
Unadjusted Inverse Odds Ratio (95% CI)	2.47 (0.62, 9.79)		0.90 (0.41, 1.95)		
p-value [1]	0.20		0.79		
Unadjusted Absolute Risk Difference (95% CI)	-0.15 (-0.37, 0.07)		0.02 (-0.14, 0.18)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*IPSS 2-Level Risk [3]					NE
Non-Responder, n(%)	24 (85.7%)	17 (70.8%)	41 (70.7%)	51 (72.9%)	
Non-missing	14 (50.0%)	10 (41.7%)	24 (41.4%)	32 (45.7%)	
Missing	10 (35.7%)	7 (29.2%)	17 (29.3%)	19 (27.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-bfi-gba-improv.sas V.03.05 Output file: t-sgp-bfi-gba-imp-ip2.pdf 29AUG2023: 9:39

Table 2.6306: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline IPSS Two-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 28)	RUX (N = 24)	MMB (N = 58)	RUX (N = 70)	p-value
BFI Fatigue Score at Week 24					
Responder, n(%)	6 (21.4%)	4 (16.7%)	17 (29.3%)	19 (27.1%)	
Unadjusted Inverse Relative Risk (95% CI)	0.78 (0.25, 2.44)		0.93 (0.53, 1.61)		
p-value [1]	0.67		0.79		
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.79
Unadjusted Inverse Odds Ratio (95% CI)	0.73 (0.18, 2.98)		0.90 (0.41, 1.95)		
p-value [1]	0.66		0.79		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.17, 0.26)		0.02 (-0.14, 0.18)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.98 (0.57, 1.67)		
p-value [2]	NE		0.94		
Adjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.69
Non-Responder, n(%)	22 (78.6%)	20 (83.3%)	41 (70.7%)	51 (72.9%)	
Non-missing	12 (42.9%)	13 (54.2%)	24 (41.4%)	32 (45.7%)	
Missing	10 (35.7%)	7 (29.2%)	17 (29.3%)	19 (27.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.6306: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline IPSS Two-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 28)	RUX (N = 24)	MMB (N = 58)	RUX (N = 70)	p-value
BFI Interference Score at Week 24					
Responder, n(%)	5 (17.9%)	8 (33.3%)	15 (25.9%)	19 (27.1%)	
Unadjusted Inverse Relative Risk (95% CI)	1.87 (0.70, 4.95)		1.05 (0.59, 1.88)		
p-value [1]	0.21		0.87		
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.31
Unadjusted Inverse Odds Ratio (95% CI)	2.30 (0.64, 8.33)		1.07 (0.49, 2.35)		
p-value [1]	0.20		0.87		
Unadjusted Absolute Risk Difference (95% CI)	-0.15 (-0.39, 0.08)		-0.01 (-0.17, 0.14)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*IPSS 2-Level Risk [3]					NE
Non-Responder, n(%)	23 (82.1%)	16 (66.7%)	43 (74.1%)	51 (72.9%)	
Non-missing	13 (46.4%)	9 (37.5%)	26 (44.8%)	32 (45.7%)	
Missing	10 (35.7%)	7 (29.2%)	17 (29.3%)	19 (27.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.6305: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 2)	RUX (N = 4)	MMB (N = 26)	RUX (N = 20)
BFI Total Score at Week 24				
Responder, n(%)	0	1 (25.0%)	4 (15.4%)	6 (30.0%)
Unadjusted Inverse Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Non-Responder, n(%)	2 (100.0%)	3 (75.0%)	22 (84.6%)	14 (70.0%)
Non-missing	1 (50.0%)	2 (50.0%)	13 (50.0%)	8 (40.0%)
Missing	1 (50.0%)	1 (25.0%)	9 (34.6%)	6 (30.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-bfi-gba-improv.sas V.03.05 Output file: t-sgp-bfi-gba-imp-ip3.pdf 29AUG2023: 9:39

Table 2.6305: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 58)	RUX (N = 70)	p-value
BFI Total Score at Week 24			
Responder, n(%)	17 (29.3%)	19 (27.1%)	
Unadjusted Inverse Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	41 (70.7%)	51 (72.9%)	
Non-missing	24 (41.4%)	32 (45.7%)	
Missing	17 (29.3%)	19 (27.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.6305: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 2)	RUX (N = 4)	MMB (N = 26)	RUX (N = 20)
BFI Fatigue Score at Week 24				
Responder, n(%)	1 (50.0%)	0	5 (19.2%)	4 (20.0%)
Unadjusted Inverse Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Non-Responder, n(%)	1 (50.0%)	4 (100.0%)	21 (80.8%)	16 (80.0%)
Non-missing	0	3 (75.0%)	12 (46.2%)	10 (50.0%)
Missing	1 (50.0%)	1 (25.0%)	9 (34.6%)	6 (30.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.6305: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 58)	RUX (N = 70)	p-value
BFI Fatigue Score at Week 24			
Responder, n(%)	17 (29.3%)	19 (27.1%)	
Unadjusted Inverse Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	41 (70.7%)	51 (72.9%)	
Non-missing	24 (41.4%)	32 (45.7%)	
Missing	17 (29.3%)	19 (27.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-bfi-gba-improv.sas V.03.05 Output file: t-sgp-bfi-gba-imp-ip3.pdf 29AUG2023: 9:39

Table 2.6305: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 2)	RUX (N = 4)	MMB (N = 26)	RUX (N = 20)
BFI Interference Score at Week 24				
Responder, n(%)	0	1 (25.0%)	5 (19.2%)	7 (35.0%)
Unadjusted Inverse Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Non-Responder, n(%)	2 (100.0%)	3 (75.0%)	21 (80.8%)	13 (65.0%)
Non-missing	1 (50.0%)	2 (50.0%)	12 (46.2%)	7 (35.0%)
Missing	1 (50.0%)	1 (25.0%)	9 (34.6%)	6 (30.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-bfi-gba-improv.sas V.03.05 Output file: t-sgp-bfi-gba-imp-ip3.pdf 29AUG2023: 9:39

Table 2.6305: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 58)	RUX (N = 70)	p-value
BFI Interference Score at Week 24			
Responder, n(%)	15 (25.9%)	19 (27.1%)	
Unadjusted Inverse Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	43 (74.1%)	51 (72.9%)	
Non-missing	26 (44.8%)	32 (45.7%)	
Missing	17 (29.3%)	19 (27.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-bfi-gba-improv.sas V.03.05 Output file: t-sgp-bfi-gba-imp-ip3.pdf 29AUG2023: 9:39

Table 2.6308: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 59)	RUX (N = 54)	MMB (N = 16)	RUX (N = 28)
BFI Total Score at Week 24				
Responder, n(%)	17 (28.8%)	18 (33.3%)	1 (6.3%)	6 (21.4%)
Unadjusted Inverse Relative Risk (95% CI)	1.16 (0.67, 2.01)		3.43 (0.45, 26.00)	
p-value [1]	0.60		0.23	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	1.24 (0.56, 2.75)		4.09 (0.45, 37.53)	
p-value [1]	0.60		0.21	
Unadjusted Absolute Risk Difference (95% CI)	-0.05 (-0.22, 0.13)		-0.15 (-0.34, 0.04)	
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE	
p-value [2]	NE		NE	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	42 (71.2%)	36 (66.7%)	15 (93.8%)	22 (78.6%)
Non-missing	25 (42.4%)	26 (48.1%)	9 (56.3%)	11 (39.3%)
Missing	17 (28.8%)	10 (18.5%)	6 (37.5%)	11 (39.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
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Table 2.6308: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 11)	RUX (N = 12)	p-value
BFI Total Score at Week 24			
Responder, n(%)	3 (27.3%)	2 (16.7%)	
Unadjusted Inverse Relative Risk (95% CI)	0.61 (0.12, 3.00)		
p-value [1]	0.54		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.32
Unadjusted Inverse Odds Ratio (95% CI)	0.53 (0.07, 4.01)		
p-value [1]	0.54		
Unadjusted Absolute Risk Difference (95% CI)	0.11 (-0.23, 0.44)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NE
Non-Responder, n(%)	8 (72.7%)	10 (83.3%)	
Non-missing	4 (36.4%)	5 (41.7%)	
Missing	4 (36.4%)	5 (41.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-bfi-gba-improv.sas V.03.05 Output file: t-sgp-bfi-gba-imp-mf.pdf 29AUG2023: 9:39

Table 2.6308: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 59)	RUX (N = 54)	MMB (N = 16)	RUX (N = 28)
BFI Fatigue Score at Week 24				
Responder, n(%)	18 (30.5%)	16 (29.6%)	1 (6.3%)	5 (17.9%)
Unadjusted Inverse Relative Risk (95% CI)	0.97 (0.55, 1.71)		2.86 (0.37, 22.36)	
p-value [1]	0.92		0.32	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	0.96 (0.43, 2.15)		3.26 (0.35, 30.74)	
p-value [1]	0.92		0.30	
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.16, 0.18)		-0.12 (-0.30, 0.07)	
Adjusted Inverse Relative Risk (95% CI) [2]	1.08 (0.62, 1.87)		NE	
p-value [2]	0.79		NE	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	41 (69.5%)	38 (70.4%)	15 (93.8%)	23 (82.1%)
Non-missing	24 (40.7%)	28 (51.9%)	9 (56.3%)	12 (42.9%)
Missing	17 (28.8%)	10 (18.5%)	6 (37.5%)	11 (39.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-bfi-gba-improv.sas V.03.05 Output file: t-sgp-bfi-gba-imp-mf.pdf 29AUG2023: 9:39

Table 2.6308: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 11)	RUX (N = 12)	p-value
BFI Fatigue Score at Week 24			
Responder, n(%)	4 (36.4%)	2 (16.7%)	
Unadjusted Inverse Relative Risk (95% CI)	0.46 (0.10, 2.03)		
p-value [1]	0.30		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.28
Unadjusted Inverse Odds Ratio (95% CI)	0.35 (0.05, 2.47)		
p-value [1]	0.29		
Unadjusted Absolute Risk Difference (95% CI)	0.20 (-0.16, 0.55)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.30
Non-Responder, n(%)	7 (63.6%)	10 (83.3%)	
Non-missing	3 (27.3%)	5 (41.7%)	
Missing	4 (36.4%)	5 (41.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-bfi-gba-improv.sas V.03.05 Output file: t-sgp-bfi-gba-imp-mf.pdf 29AUG2023: 9:39

Table 2.6308: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 59)	RUX (N = 54)	MMB (N = 16)	RUX (N = 28)
BFI Interference Score at Week 24				
Responder, n(%)	17 (28.8%)	18 (33.3%)	0	7 (25.0%)
Unadjusted Inverse Relative Risk (95% CI)	1.16 (0.67, 2.01)		8.79 (0.53, 144.52)	
p-value [1]	0.60		0.13	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	1.24 (0.56, 2.75)		11.51 (0.61, 216.40	
p-value [1]	0.60		0.10	
Unadjusted Absolute Risk Difference (95% CI)	-0.05 (-0.22, 0.13)		-0.23 (-0.41, -0.05	
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE	
p-value [2]	NE		NE	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	42 (71.2%)	36 (66.7%)	16 (100.0%)	21 (75.0%)
Non-missing	25 (42.4%)	26 (48.1%)	10 (62.5%)	10 (35.7%)
Missing	17 (28.8%)	10 (18.5%)	6 (37.5%)	11 (39.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-bfi-gba-improv.sas V.03.05 Output file: t-sgp-bfi-gba-imp-mf.pdf 29AUG2023: 9:39

Table 2.6308: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 11)	RUX (N = 12)	p-value
BFI Interference Score at Week 24			
Responder, n(%)	3 (27.3%)	2 (16.7%)	
Unadjusted Inverse Relative Risk (95% CI)	0.61 (0.12, 3.00)		
p-value [1]	0.54		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NE
Unadjusted Inverse Odds Ratio (95% CI)	0.53 (0.07, 4.01)		
p-value [1]	0.54		
Unadjusted Absolute Risk Difference (95% CI)	0.11 (-0.23, 0.44)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NE
Non-Responder, n(%)	8 (72.7%)	10 (83.3%)	
Non-missing	4 (36.4%)	5 (41.7%)	
Missing	4 (36.4%)	5 (41.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
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Table 2.6303: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Gender
Double-blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 50)	RUX (N = 56)	MMB (N = 36)	RUX (N = 38)	p-value
BFI Total Score at Week 24					
Responder, n(%)	13 (26.0%)	16 (28.6%)	8 (22.2%)	10 (26.3%)	
Unadjusted Inverse Relative Risk (95% CI)	1.10 (0.59, 2.05)		1.18 (0.53, 2.66)		
p-value [1]	0.77		0.68		
Unadjusted interaction test for Treatment*Gender [3]					0.89
Unadjusted Inverse Odds Ratio (95% CI)	1.14 (0.48, 2.68)		1.25 (0.43, 3.63)		
p-value [1]	0.77		0.68		
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.20, 0.14)		-0.04 (-0.24, 0.15)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Gender [3]					NE
Non-Responder, n(%)	37 (74.0%)	40 (71.4%)	28 (77.8%)	28 (73.7%)	
Non-missing	22 (44.0%)	26 (46.4%)	16 (44.4%)	16 (42.1%)	
Missing	15 (30.0%)	14 (25.0%)	12 (33.3%)	12 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-bfi-gba-improv.sas V.03.05 Output file: t-sgp-bfi-gba-imp-sex.pdf 29AUG2023: 9:39

Table 2.6303: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Gender
Double-blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 50)	RUX (N = 56)	MMB (N = 36)	RUX (N = 38)	p-value
BFI Fatigue Score at Week 24					
Responder, n(%)	14 (28.0%)	12 (21.4%)	9 (25.0%)	11 (28.9%)	
Unadjusted Inverse Relative Risk (95% CI)	0.77 (0.39, 1.50)		1.16 (0.54, 2.46)		
p-value [1]	0.43		0.70		
Unadjusted interaction test for Treatment*Gender [3]					0.42
Unadjusted Inverse Odds Ratio (95% CI)	0.70 (0.29, 1.70)		1.22 (0.44, 3.42)		
p-value [1]	0.43		0.70		
Unadjusted Absolute Risk Difference (95% CI)	0.07 (-0.10, 0.23)		-0.04 (-0.24, 0.16)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		1.17 (0.56, 2.44)		
p-value [2]	NE		0.67		
Adjusted interaction test for Treatment*Gender [3]					0.52
Non-Responder, n(%)	36 (72.0%)	44 (78.6%)	27 (75.0%)	27 (71.1%)	
Non-missing	21 (42.0%)	30 (53.6%)	15 (41.7%)	15 (39.5%)	
Missing	15 (30.0%)	14 (25.0%)	12 (33.3%)	12 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-bfi-gba-improv.sas V.03.05 Output file: t-sgp-bfi-gba-imp-sex.pdf 29AUG2023: 9:39

Table 2.6303: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Gender
Double-blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 50)	RUX (N = 56)	MMB (N = 36)	RUX (N = 38)	p-value
BFI Interference Score at Week 24					
Responder, n(%)	13 (26.0%)	16 (28.6%)	7 (19.4%)	11 (28.9%)	
Unadjusted Inverse Relative Risk (95% CI)	1.10 (0.59, 2.05)		1.49 (0.65, 3.42)		
p-value [1]	0.77		0.35		
Unadjusted interaction test for Treatment*Gender [3]					0.56
Unadjusted Inverse Odds Ratio (95% CI)	1.14 (0.48, 2.68)		1.69 (0.57, 4.98)		
p-value [1]	0.77		0.34		
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.20, 0.14)		-0.10 (-0.29, 0.10)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Gender [3]					NE
Non-Responder, n(%)	37 (74.0%)	40 (71.4%)	29 (80.6%)	27 (71.1%)	
Non-missing	22 (44.0%)	26 (46.4%)	17 (47.2%)	15 (39.5%)	
Missing	15 (30.0%)	14 (25.0%)	12 (33.3%)	12 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-bfi-gba-improv.sas V.03.05 Output file: t-sgp-bfi-gba-imp-sex.pdf 29AUG2023: 9:39

Table 2.6310: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline Spleen Volume
Double-blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N = 47)	RUX (N = 43)	MMB (N = 39)	RUX (N = 51)	p-value
BFI Total Score at Week 24					
Responder, n(%)	13 (27.7%)	12 (27.9%)	8 (20.5%)	14 (27.5%)	
Unadjusted Inverse Relative Risk (95% CI)	1.01 (0.52, 1.97)		1.34 (0.62, 2.87)		
p-value [1]	0.98		0.45		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.58
Unadjusted Inverse Odds Ratio (95% CI)	1.01 (0.40, 2.55)		1.47 (0.54, 3.95)		
p-value [1]	0.98		0.45		
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.19, 0.18)		-0.07 (-0.25, 0.11)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NE
Non-Responder, n(%)	34 (72.3%)	31 (72.1%)	31 (79.5%)	37 (72.5%)	
Non-missing	22 (46.8%)	19 (44.2%)	16 (41.0%)	23 (45.1%)	
Missing	12 (25.5%)	12 (27.9%)	15 (38.5%)	14 (27.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-bfi-gba-improv.sas V.03.05 Output file: t-sgp-bfi-gba-imp-svb.pdf 29AUG2023: 9:39

Table 2.6310: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline Spleen Volume
Double-blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N = 47)	RUX (N = 43)	MMB (N = 39)	RUX (N = 51)	p-value
BFI Fatigue Score at Week 24					
Responder, n(%)	13 (27.7%)	10 (23.3%)	10 (25.6%)	13 (25.5%)	
Unadjusted Inverse Relative Risk (95% CI)	0.84 (0.41, 1.72)		0.99 (0.49, 2.02)		
p-value [1]	0.63		0.99		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.74
Unadjusted Inverse Odds Ratio (95% CI)	0.79 (0.31, 2.06)		0.99 (0.38, 2.58)		
p-value [1]	0.63		0.99		
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.14, 0.22)		0.00 (-0.18, 0.18)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		1.03 (0.49, 2.15)		
p-value [2]	NE		0.95		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.95
Non-Responder, n(%)	34 (72.3%)	33 (76.7%)	29 (74.4%)	38 (74.5%)	
Non-missing	22 (46.8%)	21 (48.8%)	14 (35.9%)	24 (47.1%)	
Missing	12 (25.5%)	12 (27.9%)	15 (38.5%)	14 (27.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-bfi-gba-improv.sas V.03.05 Output file: t-sgp-bfi-gba-imp-svb.pdf 29AUG2023: 9:39

Table 2.6310: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline Spleen Volume
Double-blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N = 47)	RUX (N = 43)	MMB (N = 39)	RUX (N = 51)	p-value
BFI Interference Score at Week 24					
Responder, n(%)	14 (29.8%)	14 (32.6%)	6 (15.4%)	13 (25.5%)	
Unadjusted Inverse Relative Risk (95% CI)	1.09 (0.59, 2.02)		1.66 (0.69, 3.97)		
p-value [1]	0.78		0.26		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.43
Unadjusted Inverse Odds Ratio (95% CI)	1.14 (0.47, 2.78)		1.88 (0.64, 5.51)		
p-value [1]	0.78		0.25		
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.22, 0.16)		-0.10 (-0.27, 0.06)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NE
Non-Responder, n(%)	33 (70.2%)	29 (67.4%)	33 (84.6%)	38 (74.5%)	
Non-missing	21 (44.7%)	17 (39.5%)	18 (46.2%)	24 (47.1%)	
Missing	12 (25.5%)	12 (27.9%)	15 (38.5%)	14 (27.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-bfi-gba-improv.sas V.03.05 Output file: t-sgp-bfi-gba-imp-svb.pdf 29AUG2023: 9:39

Table 2.6309: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline TSS
Double-blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 44)	RUX (N = 55)	MMB (N = 41)	RUX (N = 38)	p-value
BFI Total Score at Week 24					
Responder, n(%)	9 (20.5%)	9 (16.4%)	11 (26.8%)	16 (42.1%)	
Unadjusted Inverse Relative Risk (95% CI)	0.80 (0.35, 1.84)		1.57 (0.84, 2.94)		
p-value [1]	0.60		0.16		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.21
Unadjusted Inverse Odds Ratio (95% CI)	0.76 (0.27, 2.12)		1.98 (0.77, 5.10)		
p-value [1]	0.60		0.16		
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.11, 0.20)		-0.15 (-0.36, 0.05)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NE
Non-Responder, n(%)	35 (79.5%)	46 (83.6%)	30 (73.2%)	22 (57.9%)	
Non-missing	26 (59.1%)	33 (60.0%)	12 (29.3%)	9 (23.7%)	
Missing	9 (20.5%)	13 (23.6%)	18 (43.9%)	13 (34.2%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-bfi-gba-improv.sas V.03.05 Output file: t-sgp-bfi-gba-imp-tss.pdf 29AUG2023: 9:39

Table 2.6309: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline TSS
Double-blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 44)	RUX (N = 55)	MMB (N = 41)	RUX (N = 38)	p-value
BFI Fatigue Score at Week 24					
Responder, n(%)	12 (27.3%)	7 (12.7%)	10 (24.4%)	15 (39.5%)	
Unadjusted Inverse Relative Risk (95% CI)	0.47 (0.20, 1.08)		1.62 (0.83, 3.15)		
p-value [1]	0.077		0.16		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.022
Unadjusted Inverse Odds Ratio (95% CI)	0.39 (0.14, 1.09)		2.02 (0.77, 5.31)		
p-value [1]	0.073		0.15		
Unadjusted Absolute Risk Difference (95% CI)	0.15 (-0.01, 0.30)		-0.15 (-0.35, 0.05)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		1.79 (0.97, 3.29)		
p-value [2]	NE		0.062		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					0.022
Non-Responder, n(%)	32 (72.7%)	48 (87.3%)	31 (75.6%)	23 (60.5%)	
Non-missing	23 (52.3%)	35 (63.6%)	13 (31.7%)	10 (26.3%)	
Missing	9 (20.5%)	13 (23.6%)	18 (43.9%)	13 (34.2%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

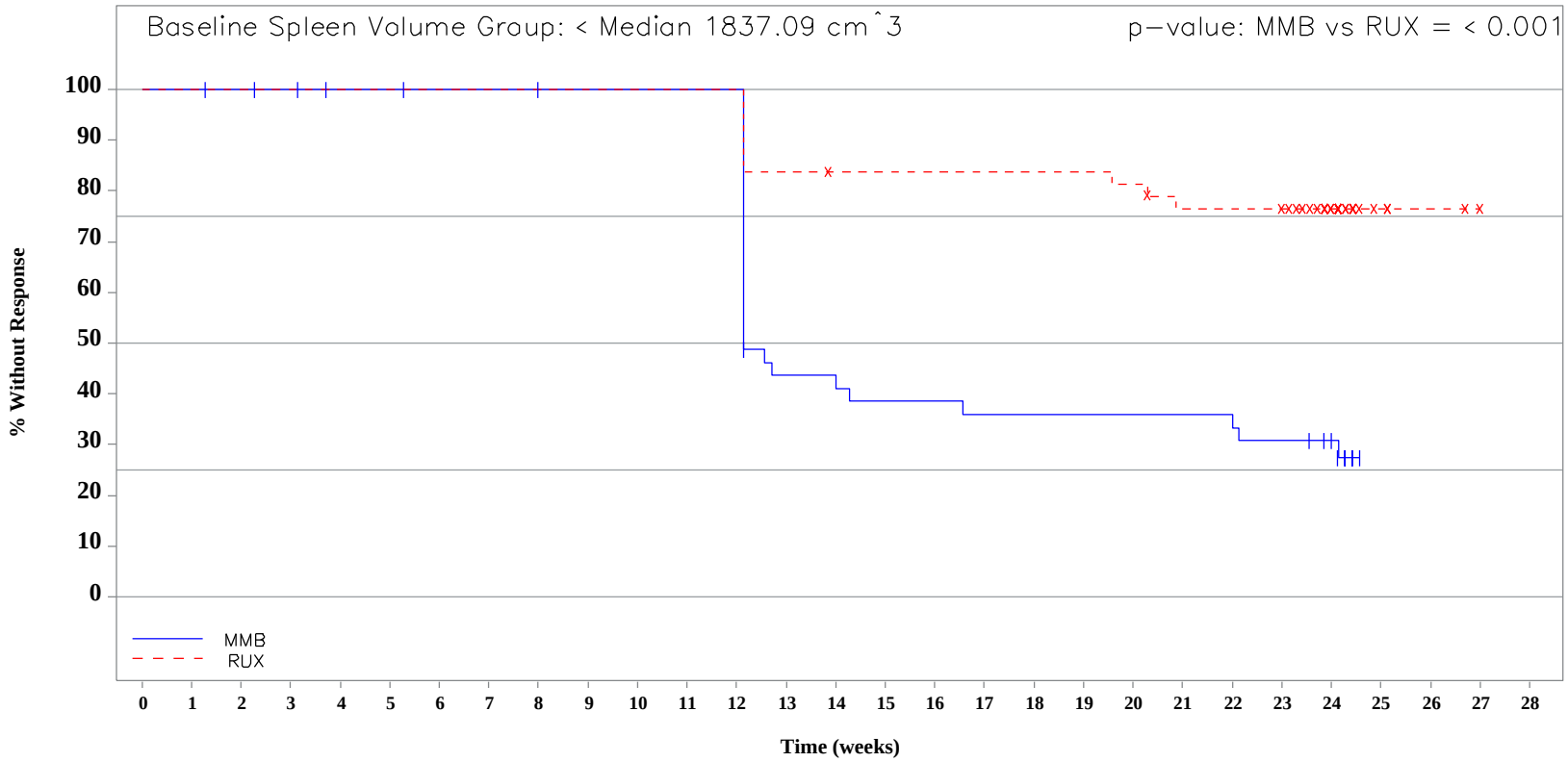
Table 2.6309: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline TSS
Double-blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 44)	RUX (N = 55)	MMB (N = 41)	RUX (N = 38)	p-value
BFI Interference Score at Week 24					
Responder, n(%)	10 (22.7%)	11 (20.0%)	9 (22.0%)	15 (39.5%)	
Unadjusted Inverse Relative Risk (95% CI)	0.88 (0.41, 1.88)		1.80 (0.89, 3.62)		
p-value [1]	0.74		0.100		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.18
Unadjusted Inverse Odds Ratio (95% CI)	0.85 (0.32, 2.23)		2.32 (0.87, 6.21)		
p-value [1]	0.74		0.094		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.14, 0.19)		-0.18 (-0.38, 0.03)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NE
Non-Responder, n(%)	34 (77.3%)	44 (80.0%)	32 (78.0%)	23 (60.5%)	
Non-missing	25 (56.8%)	31 (56.4%)	14 (34.1%)	10 (26.3%)	
Missing	9 (20.5%)	13 (23.6%)	18 (43.9%)	13 (34.2%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-bfi-gba-improv.sas V.03.05 Output file: t-sgp-bfi-gba-imp-tss.pdf 29AUG2023: 9:39

Figure 2.2210: Kaplan-Meier Plot of Time to RBC Transfusion Independent Response by Baseline Spleen Volume
Double-blind Phase
ITT-Anemic Analysis Set



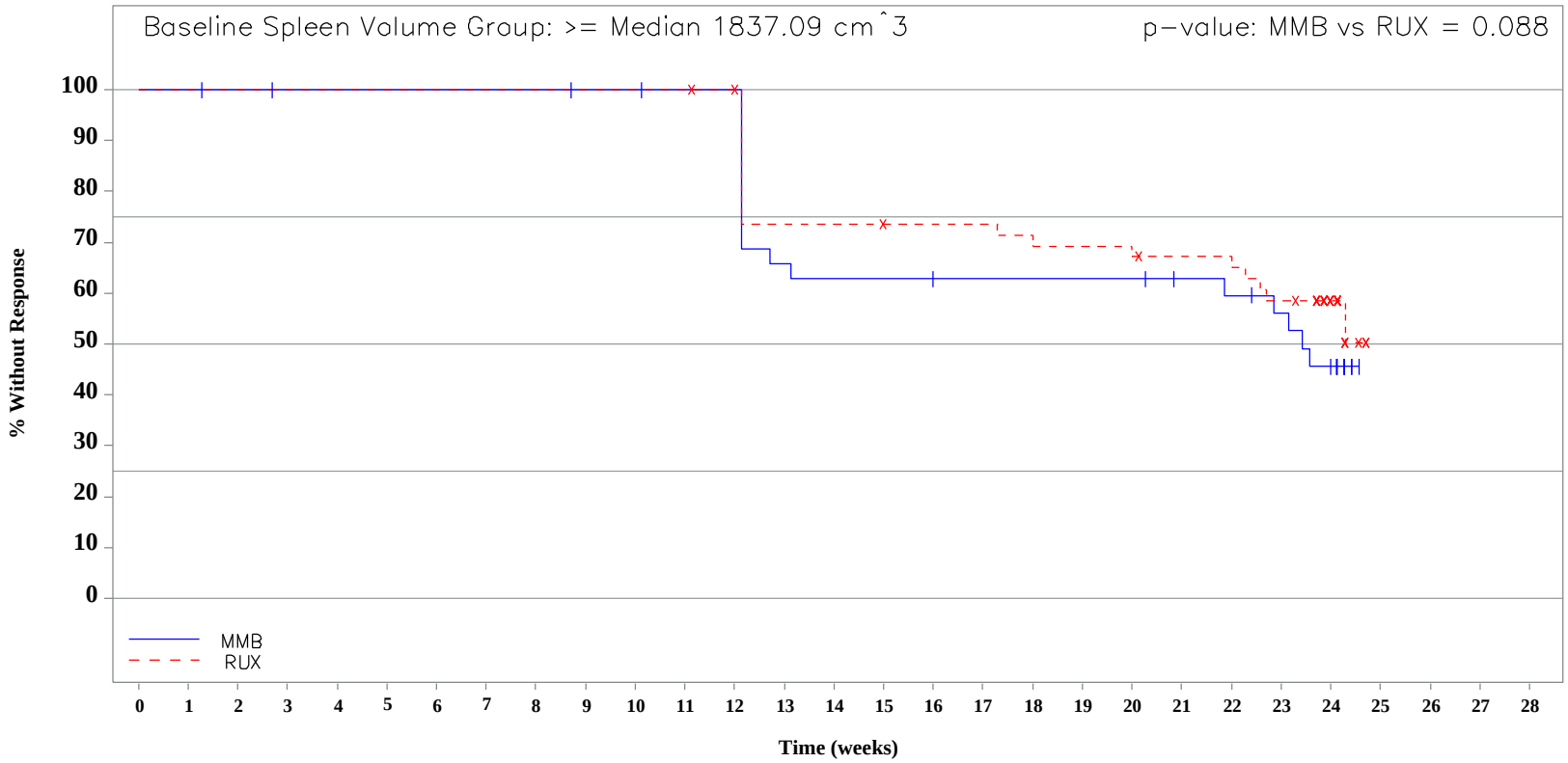
N at Risk (Events)

MMB	47 (0)	47 (0)	46 (0)	45 (0)	43 (0)	43 (0)	42 (0)	42 (0)	42 (0)	41 (0)	41 (0)	41 (0)	41 (0)	17 (23)	17 (24)	15 (25)	15 (25)	14 (26)	14 (26)	14 (26)	14 (26)	14 (26)	14 (27)	12 (28)	10 (28)	0 (29)	0 (29)	0 (29)	0 (29)
RUX	43 (0)	43 (0)	43 (0)	43 (0)	43 (0)	43 (0)	43 (0)	43 (0)	43 (0)	43 (0)	43 (0)	43 (0)	43 (0)	36 (7)	35 (7)	35 (7)	35 (7)	35 (7)	35 (7)	35 (7)	35 (7)	34 (8)	31 (10)	31 (10)	31 (10)	21 (10)	4 (10)	2 (10)	1 (10)	0 (10)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L).

Data Extracted: CRF data: 01JUL2019
Source: g-tte-ti-sub.sas V.03.05 Output file: g-tte-ti-svb.pdf 29AUG2023:15:20

Figure 2.2210: Kaplan-Meier Plot of Time to RBC Transfusion Independent Response by Baseline Spleen Volume
Double-blind Phase
ITT-Anemic Analysis Set



N at Risk (Events)

MMB	39 (0)	39 (0)	38 (0)	37 (0)	37 (0)	37 (0)	37 (0)	37 (0)	37 (0)	36 (0)	36 (0)	35 (0)	35 (0)	23 (12)	22 (13)	22 (13)	22 (13)	21 (13)	21 (13)	21 (13)	21 (13)	19 (13)	18 (14)	16 (15)	13 (18)	0 (18)	0 (18)	0 (18)	0 (18)
RUX	51 (0)	51 (0)	51 (0)	51 (0)	51 (0)	51 (0)	51 (0)	51 (0)	51 (0)	51 (0)	51 (0)	51 (0)	50 (0)	36 (13)	36 (13)	36 (13)	35 (13)	35 (13)	34 (15)	33 (15)	33 (16)	31 (16)	31 (17)	27 (20)	18 (20)	0 (21)	0 (21)	0 (21)	0 (21)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L).

Data Extracted: CRF data: 01JUL2019
Source: g-tte-ti-sub.sas V.03.05 Output file: g-tte-ti-svb.pdf 29AUG2023:15:20

Table 2.3102: Analysis of response rate of no RBC Transfusion and no Hgb<8 [g/dL] for 24 weeks by Age
Double-blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
No RBC Transfusion and no Hgb<8 [g/dL] Rate					
Responder, n(%)	8 (33.3%)	9 (25.0%)	21 (33.9%)	7 (12.1%)	
95% Exact CI	0.1563, 0.5532	0.1212, 0.4220	0.2233, 0.4701	0.0499, 0.2330	
Proportion Difference - Stratified CMH Method (95% CI)	0.03 (-0.23, 0.29)		0.26 (0.11, 0.41)		
p-value	0.83		<0.001		
Proportion Difference - Unstratified CMH Method (95% CI)	0.08 (-0.16, 0.33)		0.22 (0.07, 0.37)		
p-value	0.50		0.004		
Proportion Difference - Unstratified Exact Method (95% CI)	0.08 (-0.18, 0.34)		0.22 (0.04, 0.39)		
p-value	0.56		0.005		
Unadjusted Inverse Relative Risk (95% CI)	0.75 (0.34, 1.67)		0.36 (0.16, 0.77)		
p-value [1]	0.48		0.009		
Unadjusted interaction test for Treatment*Age Group [3]					0.19
Unadjusted Inverse Odds Ratio (95% CI)	0.67 (0.21, 2.08)		0.27 (0.10, 0.69)		
p-value [1]	0.48		0.007		
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.15, 0.32)		0.22 (0.07, 0.36)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.90 (0.40, 2.01)		NE		
p-value [2]	0.79		NE		
Adjusted interaction test for Treatment*Age Group [3]					0.099

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.3102: Analysis of response rate of no RBC Transfusion and no Hgb<8 [g/dL] for 24 weeks by Age
Double-blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Non-responder, n(%)	16 (66.7%)	27 (75.0%)	41 (66.1%)	51 (87.9%)	
RBC Transfusion or Hgb<8 [g/dL] within 24 weeks	14 (58.3%)	27 (75.0%)	38 (61.3%)	50 (86.2%)	
Discontinued prior to week 24	2 (8.3%)	0	3 (4.8%)	1 (1.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.3107: Analysis of response rate of no RBC Transfusion and no Hgb<8 [g/dL] for 24 weeks by Baseline Hemoglobin Level
Double-blind Phase
ITT-Anemic Analysis Set

	HGB <8g/dL		HGB >=8g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
No RBC Transfusion and no Hgb<8 [g/dL] Rate					
Responder, n(%)	3 (10.7%)	1 (4.8%)	26 (44.8%)	15 (20.5%)	
95% Exact CI	0.0227, 0.2823	0.0012, 0.2382	0.3174, 0.5846	0.1198, 0.3162	
Proportion Difference - Stratified CMH Method (95% CI)	0.06 (-0.13, 0.25)		0.26 (0.10, 0.42)		
p-value	0.55		0.001		
Proportion Difference - Unstratified CMH Method (95% CI)	0.06 (-0.11, 0.22)		0.24 (0.08, 0.40)		
p-value	0.48		0.003		
Proportion Difference - Unstratified Exact Method (95% CI)	0.06 (-0.23, 0.34)		0.24 (0.07, 0.40)		
p-value	0.63		0.004		
Unadjusted Inverse Relative Risk (95% CI)	0.44 (0.05, 3.98)		0.46 (0.27, 0.78)		
p-value [1]	0.47		0.004		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.98
Unadjusted Inverse Odds Ratio (95% CI)	0.42 (0.04, 4.32)		0.32 (0.15, 0.69)		
p-value [1]	0.46		0.003		
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.09, 0.21)		0.24 (0.08, 0.40)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.43 (0.26, 0.73)		
p-value [2]	NE		0.002		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-norbc-nohgb8-24-gba.sas V.03.05 Output file: t-norbchgb-24-db-gba-hgb.pdf 29AUG2023: 9:01

Table 2.3107: Analysis of response rate of no RBC Transfusion and no Hgb<8 [g/dL] for 24 weeks by Baseline Hemoglobin Level
Double-blind Phase
ITT-Anemic Analysis Set

	HGB <8g/dL		HGB >=8g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.97
Non-responder, n(%)	25 (89.3%)	20 (95.2%)	32 (55.2%)	58 (79.5%)	
RBC Transfusion or Hgb<8 [g/dL] within 24 weeks	24 (85.7%)	20 (95.2%)	28 (48.3%)	57 (78.1%)	
Discontinued prior to week 24	1 (3.6%)	0	4 (6.9%)	1 (1.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.3106: Analysis of response rate of no RBC Transfusion and no Hgb<8 [g/dL] for 24 weeks by Baseline IPSS Two-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
No RBC Transfusion and no Hgb<8 [g/dL] Rate					
Responder, n(%)	11 (39.3%)	6 (25.0%)	18 (31.0%)	10 (14.3%)	
95% Exact CI	0.2150, 0.5942	0.0977, 0.4671	0.1954, 0.4454	0.0707, 0.2471	
Proportion Difference - Stratified CMH Method (95% CI)	0.24 (-0.04, 0.52)		0.18 (0.03, 0.33)		
p-value	0.091		0.017		
Proportion Difference - Unstratified CMH Method (95% CI)	0.14 (-0.11, 0.40)		0.17 (0.02, 0.31)		
p-value	0.28		0.025		
Proportion Difference - Unstratified Exact Method (95% CI)	0.14 (-0.13, 0.40)		0.17 (-0.01, 0.33)		
p-value	0.38		0.031		
Unadjusted Inverse Relative Risk (95% CI)	0.64 (0.28, 1.46)		0.46 (0.23, 0.92)		
p-value [1]	0.29		0.028		
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.57
Unadjusted Inverse Odds Ratio (95% CI)	0.52 (0.16, 1.70)		0.37 (0.16, 0.88)		
p-value [1]	0.28		0.025		
Unadjusted Absolute Risk Difference (95% CI)	0.14 (-0.11, 0.39)		0.17 (0.02, 0.31)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.3106: Analysis of response rate of no RBC Transfusion and no Hgb<8 [g/dL] for 24 weeks by Baseline IPSS Two-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Adjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.67
Non-responder, n(%)	17 (60.7%)	18 (75.0%)	40 (69.0%)	60 (85.7%)	
RBC Transfusion or Hgb<8 [g/dL] within 24 weeks	15 (53.6%)	18 (75.0%)	37 (63.8%)	59 (84.3%)	
Discontinued prior to week 24	2 (7.1%)	0	3 (5.2%)	1 (1.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.3105: Analysis of response rate of no RBC Transfusion and no Hgb<8 [g/dL] for 24 weeks by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
No RBC Transfusion and no Hgb<8 [g/dL] Rate				
Responder, n(%)	2 (100.0%)	1 (25.0%)	9 (34.6%)	5 (25.0%)
95% Exact CI	0.1581, 1.0000	0.0063, 0.8059	0.1721, 0.5567	0.0866, 0.4910
Proportion Difference - Stratified CMH Method (95% CI)	0.50 (-0.72, 1.72)		0.19 (-0.09, 0.46)	
p-value	0.42		0.18	
Proportion Difference - Unstratified CMH Method (95% CI)	0.75 (-0.15, 1.65)		0.10 (-0.18, 0.37)	
p-value	0.10		0.49	
Proportion Difference - Unstratified Exact Method (95% CI)	0.75 (-0.23, 0.99)		0.10 (-0.20, 0.37)	
p-value	0.40		0.53	
Unadjusted Inverse Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-sg-norbc-nohgb8-24-gba.sas V.03.05 Output file: t-norbchgb-24-db-gba-ip3.pdf 29AUG2023: 9:01

Table 2.3105: Analysis of response rate of no RBC Transfusion and no Hgb<8 [g/dL] for 24 weeks by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=58)	High Risk RUX (N=70)	p-value
No RBC Transfusion and no Hgb<8 [g/dL] Rate			
Responder, n(%)	18 (31.0%)	10 (14.3%)	
95% Exact CI	0.1954, 0.4454	0.0707, 0.2471	
Proportion Difference - Stratified CMH Method (95% CI)	0.18 (0.03, 0.33)		
p-value	0.017		
Proportion Difference - Unstratified CMH Method (95% CI)	0.17 (0.02, 0.31)		
p-value	0.025		
Proportion Difference - Unstratified Exact Method (95% CI)	0.17 (-0.01, 0.33)		
p-value	0.031		
Unadjusted Inverse Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.3105: Analysis of response rate of no RBC Transfusion and no Hgb<8 [g/dL] for 24 weeks by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Non-responder, n(%)	0	3 (75.0%)	17 (65.4%)	15 (75.0%)
RBC Transfusion or Hgb<8 [g/dL] within 24 weeks	0	3 (75.0%)	15 (57.7%)	15 (75.0%)
Discontinued prior to week 24	0	0	2 (7.7%)	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.3105: Analysis of response rate of no RBC Transfusion and no Hgb<8 [g/dL] for 24 weeks by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=58)	High Risk RUX (N=70)	p-value
Non-responder, n(%)	40 (69.0%)	60 (85.7%)	
RBC Transfusion or Hgb<8 [g/dL] within 24 weeks	37 (63.8%)	59 (84.3%)	
Discontinued prior to week 24	3 (5.2%)	1 (1.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.3108: Analysis of response rate of no RBC Transfusion and no Hgb<8 [g/dL] for 24 weeks by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
No RBC Transfusion and no Hgb<8 [g/dL] Rate				
Responder, n(%)	20 (33.9%)	9 (16.7%)	5 (31.3%)	6 (21.4%)
95% Exact CI	0.2208, 0.4739	0.0792, 0.2929	0.1102, 0.5866	0.0830, 0.4095
Proportion Difference - Stratified CMH Method (95% CI)	0.18 (0.03, 0.33)		0.10 (-0.18, 0.39)	
p-value	0.019		0.48	
Proportion Difference - Unstratified CMH Method (95% CI)	0.17 (0.01, 0.33)		0.10 (-0.19, 0.38)	
p-value	0.034		0.50	
Proportion Difference - Unstratified Exact Method (95% CI)	0.17 (-0.01, 0.35)		0.10 (-0.21, 0.39)	
p-value	0.052		0.49	
Unadjusted Inverse Relative Risk (95% CI)	0.49 (0.25, 0.98)		0.69 (0.25, 1.89)	
p-value [1]	0.045		0.47	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	0.39 (0.16, 0.96)		0.60 (0.15, 2.41)	
p-value [1]	0.039		0.47	
Unadjusted Absolute Risk Difference (95% CI)	0.17 (0.02, 0.33)		0.10 (-0.18, 0.37)	
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE	
p-value [2]	NE		NE	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-norbc-nohgb8-24-gba.sas V.03.05 Output file: t-norbchgb-24-db-gba-mf.pdf 29AUG2023: 9:01

Table 2.3108: Analysis of response rate of no RBC Transfusion and no Hgb<8 [g/dL] for 24 weeks by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

(Continued)	Post-PV Myelofibrosis MMB (N=11)	Post-PV Myelofibrosis RUX (N=12)	p-value
No RBC Transfusion and no Hgb<8 [g/dL] Rate			
Responder, n(%)	4 (36.4%)	1 (8.3%)	
95% Exact CI	0.1093, 0.6921	0.0021, 0.3848	
Proportion Difference - Stratified CMH Method (95% CI)	0.41 (0.01, 0.82)		
p-value	0.043		
Proportion Difference - Unstratified CMH Method (95% CI)	0.28 (-0.07, 0.63)		
p-value	0.12		
Proportion Difference - Unstratified Exact Method (95% CI)	0.28 (-0.15, 0.62)		
p-value	0.15		
Unadjusted Inverse Relative Risk (95% CI)	0.23 (0.03, 1.75)		
p-value [1]	0.16		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.56
Unadjusted Inverse Odds Ratio (95% CI)	0.16 (0.01, 1.73)		
p-value [1]	0.13		
Unadjusted Absolute Risk Difference (95% CI)	0.28 (-0.04, 0.60)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.21

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.3108: Analysis of response rate of no RBC Transfusion and no Hgb<8 [g/dL] for 24 weeks by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
Non-responder, n(%)	39 (66.1%)	45 (83.3%)	11 (68.8%)	22 (78.6%)
RBC Transfusion or Hgb<8 [g/dL] within 24 weeks	35 (59.3%)	44 (81.5%)	11 (68.8%)	22 (78.6%)
Discontinued prior to week 24	4 (6.8%)	1 (1.9%)	0	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.3108: Analysis of response rate of no RBC Transfusion and no Hgb<8 [g/dL] for 24 weeks by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

(Continued)	Post-PV Myelofibrosis MMB (N=11)	Post-PV Myelofibrosis RUX (N=12)	p-value
Non-responder, n(%)	7 (63.6%)	11 (91.7%)	
RBC Transfusion or Hgb<8 [g/dL] within 24 weeks	6 (54.5%)	11 (91.7%)	
Discontinued prior to week 24	1 (9.1%)	0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.3104: Analysis of response rate of no RBC Transfusion and no Hgb<8 [g/dL] for 24 weeks by Region
Double-blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
No RBC Transfusion and no Hgb<8 [g/dL] Rate					
Responder, n(%)	16 (30.2%)	9 (17.6%)	13 (39.4%)	7 (16.3%)	
95% Exact CI	0.1834, 0.4434	0.0840, 0.3087	0.2291, 0.5786	0.0681, 0.3070	
Proportion Difference - Stratified CMH Method (95% CI)	0.20 (0.03, 0.37)		0.22 (0.03, 0.41)		
p-value	0.020		0.020		
Proportion Difference - Unstratified CMH Method (95% CI)	0.13 (-0.04, 0.29)		0.23 (0.03, 0.44)		
p-value	0.14		0.026		
Proportion Difference - Unstratified Exact Method (95% CI)	0.13 (-0.07, 0.31)		0.23 (0.00, 0.44)		
p-value	0.17		0.035		
Unadjusted Inverse Relative Risk (95% CI)	0.58 (0.28, 1.20)		0.41 (0.19, 0.92)		
p-value [1]	0.14		0.030		
Unadjusted interaction test for Treatment*Region [3]					0.53
Unadjusted Inverse Odds Ratio (95% CI)	0.50 (0.20, 1.25)		0.30 (0.10, 0.87)		
p-value [1]	0.14		0.027		
Unadjusted Absolute Risk Difference (95% CI)	0.13 (-0.04, 0.29)		0.23 (0.03, 0.43)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.43 (0.22, 0.83)		NE		
p-value [2]	0.012		NE		
Adjusted interaction test for Treatment*Region [3]					0.86

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-norbc-nohgb8-24-gba.sas V.03.05 Output file: t-norbchgb-24-db-gba-reg.pdf 29AUG2023: 9:01

Table 2.3104: Analysis of response rate of no RBC Transfusion and no Hgb<8 [g/dL] for 24 weeks by Region
Double-blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Non-responder, n(%)	37 (69.8%)	42 (82.4%)	20 (60.6%)	36 (83.7%)	
RBC Transfusion or Hgb<8 [g/dL] within 24 weeks	35 (66.0%)	42 (82.4%)	17 (51.5%)	35 (81.4%)	
Discontinued prior to week 24	2 (3.8%)	0	3 (9.1%)	1 (2.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.3103: Analysis of response rate of no RBC Transfusion and no Hgb<8 [g/dL] for 24 weeks by Gender
Double-blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
No RBC Transfusion and no Hgb<8 [g/dL] Rate					
Responder, n(%)	13 (26.0%)	8 (14.3%)	16 (44.4%)	8 (21.1%)	
95% Exact CI	0.1463, 0.4034	0.0638, 0.2622	0.2794, 0.6190	0.0955, 0.3732	
Proportion Difference - Stratified CMH Method (95% CI)	0.18 (0.02, 0.34)		0.21 (-0.02, 0.43)		
p-value	0.024		0.069		
Proportion Difference - Unstratified CMH Method (95% CI)	0.12 (-0.04, 0.27)		0.23 (0.02, 0.45)		
p-value	0.14		0.030		
Proportion Difference - Unstratified Exact Method (95% CI)	0.12 (-0.07, 0.30)		0.23 (0.00, 0.44)		
p-value	0.15		0.047		
Unadjusted Inverse Relative Risk (95% CI)	0.55 (0.25, 1.22)		0.47 (0.23, 0.97)		
p-value [1]	0.14		0.041		
Unadjusted interaction test for Treatment*Gender [3]					0.79
Unadjusted Inverse Odds Ratio (95% CI)	0.47 (0.18, 1.26)		0.33 (0.12, 0.92)		
p-value [1]	0.14		0.035		
Unadjusted Absolute Risk Difference (95% CI)	0.12 (-0.04, 0.27)		0.23 (0.03, 0.44)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.39 (0.19, 0.82)		NE		
p-value [2]	0.013		NE		
Adjusted interaction test for Treatment*Gender [3]					0.70

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-norbc-nohgb8-24-gba.sas V.03.05 Output file: t-norbchgb-24-db-gba-sex.pdf 29AUG2023: 9:01

Table 2.3103: Analysis of response rate of no RBC Transfusion and no Hgb<8 [g/dL] for 24 weeks by Gender
Double-blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Non-responder, n(%)	37 (74.0%)	48 (85.7%)	20 (55.6%)	30 (78.9%)	
RBC Transfusion or Hgb<8 [g/dL] within 24 weeks	37 (74.0%)	48 (85.7%)	15 (41.7%)	29 (76.3%)	
Discontinued prior to week 24	0	0	5 (13.9%)	1 (2.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.3110: Analysis of response rate of no RBC Transfusion and no Hgb<8 [g/dL] for 24 weeks by Baseline Spleen Volume
Double-blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
No RBC Transfusion and no Hgb<8 [g/dL] Rate					
Responder, n(%)	20 (42.6%)	6 (14.0%)	9 (23.1%)	10 (19.6%)	
95% Exact CI	0.2826, 0.5782	0.0530, 0.2793	0.1113, 0.3933	0.0982, 0.3312	
Proportion Difference - Stratified CMH Method (95% CI)	0.32 (0.14, 0.51)		0.07 (-0.12, 0.25)		
p-value	<0.001		0.46		
Proportion Difference - Unstratified CMH Method (95% CI)	0.29 (0.11, 0.46)		0.03 (-0.14, 0.21)		
p-value	0.002		0.70		
Proportion Difference - Unstratified Exact Method (95% CI)	0.29 (0.08, 0.48)		0.03 (-0.17, 0.24)		
p-value	0.005		0.80		
Unadjusted Inverse Relative Risk (95% CI)	0.33 (0.15, 0.74)		0.85 (0.38, 1.89)		
p-value [1]	0.007		0.69		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.095
Unadjusted Inverse Odds Ratio (95% CI)	0.22 (0.08, 0.62)		0.81 (0.29, 2.25)		
p-value [1]	0.004		0.69		
Unadjusted Absolute Risk Difference (95% CI)	0.29 (0.11, 0.46)		0.03 (-0.14, 0.21)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.73 (0.34, 1.56)		
p-value [2]	NE		0.42		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-norbc-nohgb8-24-gba.sas V.03.05 Output file: t-norbchgb-24-db-gba-spv.pdf 29AUG2023: 9:01

Table 2.3110: Analysis of response rate of no RBC Transfusion and no Hgb<8 [g/dL] for 24 weeks by Baseline Spleen Volume
Double-blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.15
Non-responder, n(%)	27 (57.4%)	37 (86.0%)	30 (76.9%)	41 (80.4%)	
RBC Transfusion or Hgb<8 [g/dL] within 24 weeks	25 (53.2%)	36 (83.7%)	27 (69.2%)	41 (80.4%)	
Discontinued prior to week 24	2 (4.3%)	1 (2.3%)	3 (7.7%)	0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.3109: Analysis of response rate of no RBC Transfusion and no Hgb<8 [g/dL] for 24 weeks by Baseline TSS
Double-blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
No RBC Transfusion and no Hgb<8 [g/dL] Rate					
Responder, n(%)	14 (31.8%)	11 (20.0%)	15 (36.6%)	5 (13.2%)	
95% Exact CI	0.1861, 0.4758	0.1043, 0.3297	0.2212, 0.5306	0.0441, 0.2809	
Proportion Difference - Stratified CMH Method (95% CI)	0.16 (-0.01, 0.34)		0.26 (0.07, 0.44)		
p-value	0.069		0.007		
Proportion Difference - Unstratified CMH Method (95% CI)	0.12 (-0.06, 0.29)		0.23 (0.05, 0.42)		
p-value	0.19		0.014		
Proportion Difference - Unstratified Exact Method (95% CI)	0.12 (-0.08, 0.31)		0.23 (0.01, 0.44)		
p-value	0.24		0.021		
Unadjusted Inverse Relative Risk (95% CI)	0.63 (0.32, 1.24)		0.36 (0.14, 0.89)		
p-value [1]	0.18		0.028		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.32
Unadjusted Inverse Odds Ratio (95% CI)	0.54 (0.21, 1.34)		0.26 (0.08, 0.82)		
p-value [1]	0.18		0.021		
Unadjusted Absolute Risk Difference (95% CI)	0.12 (-0.06, 0.29)		0.23 (0.05, 0.42)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.33 (0.14, 0.75)		
p-value [2]	NE		0.008		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.3109: Analysis of response rate of no RBC Transfusion and no Hgb<8 [g/dL] for 24 weeks by Baseline TSS
Double-blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Adjusted interaction test for Treatment*Baseline TSS Group [3]					0.42
Non-responder, n(%)	30 (68.2%)	44 (80.0%)	26 (63.4%)	33 (86.8%)	
RBC Transfusion or Hgb<8 [g/dL] within 24 weeks	29 (65.9%)	43 (78.2%)	22 (53.7%)	33 (86.8%)	
Discontinued prior to week 24	1 (2.3%)	1 (1.8%)	4 (9.8%)	0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-norbc-nohgb8-24-gba.sas V.03.05 Output file: t-norbchgb-24-db-gba-tss.pdf 29AUG2023: 9:01

Table 2.2302: Analysis of response rate of no RBC Transfusion for 24 weeks by Age
Double-blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
RBC Transfusion Free Rate					
Responder, n(%)	10 (41.7%)	12 (33.3%)	23 (37.1%)	7 (12.1%)	
95% Exact CI	0.2211, 0.6336	0.1856, 0.5097	0.2516, 0.5031	0.0499, 0.2330	
Proportion Difference - Stratified CMH Method (95% CI)	0.03 (-0.26, 0.31)		0.29 (0.14, 0.44)		
p-value	0.84		<0.001		
Proportion Difference - Unstratified CMH Method (95% CI)	0.08 (-0.17, 0.34)		0.25 (0.10, 0.40)		
p-value	0.52		<0.001		
Proportion Difference - Unstratified Exact Method (95% CI)	0.08 (-0.18, 0.34)		0.25 (0.07, 0.42)		
p-value	0.59		0.002		
Unadjusted Inverse Relative Risk (95% CI)	0.80 (0.41, 1.55)		0.33 (0.15, 0.70)		
p-value [1]	0.51		0.004		
Unadjusted interaction test for Treatment*Age Group [3]					0.072
Unadjusted Inverse Odds Ratio (95% CI)	0.70 (0.24, 2.03)		0.23 (0.09, 0.60)		
p-value [1]	0.51		0.002		
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.17, 0.33)		0.25 (0.10, 0.40)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.92 (0.47, 1.81)		NE		
p-value [2]	0.82		NE		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.2302: Analysis of response rate of no RBC Transfusion for 24 weeks by Age
Double-blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Adjusted interaction test for Treatment*Age Group [3]					0.034
Non-responder, n(%)	14 (58.3%)	24 (66.7%)	39 (62.9%)	51 (87.9%)	
RBC Transfusion within 24 weeks	12 (50.0%)	24 (66.7%)	35 (56.5%)	50 (86.2%)	
Discontinued prior to week 24	2 (8.3%)	0	4 (6.5%)	1 (1.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-norbc-24-db-gba.sas V.03.05 Output file: t-sg-norbc-24-db-gba-age.pdf 29AUG2023: 9:00

Table 2.2307: Analysis of response rate of no RBC Transfusion for 24 weeks by Baseline Hemoglobin Level
Double-blind Phase
ITT-Anemic Analysis Set

	HGB <8g/dL		HGB >=8g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
RBC Transfusion Free Rate					
Responder, n(%)	5 (17.9%)	2 (9.5%)	28 (48.3%)	17 (23.3%)	
95% Exact CI	0.0606, 0.3689	0.0117, 0.3038	0.3495, 0.6178	0.1419, 0.3465	
Proportion Difference - Stratified CMH Method (95% CI)	0.08 (-0.14, 0.30)		0.27 (0.11, 0.43)		
p-value	0.49		0.001		
Proportion Difference - Unstratified CMH Method (95% CI)	0.08 (-0.12, 0.29)		0.25 (0.09, 0.41)		
p-value	0.42		0.003		
Proportion Difference - Unstratified Exact Method (95% CI)	0.08 (-0.20, 0.36)		0.25 (0.08, 0.41)		
p-value	0.68		0.003		
Unadjusted Inverse Relative Risk (95% CI)	0.53 (0.11, 2.49)		0.48 (0.29, 0.79)		
p-value [1]	0.42		0.004		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.91
Unadjusted Inverse Odds Ratio (95% CI)	0.48 (0.08, 2.78)		0.33 (0.15, 0.69)		
p-value [1]	0.42		0.003		
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.11, 0.27)		0.25 (0.09, 0.41)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.55 (0.12, 2.55)		0.46 (0.29, 0.74)		
p-value [2]	0.44		0.001		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-sg-norbc-24-db-gba.sas V.03.05 Output file: t-sg-norbc-24-db-gba-hgb.pdf 29AUG2023: 9:00

Table 2.2307: Analysis of response rate of no RBC Transfusion for 24 weeks by Baseline Hemoglobin Level
Double-blind Phase
ITT-Anemic Analysis Set

	HGB <8g/dL		HGB >=8g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.83
Non-responder, n(%)	23 (82.1%)	19 (90.5%)	30 (51.7%)	56 (76.7%)	
RBC Transfusion within 24 weeks	21 (75.0%)	19 (90.5%)	26 (44.8%)	55 (75.3%)	
Discontinued prior to week 24	2 (7.1%)	0	4 (6.9%)	1 (1.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-sg-norbc-24-db-gba.sas V.03.05 Output file: t-sg-norbc-24-db-gba-hgb.pdf 29AUG2023: 9:00

Table 2.2306: Analysis of response rate of no RBC Transfusion for 24 weeks by Baseline IPSS Two-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
RBC Transfusion Free Rate					
Responder, n(%)	13 (46.4%)	7 (29.2%)	20 (34.5%)	12 (17.1%)	
95% Exact CI	0.2751, 0.6613	0.1262, 0.5109	0.2249, 0.4812	0.0918, 0.2803	
Proportion Difference - Stratified CMH Method (95% CI)	0.24 (-0.04, 0.53)		0.19 (0.03, 0.34)		
p-value	0.098		0.016		
Proportion Difference - Unstratified CMH Method (95% CI)	0.17 (-0.09, 0.44)		0.17 (0.02, 0.33)		
p-value	0.20		0.026		
Proportion Difference - Unstratified Exact Method (95% CI)	0.17 (-0.10, 0.43)		0.17 (0.00, 0.34)		
p-value	0.26		0.039		
Unadjusted Inverse Relative Risk (95% CI)	0.63 (0.30, 1.32)		0.50 (0.27, 0.93)		
p-value [1]	0.22		0.028		
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.64
Unadjusted Inverse Odds Ratio (95% CI)	0.48 (0.15, 1.50)		0.39 (0.17, 0.90)		
p-value [1]	0.21		0.026		
Unadjusted Absolute Risk Difference (95% CI)	0.17 (-0.09, 0.43)		0.17 (0.02, 0.32)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.2306: Analysis of response rate of no RBC Transfusion for 24 weeks by Baseline IPSS Two-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Adjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.74
Non-responder, n(%)	15 (53.6%)	17 (70.8%)	38 (65.5%)	58 (82.9%)	
RBC Transfusion within 24 weeks	12 (42.9%)	17 (70.8%)	35 (60.3%)	57 (81.4%)	
Discontinued prior to week 24	3 (10.7%)	0	3 (5.2%)	1 (1.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.2305: Analysis of response rate of no RBC Transfusion for 24 weeks by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
RBC Transfusion Free Rate				
Responder, n(%)	2 (100.0%)	1 (25.0%)	11 (42.3%)	6 (30.0%)
95% Exact CI	0.1581, 1.0000	0.0063, 0.8059	0.2335, 0.6308	0.1189, 0.5428
Proportion Difference - Stratified CMH Method (95% CI)	0.50 (-0.72, 1.72)		0.19 (-0.09, 0.47)	
p-value	0.42		0.19	
Proportion Difference - Unstratified CMH Method (95% CI)	0.75 (-0.15, 1.65)		0.12 (-0.16, 0.41)	
p-value	0.10		0.40	
Proportion Difference - Unstratified Exact Method (95% CI)	0.75 (-0.23, 0.99)		0.12 (-0.17, 0.40)	
p-value	0.40		0.54	
Unadjusted Inverse Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-sg-norbc-24-db-gba.sas V.03.05 Output file: t-sg-norbc-24-db-gba-ip3.pdf 29AUG2023: 9:00

Table 2.2305: Analysis of response rate of no RBC Transfusion for 24 weeks by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=58)	High Risk RUX (N=70)	p-value
RBC Transfusion Free Rate			
Responder, n(%)	20 (34.5%)	12 (17.1%)	
95% Exact CI	0.2249, 0.4812	0.0918, 0.2803	
Proportion Difference - Stratified CMH Method (95% CI)	0.19 (0.03, 0.34)		
p-value	0.016		
Proportion Difference - Unstratified CMH Method (95% CI)	0.17 (0.02, 0.33)		
p-value	0.026		
Proportion Difference - Unstratified Exact Method (95% CI)	0.17 (0.00, 0.34)		
p-value	0.039		
Unadjusted Inverse Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-sg-norbc-24-db-gba.sas V.03.05 Output file: t-sg-norbc-24-db-gba-ip3.pdf 29AUG2023: 9:00

Table 2.2305: Analysis of response rate of no RBC Transfusion for 24 weeks by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Non-responder, n(%)	0	3 (75.0%)	15 (57.7%)	14 (70.0%)
RBC Transfusion within 24 weeks	0	3 (75.0%)	12 (46.2%)	14 (70.0%)
Discontinued prior to week 24	0	0	3 (11.5%)	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.2305: Analysis of response rate of no RBC Transfusion for 24 weeks by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=58)	High Risk RUX (N=70)	p-value
Non-responder, n(%)	38 (65.5%)	58 (82.9%)	
RBC Transfusion within 24 weeks	35 (60.3%)	57 (81.4%)	
Discontinued prior to week 24	3 (5.2%)	1 (1.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.2308: Analysis of response rate of no RBC Transfusion for 24 weeks by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
RBC Transfusion Free Rate				
Responder, n(%)	23 (39.0%)	11 (20.4%)	5 (31.3%)	7 (25.0%)
95% Exact CI	0.2655, 0.5256	0.1063, 0.3353	0.1102, 0.5866	0.1069, 0.4487
Proportion Difference - Stratified CMH Method (95% CI)	0.19 (0.03, 0.35)		0.07 (-0.22, 0.36)	
p-value	0.020		0.63	
Proportion Difference - Unstratified CMH Method (95% CI)	0.19 (0.02, 0.35)		0.06 (-0.23, 0.35)	
p-value	0.029		0.67	
Proportion Difference - Unstratified Exact Method (95% CI)	0.19 (0.00, 0.36)		0.06 (-0.25, 0.36)	
p-value	0.040		0.73	
Unadjusted Inverse Relative Risk (95% CI)	0.52 (0.28, 0.97)		0.80 (0.30, 2.11)	
p-value [1]	0.039		0.65	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	0.40 (0.17, 0.93)		0.73 (0.19, 2.86)	
p-value [1]	0.034		0.65	
Unadjusted Absolute Risk Difference (95% CI)	0.19 (0.02, 0.35)		0.06 (-0.22, 0.34)	
Adjusted Inverse Relative Risk (95% CI) [2]	0.52 (0.28, 0.94)		NE	
p-value [2]	0.032		NE	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.2308: Analysis of response rate of no RBC Transfusion for 24 weeks by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

(Continued)	Post-PV Myelofibrosis MMB (N=11)	Post-PV Myelofibrosis RUX (N=12)	p-value
RBC Transfusion Free Rate			
Responder, n(%)	5 (45.5%)	1 (8.3%)	
95% Exact CI	0.1675, 0.7662	0.0021, 0.3848	
Proportion Difference - Stratified CMH Method (95% CI)	0.48 (0.07, 0.89)		
p-value	0.021		
Proportion Difference - Unstratified CMH Method (95% CI)	0.37 (0.01, 0.73)		
p-value	0.044		
Proportion Difference - Unstratified Exact Method (95% CI)	0.37 (-0.06, 0.70)		
p-value	0.069		
Unadjusted Inverse Relative Risk (95% CI)	0.18 (0.03, 1.33)		
p-value [1]	0.094		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.29
Unadjusted Inverse Odds Ratio (95% CI)	0.11 (0.01, 1.16)		
p-value [1]	0.066		
Unadjusted Absolute Risk Difference (95% CI)	0.37 (0.04, 0.70)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.2308: Analysis of response rate of no RBC Transfusion for 24 weeks by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-responder, n(%)	36 (61.0%)	43 (79.6%)	11 (68.8%)	21 (75.0%)
RBC Transfusion within 24 weeks	31 (52.5%)	42 (77.8%)	11 (68.8%)	21 (75.0%)
Discontinued prior to week 24	5 (8.5%)	1 (1.9%)	0	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.2308: Analysis of response rate of no RBC Transfusion for 24 weeks by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

(Continued)	Post-PV Myelofibrosis MMB (N=11)	Post-PV Myelofibrosis RUX (N=12)	p-value
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.11
Non-responder, n(%)	6 (54.5%)	11 (91.7%)	
RBC Transfusion within 24 weeks	5 (45.5%)	11 (91.7%)	
Discontinued prior to week 24	1 (9.1%)	0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.2304: Analysis of response rate of no RBC Transfusion for 24 weeks by Region
Double-blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
RBC Transfusion Free Rate					
Responder, n(%)	17 (32.1%)	9 (17.6%)	16 (48.5%)	10 (23.3%)	
95% Exact CI	0.1992, 0.4632	0.0840, 0.3087	0.3080, 0.6646	0.1176, 0.3863	
Proportion Difference - Stratified CMH Method (95% CI)	0.22 (0.05, 0.39)		0.25 (0.04, 0.46)		
p-value	0.010		0.019		
Proportion Difference - Unstratified CMH Method (95% CI)	0.14 (-0.02, 0.31)		0.25 (0.04, 0.47)		
p-value	0.089		0.022		
Proportion Difference - Unstratified Exact Method (95% CI)	0.14 (-0.05, 0.33)		0.25 (0.03, 0.46)		
p-value	0.11		0.029		
Unadjusted Inverse Relative Risk (95% CI)	0.55 (0.27, 1.12)		0.48 (0.25, 0.92)		
p-value [1]	0.099		0.026		
Unadjusted interaction test for Treatment*Region [3]					0.78
Unadjusted Inverse Odds Ratio (95% CI)	0.45 (0.18, 1.14)		0.32 (0.12, 0.86)		
p-value [1]	0.093		0.024		
Unadjusted Absolute Risk Difference (95% CI)	0.14 (-0.02, 0.31)		0.25 (0.04, 0.46)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.41 (0.21, 0.78)		NE		
p-value [2]	0.006		NE		
Adjusted interaction test for Treatment*Region [3]					0.92

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-norbc-24-db-gba.sas V.03.05 Output file: t-sg-norbc-24-db-gba-reg.pdf 29AUG2023: 9:00

Table 2.2304: Analysis of response rate of no RBC Transfusion for 24 weeks by Region
Double-blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Non-responder, n(%)	36 (67.9%)	42 (82.4%)	17 (51.5%)	33 (76.7%)	
RBC Transfusion within 24 weeks	34 (64.2%)	42 (82.4%)	13 (39.4%)	32 (74.4%)	
Discontinued prior to week 24	2 (3.8%)	0	4 (12.1%)	1 (2.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.2303: Analysis of response rate of no RBC Transfusion for 24 weeks by Gender
Double-blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
RBC Transfusion Free Rate					
Responder, n(%)	16 (32.0%)	9 (16.1%)	17 (47.2%)	10 (26.3%)	
95% Exact CI	0.1952, 0.4670	0.0762, 0.2833	0.3041, 0.6451	0.1340, 0.4310	
Proportion Difference - Stratified CMH Method (95% CI)	0.22 (0.06, 0.39)		0.17 (-0.06, 0.41)		
p-value	0.009		0.14		
Proportion Difference - Unstratified CMH Method (95% CI)	0.16 (0.00, 0.32)		0.21 (-0.01, 0.43)		
p-value	0.057		0.061		
Proportion Difference - Unstratified Exact Method (95% CI)	0.16 (-0.03, 0.34)		0.21 (-0.03, 0.42)		
p-value	0.068		0.091		
Unadjusted Inverse Relative Risk (95% CI)	0.50 (0.24, 1.03)		0.56 (0.30, 1.05)		
p-value [1]	0.062		0.071		
Unadjusted interaction test for Treatment*Gender [3]					0.83
Unadjusted Inverse Odds Ratio (95% CI)	0.41 (0.16, 1.03)		0.40 (0.15, 1.06)		
p-value [1]	0.058		0.065		
Unadjusted Absolute Risk Difference (95% CI)	0.16 (0.00, 0.32)		0.21 (-0.01, 0.42)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.38 (0.19, 0.76)		NE		
p-value [2]	0.006		NE		
Adjusted interaction test for Treatment*Gender [3]					0.37

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-norbc-24-db-gba.sas V.03.05 Output file: t-sg-norbc-24-db-gba-sex.pdf 29AUG2023: 9:00

Table 2.2303: Analysis of response rate of no RBC Transfusion for 24 weeks by Gender
Double-blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Non-responder, n(%)	34 (68.0%)	47 (83.9%)	19 (52.8%)	28 (73.7%)	
RBC Transfusion within 24 weeks	34 (68.0%)	47 (83.9%)	13 (36.1%)	27 (71.1%)	
Discontinued prior to week 24	0	0	6 (16.7%)	1 (2.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-norbc-24-db-gba.sas V.03.05 Output file: t-sg-norbc-24-db-gba-sex.pdf 29AUG2023: 9:00

Table 2.2310: Analysis of response rate of no RBC Transfusion for 24 weeks by Baseline Spleen Volume
Double-blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
RBC Transfusion Free Rate					
Responder, n(%)	22 (46.8%)	8 (18.6%)	11 (28.2%)	11 (21.6%)	
95% Exact CI	0.3211, 0.6192	0.0839, 0.3340	0.1500, 0.4487	0.1129, 0.3532	
Proportion Difference - Stratified CMH Method (95% CI)	0.31 (0.12, 0.50)		0.09 (-0.10, 0.29)		
p-value	0.002		0.35		
Proportion Difference - Unstratified CMH Method (95% CI)	0.28 (0.09, 0.47)		0.07 (-0.12, 0.25)		
p-value	0.003		0.48		
Proportion Difference - Unstratified Exact Method (95% CI)	0.28 (0.07, 0.47)		0.07 (-0.14, 0.27)		
p-value	0.007		0.62		
Unadjusted Inverse Relative Risk (95% CI)	0.40 (0.20, 0.80)		0.76 (0.37, 1.58)		
p-value [1]	0.009		0.47		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.20
Unadjusted Inverse Odds Ratio (95% CI)	0.26 (0.10, 0.68)		0.70 (0.27, 1.84)		
p-value [1]	0.006		0.47		
Unadjusted Absolute Risk Difference (95% CI)	0.28 (0.10, 0.47)		0.07 (-0.11, 0.25)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.69 (0.34, 1.40)		
p-value [2]	NE		0.30		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.2310: Analysis of response rate of no RBC Transfusion for 24 weeks by Baseline Spleen Volume
Double-blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.32
Non-responder, n(%)	25 (53.2%)	35 (81.4%)	28 (71.8%)	40 (78.4%)	
RBC Transfusion within 24 weeks	22 (46.8%)	34 (79.1%)	25 (64.1%)	40 (78.4%)	
Discontinued prior to week 24	3 (6.4%)	1 (2.3%)	3 (7.7%)	0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.2309: Analysis of response rate of no RBC Transfusion for 24 weeks by Baseline TSS
Double-blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
RBC Transfusion Free Rate					
Responder, n(%)	18 (40.9%)	11 (20.0%)	15 (36.6%)	8 (21.1%)	
95% Exact CI	0.2634, 0.5675	0.1043, 0.3297	0.2212, 0.5306	0.0955, 0.3732	
Proportion Difference - Stratified CMH Method (95% CI)	0.25 (0.07, 0.43)		0.18 (-0.02, 0.38)		
p-value	0.007		0.083		
Proportion Difference - Unstratified CMH Method (95% CI)	0.21 (0.03, 0.39)		0.16 (-0.04, 0.36)		
p-value	0.025		0.13		
Proportion Difference - Unstratified Exact Method (95% CI)	0.21 (0.01, 0.40)		0.16 (-0.07, 0.36)		
p-value	0.028		0.15		
Unadjusted Inverse Relative Risk (95% CI)	0.49 (0.26, 0.92)		0.58 (0.28, 1.20)		
p-value [1]	0.028		0.14		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.74
Unadjusted Inverse Odds Ratio (95% CI)	0.36 (0.15, 0.88)		0.46 (0.17, 1.26)		
p-value [1]	0.025		0.13		
Unadjusted Absolute Risk Difference (95% CI)	0.21 (0.03, 0.39)		0.16 (-0.04, 0.35)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.53 (0.27, 1.06)		
p-value [2]	NE		0.072		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.2309: Analysis of response rate of no RBC Transfusion for 24 weeks by Baseline TSS
Double-blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Adjusted interaction test for Treatment*Baseline TSS Group [3]					0.56
Non-responder, n(%)	26 (59.1%)	44 (80.0%)	26 (63.4%)	30 (78.9%)	
RBC Transfusion within 24 weeks	24 (54.5%)	43 (78.2%)	22 (53.7%)	30 (78.9%)	
Discontinued prior to week 24	2 (4.5%)	1 (1.8%)	4 (9.8%)	0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.2702: Analysis of RBC Transfusion Independent Response Rate at Week 24 by Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
RBC Transfusion Independent Rate at Week 24					
Responder, n(%)	11 (45.8%)	13 (36.1%)	29 (46.8%)	12 (20.7%)	
95% Exact CI	0.2555, 0.6718	0.2082, 0.5378	0.3398, 0.5988	0.1117, 0.3335	
Proportion Difference - Stratified CMH Method (95% CI)	0.07 (-0.22, 0.37)		0.28 (0.11, 0.45)		
p-value	0.63		0.001		
Proportion Difference - Unstratified CMH Method (95% CI)	0.10 (-0.16, 0.36)		0.26 (0.10, 0.42)		
p-value	0.46		0.002		
Proportion Difference - Unstratified Exact Method (95% CI)	0.10 (-0.17, 0.35)		0.26 (0.08, 0.43)		
p-value	0.59		0.004		
Unadjusted Inverse Relative Risk (95% CI)	0.79 (0.43, 1.46)		0.44 (0.25, 0.78)		
p-value [1]	0.45		0.005		
Unadjusted interaction test for Treatment*Age Group [3]					0.17
Unadjusted Inverse Odds Ratio (95% CI)	0.67 (0.23, 1.91)		0.30 (0.13, 0.67)		
p-value [1]	0.45		0.003		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.16, 0.35)		0.26 (0.10, 0.42)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.83 (0.43, 1.60)		NE		
p-value [2]	0.58		NE		
Adjusted interaction test for Treatment*Age Group [3]					0.19

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti-resp.sas V.03.05 Output file: t-subgrp-rbcti24-age-gba.pdf 29AUG2023: 9:34

Table 2.2702: Analysis of RBC Transfusion Independent Response Rate at Week 24 by Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Non-Responder, n(%)	13 (54.2%)	23 (63.9%)	33 (53.2%)	46 (79.3%)	
Transfusion (except bleeding) in the last 12 weeks	7 (29.2%)	16 (44.4%)	19 (30.6%)	39 (67.2%)	
Any Hgb assessment < 8g/dL in the last 12 weeks	7 (29.2%)	18 (50.0%)	16 (25.8%)	27 (46.6%)	
Last Participation date < Day 162 in DB phase	4 (16.7%)	3 (8.3%)	12 (19.4%)	5 (8.6%)	
Other	3 (12.5%)	11 (30.6%)	9 (14.5%)	14 (24.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model,
including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified
Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti-resp.sas V.03.05 Output file: t-subgrp-rbcti24-age-gba.pdf 29AUG2023: 9:34

Table 2.2704: Analysis of RBC Transfusion Independent Response Rate at Week 24 by Region
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
RBC Transfusion Independent Rate at Week 24					
Responder, n(%)	21 (39.6%)	13 (25.5%)	19 (57.6%)	12 (27.9%)	
95% Exact CI	0.2645, 0.5400	0.1433, 0.3963	0.3922, 0.7452	0.1533, 0.4367	
Proportion Difference - Stratified CMH Method (95% CI)	0.20 (0.01, 0.38)		0.29 (0.08, 0.51)		
p-value	0.042		0.008		
Proportion Difference - Unstratified CMH Method (95% CI)	0.14 (-0.04, 0.32)		0.30 (0.08, 0.52)		
p-value	0.12		0.008		
Proportion Difference - Unstratified Exact Method (95% CI)	0.14 (-0.05, 0.33)		0.30 (0.07, 0.50)		
p-value	0.15		0.011		
Unadjusted Inverse Relative Risk (95% CI)	0.64 (0.36, 1.14)		0.48 (0.28, 0.85)		
p-value [1]	0.13		0.012		
Unadjusted interaction test for Treatment*Region [3]					0.49
Unadjusted Inverse Odds Ratio (95% CI)	0.52 (0.23, 1.20)		0.29 (0.11, 0.74)		
p-value [1]	0.13		0.010		
Unadjusted Absolute Risk Difference (95% CI)	0.14 (-0.04, 0.32)		0.30 (0.08, 0.51)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.54 (0.31, 0.95)		NE		
p-value [2]	0.031		NE		
Adjusted interaction test for Treatment*Region [3]					0.70

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti-resp.sas V.03.05 Output file: t-subgrp-rbcti24-geo-gba.pdf 29AUG2023: 9:35

Table 2.2704: Analysis of RBC Transfusion Independent Response Rate at Week 24 by Region
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Non-Responder, n(%)	32 (60.4%)	38 (74.5%)	14 (42.4%)	31 (72.1%)	
Transfusion (except bleeding) in the last 12 weeks	21 (39.6%)	31 (60.8%)	5 (15.2%)	24 (55.8%)	
Any Hgb assessment < 8g/dL in the last 12 weeks	17 (32.1%)	20 (39.2%)	6 (18.2%)	25 (58.1%)	
Last Participation date < Day 162 in DB phase	10 (18.9%)	5 (9.8%)	6 (18.2%)	3 (7.0%)	
Other	7 (13.2%)	10 (19.6%)	5 (15.2%)	15 (34.9%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti-resp.sas V.03.05 Output file: t-subgrp-rbcti24-geo-gba.pdf 29AUG2023: 9:35

Table 2.2707: Analysis of RBC Transfusion Independent Response Rate at Week 24 by Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
RBC Transfusion Independent Rate at Week 24					
Responder, n(%)	8 (28.6%)	3 (14.3%)	32 (55.2%)	22 (30.1%)	
95% Exact CI	0.1322, 0.4867	0.0305, 0.3634	0.4154, 0.6826	0.1994, 0.4200	
Proportion Difference - Stratified CMH Method (95% CI)	0.14 (-0.11, 0.39)		0.27 (0.10, 0.44)		
p-value	0.26		0.002		
Proportion Difference - Unstratified CMH Method (95% CI)	0.14 (-0.09, 0.38)		0.25 (0.08, 0.42)		
p-value	0.23		0.003		
Proportion Difference - Unstratified Exact Method (95% CI)	0.14 (-0.15, 0.41)		0.25 (0.08, 0.41)		
p-value	0.31		0.004		
Unadjusted Inverse Relative Risk (95% CI)	0.50 (0.15, 1.66)		0.55 (0.36, 0.83)		
p-value [1]	0.26		0.005		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.89
Unadjusted Inverse Odds Ratio (95% CI)	0.42 (0.10, 1.82)		0.35 (0.17, 0.72)		
p-value [1]	0.24		0.004		
Unadjusted Absolute Risk Difference (95% CI)	0.14 (-0.08, 0.37)		0.25 (0.08, 0.42)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.50 (0.15, 1.63)		0.52 (0.35, 0.79)		
p-value [2]	0.25		0.002		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.95

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel; RBC = Red Blood Cell.
[1] p-values were from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti-resp.sas V.03.05 Output file: t-subgrp-rbcti24-hgb-gba.pdf 29AUG2023: 9:35

Table 2.2707: Analysis of RBC Transfusion Independent Response Rate at Week 24 by Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Non-Responder, n(%)	20 (71.4%)	18 (85.7%)	26 (44.8%)	51 (69.9%)	
Transfusion (except bleeding) in the last 12 weeks	11 (39.3%)	13 (61.9%)	15 (25.9%)	42 (57.5%)	
Any Hgb assessment < 8g/dL in the last 12 weeks	13 (46.4%)	12 (57.1%)	10 (17.2%)	33 (45.2%)	
Last Participation date < Day 162 in DB phase	6 (21.4%)	4 (19.0%)	10 (17.2%)	4 (5.5%)	
Other	7 (25.0%)	8 (38.1%)	5 (8.6%)	17 (23.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel; RBC = Red Blood Cell.
[1] p-values were from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti-resp.sas V.03.05 Output file: t-subgrp-rbcti24-hgb-gba.pdf 29AUG2023: 9:35

Table 2.2706: Analysis of RBC Transfusion Independent Response Rate at Week 24 by Baseline IPSS Two-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
RBC Transfusion Independent Rate at Week 24					
Responder, n(%)	14 (50.0%)	8 (33.3%)	26 (44.8%)	17 (24.3%)	
95% Exact CI	0.3065, 0.6935	0.1563, 0.5532	0.3174, 0.5846	0.1483, 0.3601	
Proportion Difference - Stratified CMH Method (95% CI)	0.26 (-0.04, 0.55)		0.21 (0.05, 0.38)		
p-value	0.086		0.012		
Proportion Difference - Unstratified CMH Method (95% CI)	0.17 (-0.10, 0.44)		0.21 (0.04, 0.37)		
p-value	0.23		0.014		
Proportion Difference - Unstratified Exact Method (95% CI)	0.17 (-0.11, 0.43)		0.21 (0.03, 0.37)		
p-value	0.27		0.016		
Unadjusted Inverse Relative Risk (95% CI)	0.67 (0.34, 1.31)		0.54 (0.33, 0.90)		
p-value [1]	0.24		0.017		
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.64
Unadjusted Inverse Odds Ratio (95% CI)	0.50 (0.16, 1.54)		0.39 (0.19, 0.84)		
p-value [1]	0.23		0.015		
Unadjusted Absolute Risk Difference (95% CI)	0.17 (-0.10, 0.43)		0.21 (0.04, 0.37)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.55 (0.31, 0.97)		NE		
p-value [2]	0.040		NE		
Adjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti-resp.sas V.03.05 Output file: t-subgrp-rbcti24-ipss2-gba.pdf 29AUG2023: 9:35

Table 2.2706: Analysis of RBC Transfusion Independent Response Rate at Week 24 by Baseline IPSS Two-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Non-Responder, n(%)	14 (50.0%)	16 (66.7%)	32 (55.2%)	53 (75.7%)	
Transfusion (except bleeding) in the last 12 weeks	8 (28.6%)	12 (50.0%)	18 (31.0%)	43 (61.4%)	
Any Hgb assessment < 8g/dL in the last 12 weeks	5 (17.9%)	11 (45.8%)	18 (31.0%)	34 (48.6%)	
Last Participation date < Day 162 in DB phase	4 (14.3%)	2 (8.3%)	12 (20.7%)	6 (8.6%)	
Other	3 (10.7%)	6 (25.0%)	9 (15.5%)	19 (27.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model,
including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified
Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti-resp.sas V.03.05 Output file: t-subgrp-rbcti24-ipss2-gba.pdf 29AUG2023: 9:35

Table 2.2705: Subgroup Analysis of RBC Transfusion Independent Response Rate at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
RBC Transfusion Independent Rate at Week 24				
Responder, n(%)	2 (100.0%)	2 (50.0%)	12 (46.2%)	6 (30.0%)
95% Exact CI	0.1581, 1.0000	0.0676, 0.9324	0.2659, 0.6663	0.1189, 0.5428
Proportion Difference - Stratified CMH Method (95% CI)	0.00 (-1.03, 1.03)		0.24 (-0.06, 0.53)	
p-value	1.00		0.11	
Proportion Difference - Unstratified CMH Method (95% CI)	0.50 (-0.42, 1.42)		0.16 (-0.12, 0.45)	
p-value	0.29		0.27	
Proportion Difference - Unstratified Exact Method (95% CI)	0.50 (-0.45, 0.99)		0.16 (-0.13, 0.43)	
p-value	0.47		0.36	
Unadjusted Inverse Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel; RBC = Red Blood Cell.
[1] p-values were from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti-resp.sas V.03.05 Output file: t-subgrp-rbcti24-ipss3-gba.pdf 29AUG2023: 9:36

Table 2.2705: Subgroup Analysis of RBC Transfusion Independent Response Rate at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N=58)	RUX (N=70)	p-value
RBC Transfusion Independent Rate at Week 24			
Responder, n(%)	26 (44.8%)	17 (24.3%)	
95% Exact CI	0.3174, 0.5846	0.1483, 0.3601	
Proportion Difference - Stratified CMH Method (95% CI)	0.21 (0.05, 0.38)		
p-value	0.012		
Proportion Difference - Unstratified CMH Method (95% CI)	0.21 (0.04, 0.37)		
p-value	0.014		
Proportion Difference - Unstratified Exact Method (95% CI)	0.21 (0.03, 0.37)		
p-value	0.016		
Unadjusted Inverse Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel; RBC = Red Blood Cell.
[1] p-values were from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti-resp.sas V.03.05 Output file: t-subgrp-rbcti24-ipss3-gba.pdf 29AUG2023: 9:36

Table 2.2705: Subgroup Analysis of RBC Transfusion Independent Response Rate at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Non-Responder, n(%)	0	2 (50.0%)	14 (53.8%)	14 (70.0%)
Transfusion (except bleeding) in the last 12 weeks	0	2 (50.0%)	8 (30.8%)	10 (50.0%)
Any Hgb assessment < 8g/dL in the last 12 weeks	0	2 (50.0%)	5 (19.2%)	9 (45.0%)
Last Participation date < Day 162 in DB phase	0	0	4 (15.4%)	2 (10.0%)
Other	0	0	3 (11.5%)	6 (30.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel; RBC = Red Blood Cell.
[1] p-values were from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model,
including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified
Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti-resp.sas V.03.05 Output file: t-subgrp-rbcti24-ipss3-gba.pdf 29AUG2023: 9:36

Table 2.2705: Subgroup Analysis of RBC Transfusion Independent Response Rate at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N=58)	RUX (N=70)	p-value
Non-Responder, n(%)	32 (55.2%)	53 (75.7%)	
Transfusion (except bleeding) in the last 12 weeks	18 (31.0%)	43 (61.4%)	
Any Hgb assessment < 8g/dL in the last 12 weeks	18 (31.0%)	34 (48.6%)	
Last Participation date < Day 162 in DB phase	12 (20.7%)	6 (8.6%)	
Other	9 (15.5%)	19 (27.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel; RBC = Red Blood Cell.
[1] p-values were from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti-resp.sas V.03.05 Output file: t-subgrp-rbcti24-ipss3-gba.pdf 29AUG2023: 9:36

Table 2.2708: Analysis of RBC Transfusion Independent Response Rate at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
RBC Transfusion Independent Rate at Week 24				
Responder, n(%)	29 (49.2%)	18 (33.3%)	5 (31.3%)	6 (21.4%)
95% Exact CI	0.3589, 0.6250	0.2109, 0.4747	0.1102, 0.5866	0.0830, 0.4095
Proportion Difference - Stratified CMH Method (95% CI)	0.16 (-0.02, 0.34)		0.10 (-0.18, 0.39)	
p-value	0.088		0.48	
Proportion Difference - Unstratified CMH Method (95% CI)	0.16 (-0.02, 0.34)		0.10 (-0.19, 0.38)	
p-value	0.087		0.50	
Proportion Difference - Unstratified Exact Method (95% CI)	0.16 (-0.03, 0.34)		0.10 (-0.21, 0.39)	
p-value	0.13		0.49	
Unadjusted Inverse Relative Risk (95% CI)	0.68 (0.43, 1.07)		0.69 (0.25, 1.89)	
p-value [1]	0.096		0.47	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	0.52 (0.24, 1.11)		0.60 (0.15, 2.41)	
p-value [1]	0.090		0.47	
Unadjusted Absolute Risk Difference (95% CI)	0.16 (-0.02, 0.34)		0.10 (-0.18, 0.37)	
Adjusted Inverse Relative Risk (95% CI) [2]	0.68 (0.43, 1.07)		NE	
p-value [2]	0.094		NE	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti-resp.sas V.03.05 Output file: t-subgrp-rbcti24-mf-gba.pdf 29AUG2023: 9:37

Table 2.2708: Analysis of RBC Transfusion Independent Response Rate at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=11)	RUX (N=12)	p-value
RBC Transfusion Independent Rate at Week 24			
Responder, n(%)	6 (54.5%)	1 (8.3%)	
95% Exact CI	0.2338, 0.8325	0.0021, 0.3848	
Proportion Difference - Stratified CMH Method (95% CI)	0.55 (0.14, 0.96)		
p-value	0.008		
Proportion Difference - Unstratified CMH Method (95% CI)	0.46 (0.10, 0.82)		
p-value	0.012		
Proportion Difference - Unstratified Exact Method (95% CI)	0.46 (0.03, 0.77)		
p-value	0.027		
Unadjusted Inverse Relative Risk (95% CI)	0.15 (0.02, 1.08)		
p-value [1]	0.059		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.15
Unadjusted Inverse Odds Ratio (95% CI)	0.08 (0.01, 0.81)		
p-value [1]	0.033		
Unadjusted Absolute Risk Difference (95% CI)	0.46 (0.13, 0.80)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.045

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti-resp.sas V.03.05 Output file: t-subgrp-rbcti24-mf-gba.pdf 29AUG2023: 9:37

Table 2.2708: Analysis of RBC Transfusion Independent Response Rate at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
Non-Responder, n(%)	30 (50.8%)	36 (66.7%)	11 (68.8%)	22 (78.6%)
Transfusion (except bleeding) in the last 12 weeks	16 (27.1%)	27 (50.0%)	8 (50.0%)	19 (67.9%)
Any Hgb assessment < 8g/dL in the last 12 weeks	15 (25.4%)	24 (44.4%)	6 (37.5%)	16 (57.1%)
Last Participation date < Day 162 in DB phase	10 (16.9%)	4 (7.4%)	3 (18.8%)	2 (7.1%)
Other	6 (10.2%)	11 (20.4%)	5 (31.3%)	10 (35.7%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti-resp.sas V.03.05 Output file: t-subgrp-rbcti24-mf-gba.pdf 29AUG2023: 9:37

Table 2.2708: Analysis of RBC Transfusion Independent Response Rate at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=11)	RUX (N=12)	p-value
Non-Responder, n(%)	5 (45.5%)	11 (91.7%)	
Transfusion (except bleeding) in the last 12 weeks	2 (18.2%)	9 (75.0%)	
Any Hgb assessment < 8g/dL in the last 12 weeks	2 (18.2%)	5 (41.7%)	
Last Participation date < Day 162 in DB phase	3 (27.3%)	2 (16.7%)	
Other	1 (9.1%)	4 (33.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti-resp.sas V.03.05 Output file: t-subgrp-rbcti24-mf-gba.pdf 29AUG2023: 9:37

Table 2.2703: Analysis of RBC Transfusion Independent Response Rate at Week 24 by Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
RBC Transfusion Independent Rate at Week 24					
Responder, n(%)	20 (40.0%)	16 (28.6%)	20 (55.6%)	9 (23.7%)	
95% Exact CI	0.2641, 0.5482	0.1730, 0.4221	0.3810, 0.7206	0.1144, 0.4024	
Proportion Difference - Stratified CMH Method (95% CI)	0.18 (0.00, 0.37)		0.29 (0.06, 0.53)		
p-value	0.055		0.016		
Proportion Difference - Unstratified CMH Method (95% CI)	0.11 (-0.07, 0.30)		0.32 (0.10, 0.53)		
p-value	0.22		0.004		
Proportion Difference - Unstratified Exact Method (95% CI)	0.11 (-0.08, 0.30)		0.32 (0.09, 0.52)		
p-value	0.23		0.008		
Unadjusted Inverse Relative Risk (95% CI)	0.71 (0.42, 1.22)		0.43 (0.22, 0.81)		
p-value [1]	0.22		0.009		
Unadjusted interaction test for Treatment*Gender [3]					0.22
Unadjusted Inverse Odds Ratio (95% CI)	0.60 (0.27, 1.35)		0.25 (0.09, 0.67)		
p-value [1]	0.22		0.006		
Unadjusted Absolute Risk Difference (95% CI)	0.11 (-0.07, 0.29)		0.32 (0.11, 0.53)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.58 (0.35, 0.99)		0.46 (0.24, 0.88)		
p-value [2]	0.045		0.018		
Adjusted interaction test for Treatment*Gender [3]					0.48

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel; RBC = Red Blood Cell.
[1] p-values were from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti-resp.sas V.03.05 Output file: t-subgrp-rbcti24-sex-gba.pdf 29AUG2023: 9:35

Table 2.2703: Analysis of RBC Transfusion Independent Response Rate at Week 24 by Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Non-Responder, n(%)	30 (60.0%)	40 (71.4%)	16 (44.4%)	29 (76.3%)	
Transfusion (except bleeding) in the last 12 weeks	21 (42.0%)	32 (57.1%)	5 (13.9%)	23 (60.5%)	
Any Hgb assessment < 8g/dL in the last 12 weeks	18 (36.0%)	26 (46.4%)	5 (13.9%)	19 (50.0%)	
Last Participation date < Day 162 in DB phase	6 (12.0%)	6 (10.7%)	10 (27.8%)	2 (5.3%)	
Other	9 (18.0%)	15 (26.8%)	3 (8.3%)	10 (26.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel; RBC = Red Blood Cell.
[1] p-values were from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model,
including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified
Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti-resp.sas V.03.05 Output file: t-subgrp-rbcti24-sex-gba.pdf 29AUG2023: 9:35

Table 2.2710: Analysis of RBC Transfusion Independent Response Rate at Week 24 by Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	<Median (1837.09 cm^3)		>=Median (1837.09 cm^3)		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
RBC Transfusion Independent Rate at Week 24					
Responder, n(%)	26 (55.3%)	8 (18.6%)	14 (35.9%)	17 (33.3%)	
95% Exact CI	0.4012, 0.6983	0.0839, 0.3340	0.2120, 0.5282	0.2076, 0.4792	
Proportion Difference - Stratified CMH Method (95% CI)	0.38 (0.18, 0.59)		0.10 (-0.11, 0.31)		
p-value	<0.001		0.34		
Proportion Difference - Unstratified CMH Method (95% CI)	0.37 (0.18, 0.55)		0.03 (-0.18, 0.23)		
p-value	<0.001		0.80		
Proportion Difference - Unstratified Exact Method (95% CI)	0.37 (0.16, 0.55)		0.03 (-0.18, 0.23)		
p-value	<0.001		0.83		
Unadjusted Inverse Relative Risk (95% CI)	0.34 (0.17, 0.66)		0.93 (0.52, 1.64)		
p-value [1]	0.002		0.80		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.018
Unadjusted Inverse Odds Ratio (95% CI)	0.18 (0.07, 0.48)		0.89 (0.37, 2.14)		
p-value [1]	<0.001		0.80		
Unadjusted Absolute Risk Difference (95% CI)	0.37 (0.18, 0.55)		0.03 (-0.17, 0.22)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.75 (0.43, 1.29)		
p-value [2]	NE		0.29		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.042

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti-resp.sas V.03.05 Output file: t-subgrp-rbcti24-svb-gba.pdf 29AUG2023: 9:36

Table 2.2710: Analysis of RBC Transfusion Independent Response Rate at Week 24 by Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	<Median (1837.09 cm^3)		>=Median (1837.09 cm^3)		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Non-Responder, n(%)	21 (44.7%)	35 (81.4%)	25 (64.1%)	34 (66.7%)	
Transfusion (except bleeding) in the last 12 weeks	14 (29.8%)	29 (67.4%)	12 (30.8%)	26 (51.0%)	
Any Hgb assessment < 8g/dL in the last 12 weeks	12 (25.5%)	24 (55.8%)	11 (28.2%)	21 (41.2%)	
Last Participation date < Day 162 in DB phase	7 (14.9%)	4 (9.3%)	9 (23.1%)	4 (7.8%)	
Other	4 (8.5%)	15 (34.9%)	8 (20.5%)	10 (19.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti-resp.sas V.03.05 Output file: t-subgrp-rbcti24-svb-gba.pdf 29AUG2023: 9:36

Table 2.2709: Analysis of RBC Transfusion Independent Response Rate at Week 24 by Baseline TSS
Double-Blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
RBC Transfusion Independent Rate at Week 24					
Responder, n(%)	21 (47.7%)	17 (30.9%)	18 (43.9%)	8 (21.1%)	
95% Exact CI	0.3246, 0.6331	0.1914, 0.4481	0.2847, 0.6025	0.0955, 0.3732	
Proportion Difference - Stratified CMH Method (95% CI)	0.21 (0.02, 0.40)		0.25 (0.04, 0.45)		
p-value	0.033		0.019		
Proportion Difference - Unstratified CMH Method (95% CI)	0.17 (-0.03, 0.36)		0.23 (0.03, 0.43)		
p-value	0.089		0.028		
Proportion Difference - Unstratified Exact Method (95% CI)	0.17 (-0.03, 0.36)		0.23 (0.01, 0.43)		
p-value	0.100		0.035		
Unadjusted Inverse Relative Risk (95% CI)	0.65 (0.39, 1.07)		0.48 (0.24, 0.97)		
p-value [1]	0.090		0.041		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.49
Unadjusted Inverse Odds Ratio (95% CI)	0.49 (0.22, 1.12)		0.34 (0.13, 0.92)		
p-value [1]	0.089		0.034		
Unadjusted Absolute Risk Difference (95% CI)	0.17 (-0.02, 0.36)		0.23 (0.03, 0.43)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.45 (0.23, 0.88)		
p-value [2]	NE		0.020		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					0.58

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti-resp.sas V.03.05 Output file: t-subgrp-rbcti24-tss-gba.pdf 29AUG2023: 9:36

Table 2.2709: Analysis of RBC Transfusion Independent Response Rate at Week 24 by Baseline TSS
Double-Blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Non-Responder, n(%)	23 (52.3%)	38 (69.1%)	23 (56.1%)	30 (78.9%)	
Transfusion (except bleeding) in the last 12 weeks	16 (36.4%)	32 (58.2%)	10 (24.4%)	22 (57.9%)	
Any Hgb assessment < 8g/dL in the last 12 weeks	17 (38.6%)	25 (45.5%)	6 (14.6%)	19 (50.0%)	
Last Participation date < Day 162 in DB phase	3 (6.8%)	4 (7.3%)	13 (31.7%)	4 (10.5%)	
Other	10 (22.7%)	15 (27.3%)	2 (4.9%)	9 (23.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model,
including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified
Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti-resp.sas V.03.05 Output file: t-subgrp-rbcti24-tss-gba.pdf 29AUG2023: 9:36

Table 2.3502: Analysis of Time to RBC Transfusion Independent Response by Age
Double-blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Subjects with Event					
RBC Transfusion Independent Response, n(%)	13 (54.2%)	14 (38.9%)	34 (54.8%)	17 (29.3%)	
Censor					
Subjects Censored, n(%)	11 (45.8%)	22 (61.1%)	28 (45.2%)	41 (70.7%)	
Kaplan-Meier Estimate of Time to RBC Transfusion Independent Response (Weeks)					
25-percentile (95% CI)	12.14 (NE, NE)	12.14 (12.14, 24.29)	12.14 (NE, NE)	20.29 (12.14, NE)	
Median (95% CI)	23.57 (12.14, NE)	24.29 (22.00, NE)	14.29 (12.14, 23.14)	NE (NE, NE)	
75-percentile (95% CI)	NE (24.14, NE)	NE (24.29, NE)	NE (23.14, NE)	NE (NE, NE)	
Min, Max	5.29, 24.57	11.14, 24.71	1.29, 24.57	12.00, 27.00	
Stratified Log-Rank Test p-value	0.15		< 0.001		
Adjusted Inverse Hazard Ratio (95% CI)	0.46 (0.20, 1.07)		0.25 (0.14, 0.47)		
Unstratified Log-Rank Test p-value	0.27		< 0.001		
Unadjusted Inverse Hazard Ratio (95% CI)	0.64 (0.30, 1.36)		0.35 (0.20, 0.64)		
P-value for interaction test					0.27

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-tte-ti-sub.sas V.03.05 Output file: t-tte-ti-age.pdf 24AUG2023:12:43

Table 2.3504: Analysis of Time to RBC Transfusion Independent Response by Region
Double-blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Subjects with Event					
RBC Transfusion Independent Response, n(%)	26 (49.1%)	16 (31.4%)	21 (63.6%)	15 (34.9%)	
Censor					
Subjects Censored, n(%)	27 (50.9%)	35 (68.6%)	12 (36.4%)	28 (65.1%)	
Kaplan-Meier Estimate of Time to RBC Transfusion Independent Response (Weeks)					
25-percentile (95% CI)	12.14 (NE, NE)	17.29 (12.14, NE)	12.14 (NE, NE)	20.86 (12.14, NE)	
Median (95% CI)	22.00 (12.14, NE)	NE (NE, NE)	12.71 (12.14, 23.57)	NE (24.29, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (21.86, NE)	NE (NE, NE)	
Min, Max	1.29, 24.57	11.14, 27.00	2.71, 24.57	12.14, 25.14	
Stratified Log-Rank Test p-value	0.003		< 0.001		
Adjusted Inverse Hazard Ratio (95% CI)	0.35 (0.18, 0.67)		0.22 (0.11, 0.46)		
Unstratified Log-Rank Test p-value	0.022		0.002		
Unadjusted Inverse Hazard Ratio (95% CI)	0.50 (0.27, 0.93)		0.35 (0.18, 0.69)		
P-value for interaction test					0.56

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-tte-ti-sub.sas V.03.05 Output file: t-tte-ti-geo.pdf 24AUG2023:12:43

Table 2.3507: Analysis of Time to RBC Transfusion Independent Response by Baseline Hemoglobin Level
Double-blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Subjects with Event					
RBC Transfusion Independent Response, n(%)	10 (35.7%)	3 (14.3%)	37 (63.8%)	28 (38.4%)	
Censor					
Subjects Censored, n(%)	18 (64.3%)	18 (85.7%)	21 (36.2%)	45 (61.6%)	
Kaplan-Meier Estimate of Time to RBC Transfusion Independent Response (Weeks)					
25-percentile (95% CI)	14.00 (12.14, 24.14)	NE (12.14, NE)	12.14 (NE, NE)	12.14 (12.14, 22.29)	
Median (95% CI)	NE (14.29, NE)	NE (NE, NE)	12.14 (12.14, 21.86)	NE (24.29, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (21.86, NE)	NE (NE, NE)	
Min, Max	1.29, 24.43	11.14, 24.71	1.29, 24.57	12.14, 27.00	
Stratified Log-Rank Test p-value	0.069		< 0.001		
Adjusted Inverse Hazard Ratio (95% CI)	0.33 (0.09, 1.20)		0.32 (0.19, 0.53)		
Unstratified Log-Rank Test p-value	0.074		< 0.001		
Unadjusted Inverse Hazard Ratio (95% CI)	0.33 (0.09, 1.19)		0.39 (0.24, 0.65)		
P-value for interaction test					0.87

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-tte-ti-sub.sas V.03.05 Output file: t-tte-ti-hgb.pdf 24AUG2023:12:43

Table 2.3506: Analysis of Time to RBC Transfusion Independent Response by Baseline IPSS Two-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Subjects with Event					
RBC Transfusion Independent Response, n(%)	15 (53.6%)	8 (33.3%)	32 (55.2%)	23 (32.9%)	
Censor					
Subjects Censored, n(%)	13 (46.4%)	16 (66.7%)	26 (44.8%)	47 (67.1%)	
Kaplan-Meier Estimate of Time to RBC Transfusion Independent Response (Weeks)					
25-percentile (95% CI)	12.14 (NE, NE)	12.14 (12.14, NE)	12.14 (NE, NE)	20.00 (12.14, 24.29)	
Median (95% CI)	12.71 (12.14, NE)	NE (22.00, NE)	21.86 (12.14, 23.57)	NE (24.29, NE)	
75-percentile (95% CI)	NE (16.57, NE)	NE (NE, NE)	NE (23.57, NE)	NE (NE, NE)	
Min, Max	2.71, 24.57	11.14, 25.14	1.29, 24.57	12.00, 27.00	
Stratified Log-Rank Test p-value	0.005		< 0.001		
Adjusted Inverse Hazard Ratio (95% CI)	0.25 (0.10, 0.63)		0.32 (0.18, 0.57)		
Unstratified Log-Rank Test p-value	0.080		< 0.001		
Unadjusted Inverse Hazard Ratio (95% CI)	0.47 (0.20, 1.12)		0.41 (0.24, 0.71)		
P-value for interaction test					0.96

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-tte-ti-sub.sas V.03.05 Output file: t-tte-ti-ipss2.pdf 24AUG2023:12:43

Table 2.3505: Analysis of Time to RBC Transfusion Independent Response by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Subjects with Event				
RBC Transfusion Independent Response, n(%)	2 (100.0%)	2 (50.0%)	13 (50.0%)	6 (30.0%)
Censor				
Subjects Censored, n(%)	0	2 (50.0%)	13 (50.0%)	14 (70.0%)
Kaplan-Meier Estimate of Time to RBC Transfusion Independent Response (Weeks)				
25-percentile (95% CI)	12.14 (NE, NE)	17.07 (12.14, NE)	12.14 (NE, NE)	12.14 (12.14, NE)
Median (95% CI)	12.14 (NE, NE)	NE (12.14, NE)	16.57 (12.14, NE)	NE (12.14, NE)
75-percentile (95% CI)	12.14 (NE, NE)	NE (12.14, NE)	NE (22.14, NE)	NE (NE, NE)
Min, Max	12.14, 12.14	12.14, 24.14	2.71, 24.57	11.14, 25.14
Stratified Log-Rank Test p-value	NA		NA	
Adjusted Inverse Hazard Ratio (95% CI)	NA		NA	
Unstratified Log-Rank Test p-value	NA		NA	
Unadjusted Inverse Hazard Ratio (95% CI)	NA		NA	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-tte-ti-sub.sas V.03.05 Output file: t-tte-ti-ipss3.pdf 24AUG2023:12:43

Table 2.3505: Analysis of Time to RBC Transfusion Independent Response by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=58)	High Risk RUX (N=70)	p-value
Subjects with Event			
RBC Transfusion Independent Response, n(%)	32 (55.2%)	23 (32.9%)	
Censor			
Subjects Censored, n(%)	26 (44.8%)	47 (67.1%)	
Kaplan-Meier Estimate of Time to RBC Transfusion Independent Response (Weeks)			
25-percentile (95% CI)	12.14 (NE, NE)	20.00 (12.14, 24.29)	
Median (95% CI)	21.86 (12.14, 23.57)	NE (24.29, NE)	
75-percentile (95% CI)	NE (23.57, NE)	NE (NE, NE)	
Min, Max	1.29, 24.57	12.00, 27.00	
Stratified Log-Rank Test p-value	NA		
Adjusted Inverse Hazard Ratio (95% CI)	NA		
Unstratified Log-Rank Test p-value	NA		
Unadjusted Inverse Hazard Ratio (95% CI)	NA		
P-value for interaction test			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-tte-ti-sub.sas V.03.05 Output file: t-tte-ti-ipss3.pdf 24AUG2023:12:43

Table 2.3508: Analysis of Time to RBC Transfusion Independent Response by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

	Post-ET Myelofibrosis		Post-PV Myelofibrosis	
	MMB (N=16)	RUX (N=28)	MMB (N=11)	RUX (N=12)
Subjects with Event				
RBC Transfusion Independent Response, n(%)	6 (37.5%)	8 (28.6%)	6 (54.5%)	2 (16.7%)
Censor				
Subjects Censored, n(%)	10 (62.5%)	20 (71.4%)	5 (45.5%)	10 (83.3%)
Kaplan-Meier Estimate of Time to RBC Transfusion Independent Response (Weeks)				
25-percentile (95% CI)	12.14 (12.14, NE)	12.14 (12.14, NE)	12.14 (12.14, 12.71)	NE (12.14, NE)
Median (95% CI)	NE (12.14, NE)	NE (20.86, NE)	12.43 (12.14, NE)	NE (12.14, NE)
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (12.14, NE)	NE (NE, NE)
Min, Max	1.29, 24.57	11.14, 27.00	1.29, 24.29	12.14, 24.29
Stratified Log-Rank Test p-value	0.14		0.025	
Adjusted Inverse Hazard Ratio (95% CI)	0.35 (0.11, 1.18)		0.10 (0.02, 0.65)	
Unstratified Log-Rank Test p-value	0.44		0.010	
Unadjusted Inverse Hazard Ratio (95% CI)	0.65 (0.22, 1.86)		0.16 (0.03, 0.81)	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-tte-ti-sub.sas V.03.05 Output file: t-tte-ti-mf.pdf 24AUG2023:12:43

Table 2.3508: Analysis of Time to RBC Transfusion Independent Response by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

(Continued)	Primary Myelofibrosis MMB (N=59)	Primary Myelofibrosis RUX (N=54)	p-value
Subjects with Event			
RBC Transfusion Independent Response, n(%)	35 (59.3%)	21 (38.9%)	
Censor			
Subjects Censored, n(%)	24 (40.7%)	33 (61.1%)	
Kaplan-Meier Estimate of Time to RBC Transfusion Independent Response (Weeks)			
25-percentile (95% CI)	12.14 (NE, NE)	19.57 (12.14, 22.71)	
Median (95% CI)	16.57 (12.14, 23.43)	NE (22.57, NE)	
75-percentile (95% CI)	NE (23.43, NE)	NE (NE, NE)	
Min, Max	2.29, 24.57	12.14, 25.14	
Stratified Log-Rank Test p-value	0.007		
Adjusted Inverse Hazard Ratio (95% CI)	0.38 (0.22, 0.67)		
Unstratified Log-Rank Test p-value	0.005		
Unadjusted Inverse Hazard Ratio (95% CI)	0.47 (0.27, 0.81)		
P-value for interaction test			0.17

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-tte-ti-sub.sas V.03.05 Output file: t-tte-ti-mf.pdf 24AUG2023:12:43

Table 2.3503: Analysis of Time to RBC Transfusion Independent Response by Gender
Double-blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Subjects with Event					
RBC Transfusion Independent Response, n(%)	25 (50.0%)	19 (33.9%)	22 (61.1%)	12 (31.6%)	
Censor					
Subjects Censored, n(%)	25 (50.0%)	37 (66.1%)	14 (38.9%)	26 (68.4%)	
Kaplan-Meier Estimate of Time to RBC Transfusion Independent Response (Weeks)					
25-percentile (95% CI)	12.14 (12.14, 14.00)	20.00 (12.14, 24.29)	12.14 (NE, NE)	12.14 (12.14, NE)	
Median (95% CI)	23.43 (13.14, NE)	NE (24.29, NE)	12.14 (12.14, 22.14)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	24.14 (12.14, NE)	NE (NE, NE)	
Min, Max	2.29, 24.57	11.14, 26.71	1.29, 24.57	12.14, 27.00	
Stratified Log-Rank Test p-value	0.010		0.001		
Adjusted Inverse Hazard Ratio (95% CI)	0.40 (0.22, 0.76)		0.24 (0.11, 0.52)		
Unstratified Log-Rank Test p-value	0.064		< 0.001		
Unadjusted Inverse Hazard Ratio (95% CI)	0.57 (0.31, 1.03)		0.29 (0.14, 0.59)		
P-value for interaction test					0.18

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-tte-ti-sub.sas V.03.05 Output file: t-tte-ti-sex.pdf 24AUG2023:12:43

Table 2.3510: Analysis of Time to RBC Transfusion Independent Response by Baseline Spleen Volume
Double-blind Phase
ITT-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Subjects with Event					
RBC Transfusion Independent Response, n(%)	29 (61.7%)	10 (23.3%)	18 (46.2%)	21 (41.2%)	
Censor					
Subjects Censored, n(%)	18 (38.3%)	33 (76.7%)	21 (53.8%)	30 (58.8%)	
Kaplan-Meier Estimate of Time to RBC Transfusion Independent Response (Weeks)					
25-percentile (95% CI)	12.14 (NE, NE)	NE (12.14, NE)	12.14 (12.14, 21.86)	12.14 (12.14, 22.29)	
Median (95% CI)	12.14 (12.14, 22.00)	NE (NE, NE)	23.43 (12.71, NE)	NE (22.00, NE)	
75-percentile (95% CI)	NE (14.29, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	1.29, 24.57	12.14, 27.00	1.29, 24.57	11.14, 24.71	
Stratified Log-Rank Test p-value	< 0.001		0.088		
Adjusted Inverse Hazard Ratio (95% CI)	0.14 (0.06, 0.31)		0.52 (0.27, 1.02)		
Unstratified Log-Rank Test p-value	< 0.001		0.43		
Unadjusted Inverse Hazard Ratio (95% CI)	0.22 (0.11, 0.46)		0.78 (0.41, 1.46)		
P-value for interaction test					0.010

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-tte-ti-sub.sas V.03.05 Output file: t-tte-ti-svb.pdf 24AUG2023:12:43

Table 2.3509: Analysis of Time to RBC Transfusion Independent Response by Baseline TSS
Double-blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Subjects with Event					
RBC Transfusion Independent Response, n(%)	26 (59.1%)	20 (36.4%)	20 (48.8%)	11 (28.9%)	
Censor					
Subjects Censored, n(%)	18 (40.9%)	35 (63.6%)	21 (51.2%)	27 (71.1%)	
Kaplan-Meier Estimate of Time to RBC Transfusion Independent Response (Weeks)					
25-percentile (95% CI)	12.14 (12.14, 12.57)	18.00 (12.14, 22.29)	12.14 (NE, NE)	22.71 (12.14, NE)	
Median (95% CI)	16.57 (12.14, NE)	NE (22.00, NE)	12.43 (12.14, NE)	NE (24.29, NE)	
75-percentile (95% CI)	NE (23.14, NE)	NE (NE, NE)	NE (24.14, NE)	NE (NE, NE)	
Min, Max	1.29, 24.57	11.14, 26.71	1.29, 24.57	12.00, 27.00	
Stratified Log-Rank Test p-value	0.003		0.001		
Adjusted Inverse Hazard Ratio (95% CI)	0.36 (0.19, 0.67)		0.25 (0.12, 0.56)		
Unstratified Log-Rank Test p-value	0.012		0.013		
Unadjusted Inverse Hazard Ratio (95% CI)	0.49 (0.27, 0.88)		0.39 (0.19, 0.82)		
P-value for interaction test					0.61

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment. Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-tte-ti-sub.sas V.03.05 Output file: t-tte-ti-tss.pdf 24AUG2023:12:43

Table 2.3802: Analysis of RBC Transfusion Dependence Rate at Week 24 by Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Not-Dependent, n(%)	13 (54.2%)	15 (41.7%)	32 (51.6%)	21 (36.2%)	
Transfusion Requiring, n(%)	2 (8.3%)	2 (5.6%)	3 (4.8%)	9 (15.5%)	
Transfusion Independent, n(%)	11 (45.8%)	13 (36.1%)	29 (46.8%)	12 (20.7%)	
Dependent, n(%)	11 (45.8%)	21 (58.3%)	30 (48.4%)	37 (63.8%)	
95% Exact CI	0.2555, 0.6718	0.4076, 0.7449	0.3550, 0.6144	0.5012, 0.7601	
Proportion Difference - Stratified CMH Method (95% CI)	-0.11 (-0.41, 0.20)		-0.17 (-0.35, 0.01)		
p-value	0.49		0.071		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.13 (-0.39, 0.14)		-0.15 (-0.33, 0.02)		
p-value	0.35		0.088		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.13 (-0.38, 0.14)		-0.15 (-0.33, 0.03)		
p-value	0.43		0.10		
Unadjusted Relative Risk (95% CI)	0.79 (0.47, 1.32)		0.76 (0.55, 1.05)		
p-value [1]	0.36		0.092		
Unadjusted interaction test for Treatment*Age Group [3]					0.91
Unadjusted Odds Ratio (95% CI)	0.60 (0.21, 1.71)		0.53 (0.26, 1.11)		
p-value [1]	0.34		0.091		
Unadjusted Absolute Risk Difference (95% CI)	-0.13 (-0.38, 0.13)		-0.15 (-0.33, 0.02)		
Adjusted Relative Risk (95% CI) [2]	0.82 (0.48, 1.39)		0.74 (0.54, 1.01)		
p-value [2]	0.46		0.059		
Adjusted interaction test for Treatment*Age Group [3]					0.95

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.3802: Analysis of RBC Transfusion Dependence Rate at Week 24 by Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
>=4 units transfused in the last 8 weeks	4 (16.7%)	6 (16.7%)	10 (16.1%)	23 (39.7%)	
Any Hgb assessment < 8g/dL in the last 8 weeks	6 (25.0%)	18 (50.0%)	14 (22.6%)	25 (43.1%)	
Last Participation date < Day 162 in DB phase	4 (16.7%)	3 (8.3%)	12 (19.4%)	5 (8.6%)	
Other	4 (16.7%)	10 (27.8%)	7 (11.3%)	16 (27.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbctd24-gba.sas V.03.05 Output file: t-rbctd24-gba-age.pdf 29AUG2023: 9:35

Table 2.3808: Analysis of RBC Transfusion Dependence Rate at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
Not-Dependent, n(%)	32 (54.2%)	24 (44.4%)	7 (43.8%)	8 (28.6%)
Transfusion Requiring, n(%)	3 (5.1%)	6 (11.1%)	2 (12.5%)	2 (7.1%)
Transfusion Independent, n(%)	29 (49.2%)	18 (33.3%)	5 (31.3%)	6 (21.4%)
Dependent, n(%)	27 (45.8%)	30 (55.6%)	9 (56.3%)	20 (71.4%)
95% Exact CI	0.3272, 0.5925	0.4140, 0.6908	0.2988, 0.8025	0.5133, 0.8678
Proportion Difference - Stratified CMH Method (95% CI)	-0.10 (-0.28, 0.09)		-0.17 (-0.49, 0.16)	
p-value	0.31		0.31	
Proportion Difference - Unstratified CMH Method (95% CI)	-0.10 (-0.28, 0.09)		-0.15 (-0.46, 0.15)	
p-value	0.30		0.33	
Proportion Difference - Unstratified Exact Method (95% CI)	-0.10 (-0.28, 0.09)		-0.15 (-0.44, 0.16)	
p-value	0.35		0.34	
Unadjusted Relative Risk (95% CI)	0.82 (0.57, 1.19)		0.79 (0.48, 1.29)	
p-value [1]	0.30		0.34	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Odds Ratio (95% CI)	0.68 (0.32, 1.42)		0.51 (0.14, 1.86)	
p-value [1]	0.30		0.31	
Unadjusted Absolute Risk Difference (95% CI)	-0.10 (-0.28, 0.09)		-0.15 (-0.45, 0.14)	
Adjusted Relative Risk (95% CI) [2]	0.83 (0.58, 1.19)		0.77 (0.47, 1.26)	
p-value [2]	0.30		0.30	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.3808: Analysis of RBC Transfusion Dependence Rate at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=11)	RUX (N=12)	p-value
Not-Dependent, n(%)	6 (54.5%)	4 (33.3%)	
Transfusion Requiring, n(%)	0	3 (25.0%)	
Transfusion Independent, n(%)	6 (54.5%)	1 (8.3%)	
Dependent, n(%)	5 (45.5%)	8 (66.7%)	
95% Exact CI	0.1675, 0.7662	0.3489, 0.9008	
Proportion Difference - Stratified CMH Method (95% CI)	-0.29 (-0.75, 0.18)		
p-value	0.23		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.21 (-0.63, 0.21)		
p-value	0.32		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.21 (-0.59, 0.22)		
p-value	0.41		
Unadjusted Relative Risk (95% CI)	0.68 (0.32, 1.46)		
p-value [1]	0.32		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.90
Unadjusted Odds Ratio (95% CI)	0.42 (0.08, 2.25)		
p-value [1]	0.31		
Unadjusted Absolute Risk Difference (95% CI)	-0.21 (-0.61, 0.19)		
Adjusted Relative Risk (95% CI) [2]	0.60 (0.30, 1.18)		
p-value [2]	0.14		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.69

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.3808: Analysis of RBC Transfusion Dependence Rate at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
>=4 units transfused in the last 8 weeks	9 (15.3%)	15 (27.8%)	3 (18.8%)	10 (35.7%)
Any Hgb assessment < 8g/dL in the last 8 weeks	13 (22.0%)	23 (42.6%)	5 (31.3%)	15 (53.6%)
Last Participation date < Day 162 in DB phase	10 (16.9%)	4 (7.4%)	3 (18.8%)	2 (7.1%)
Other	7 (11.9%)	15 (27.8%)	2 (12.5%)	9 (32.1%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.3808: Analysis of RBC Transfusion Dependence Rate at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=11)	RUX (N=12)	p-value
>=4 units transfused in the last 8 weeks	2 (18.2%)	4 (33.3%)	
Any Hgb assessment < 8g/dL in the last 8 weeks	2 (18.2%)	5 (41.7%)	
Last Participation date < Day 162 in DB phase	3 (27.3%)	2 (16.7%)	
Other	2 (18.2%)	2 (16.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.3807: Analysis of RBC Transfusion Dependence Rate at Week 24 by Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Not-Dependent, n(%)	11 (39.3%)	5 (23.8%)	34 (58.6%)	31 (42.5%)	
Transfusion Requiring, n(%)	3 (10.7%)	2 (9.5%)	2 (3.4%)	9 (12.3%)	
Transfusion Independent, n(%)	8 (28.6%)	3 (14.3%)	32 (55.2%)	22 (30.1%)	
Dependent, n(%)	17 (60.7%)	16 (76.2%)	24 (41.4%)	42 (57.5%)	
95% Exact CI	0.4058, 0.7850	0.5283, 0.9178	0.2860, 0.5507	0.4541, 0.6903	
Proportion Difference - Stratified CMH Method (95% CI)	-0.15 (-0.41, 0.12)		-0.17 (-0.35, 0.00)		
p-value	0.28		0.052		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.15 (-0.42, 0.11)		-0.16 (-0.33, 0.01)		
p-value	0.25		0.065		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.15 (-0.42, 0.13)		-0.16 (-0.33, 0.01)		
p-value	0.36		0.080		
Unadjusted Relative Risk (95% CI)	0.80 (0.54, 1.17)		0.72 (0.50, 1.04)		
p-value [1]	0.24		0.076		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.70
Unadjusted Odds Ratio (95% CI)	0.48 (0.14, 1.70)		0.52 (0.26, 1.05)		
p-value [1]	0.26		0.067		
Unadjusted Absolute Risk Difference (95% CI)	-0.15 (-0.41, 0.10)		-0.16 (-0.33, 0.01)		
Adjusted Relative Risk (95% CI) [2]	0.81 (0.56, 1.17)		0.70 (0.49, 1.00)		
p-value [2]	0.25		0.052		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.59

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbctd24-gba.sas V.03.05 Output file: t-rbctd24-gba-hgb.pdf 29AUG2023: 9:36

Table 2.3807: Analysis of RBC Transfusion Dependence Rate at Week 24 by Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
>=4 units transfused in the last 8 weeks	5 (17.9%)	7 (33.3%)	9 (15.5%)	22 (30.1%)	
Any Hgb assessment < 8g/dL in the last 8 weeks	11 (39.3%)	10 (47.6%)	9 (15.5%)	33 (45.2%)	
Last Participation date < Day 162 in DB phase	6 (21.4%)	4 (19.0%)	10 (17.2%)	4 (5.5%)	
Other	9 (32.1%)	6 (28.6%)	2 (3.4%)	20 (27.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.3806: Analysis of RBC Transfusion Dependence Rate at Week 24 by Baseline IPSS Two-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Not-Dependent, n(%)	17 (60.7%)	9 (37.5%)	28 (48.3%)	27 (38.6%)	
Transfusion Requiring, n(%)	3 (10.7%)	1 (4.2%)	2 (3.4%)	10 (14.3%)	
Transfusion Independent, n(%)	14 (50.0%)	8 (33.3%)	26 (44.8%)	17 (24.3%)	
Dependent, n(%)	11 (39.3%)	15 (62.5%)	30 (51.7%)	43 (61.4%)	
95% Exact CI	0.2150, 0.5942	0.4059, 0.8120	0.3822, 0.6505	0.4903, 0.7283	
Proportion Difference - Stratified CMH Method (95% CI)	-0.29 (-0.58, 0.00)		-0.10 (-0.27, 0.08)		
p-value	0.054		0.28		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.23 (-0.50, 0.04)		-0.10 (-0.27, 0.08)		
p-value	0.093		0.27		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.23 (-0.48, 0.05)		-0.10 (-0.27, 0.08)		
p-value	0.16		0.29		
Unadjusted Relative Risk (95% CI)	0.63 (0.36, 1.09)		0.84 (0.62, 1.15)		
p-value [1]	0.10		0.28		
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.36
Unadjusted Odds Ratio (95% CI)	0.39 (0.13, 1.19)		0.67 (0.33, 1.36)		
p-value [1]	0.098		0.27		
Unadjusted Absolute Risk Difference (95% CI)	-0.23 (-0.50, 0.03)		-0.10 (-0.27, 0.07)		
Adjusted Relative Risk (95% CI) [2]	0.56 (0.33, 0.94)		0.84 (0.62, 1.14)		
p-value [2]	0.029		0.26		
Adjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.25

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.3806: Analysis of RBC Transfusion Dependence Rate at Week 24 by Baseline IPSS Two-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
>=4 units transfused in the last 8 weeks	5 (17.9%)	8 (33.3%)	9 (15.5%)	21 (30.0%)	
Any Hgb assessment < 8g/dL in the last 8 weeks	4 (14.3%)	11 (45.8%)	16 (27.6%)	32 (45.7%)	
Last Participation date < Day 162 in DB phase	4 (14.3%)	2 (8.3%)	12 (20.7%)	6 (8.6%)	
Other	3 (10.7%)	7 (29.2%)	8 (13.8%)	19 (27.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.3805: Analysis of RBC Transfusion Dependence Rate at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Not-Dependent, n(%)	2 (100.0%)	2 (50.0%)	15 (57.7%)	7 (35.0%)
Transfusion Requiring, n(%)	0	0	3 (11.5%)	1 (5.0%)
Transfusion Independent, n(%)	2 (100.0%)	2 (50.0%)	12 (46.2%)	6 (30.0%)
Dependent, n(%)	0	2 (50.0%)	11 (42.3%)	13 (65.0%)
95% Exact CI	0.0000, 0.8419	0.0676, 0.9324	0.2335, 0.6308	0.4078, 0.8461
Proportion Difference - Stratified CMH Method (95% CI)	0.00 (-1.03, 1.03)		-0.27 (-0.56, 0.03)	
p-value	1.00		0.077	
Proportion Difference - Unstratified CMH Method (95% CI)	-0.50 (-1.42, 0.42)		-0.23 (-0.52, 0.06)	
p-value	0.29		0.12	
Proportion Difference - Unstratified Exact Method (95% CI)	-0.50 (-0.99, 0.45)		-0.23 (-0.49, 0.07)	
p-value	0.47		0.15	
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbctd24-gba.sas V.03.05 Output file: t-rbctd24-gba-ip3.pdf 29AUG2023: 9:37

Table 2.3805: Analysis of RBC Transfusion Dependence Rate at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N=58)	RUX (N=70)	p-value
Not-Dependent, n(%)	28 (48.3%)	27 (38.6%)	
Transfusion Requiring, n(%)	2 (3.4%)	10 (14.3%)	
Transfusion Independent, n(%)	26 (44.8%)	17 (24.3%)	
Dependent, n(%)	30 (51.7%)	43 (61.4%)	
95% Exact CI	0.3822, 0.6505	0.4903, 0.7283	
Proportion Difference - Stratified CMH Method (95% CI)	-0.10 (-0.27, 0.08)		
p-value	0.28		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.10 (-0.27, 0.08)		
p-value	0.27		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.10 (-0.27, 0.08)		
p-value	0.29		
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.3805: Analysis of RBC Transfusion Dependence Rate at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
>=4 units transfused in the last 8 weeks	0	1 (25.0%)	5 (19.2%)	7 (35.0%)
Any Hgb assessment < 8g/dL in the last 8 weeks	0	2 (50.0%)	4 (15.4%)	9 (45.0%)
Last Participation date < Day 162 in DB phase	0	0	4 (15.4%)	2 (10.0%)
Other	0	0	3 (11.5%)	7 (35.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.3805: Analysis of RBC Transfusion Dependence Rate at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N=58)	RUX (N=70)	p-value
>=4 units transfused in the last 8 weeks	9 (15.5%)	21 (30.0%)	
Any Hgb assessment < 8g/dL in the last 8 weeks	16 (27.6%)	32 (45.7%)	
Last Participation date < Day 162 in DB phase	12 (20.7%)	6 (8.6%)	
Other	8 (13.8%)	19 (27.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.3804: Analysis of RBC Transfusion Dependence Rate at Week 24 by Region
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Not-Dependent, n(%)	25 (47.2%)	21 (41.2%)	20 (60.6%)	15 (34.9%)	
Transfusion Requiring, n(%)	4 (7.5%)	8 (15.7%)	1 (3.0%)	3 (7.0%)	
Transfusion Independent, n(%)	21 (39.6%)	13 (25.5%)	19 (57.6%)	12 (27.9%)	
Dependent, n(%)	28 (52.8%)	30 (58.8%)	13 (39.4%)	28 (65.1%)	
95% Exact CI	0.3864, 0.6670	0.4417, 0.7242	0.2291, 0.5786	0.4907, 0.7899	
Proportion Difference - Stratified CMH Method (95% CI)	-0.11 (-0.31, 0.08)		-0.27 (-0.49, -0.04)		
p-value	0.26		0.019		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.06 (-0.25, 0.13)		-0.26 (-0.48, -0.03)		
p-value	0.54		0.024		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.06 (-0.25, 0.13)		-0.26 (-0.47, -0.03)		
p-value	0.56		0.037		
Unadjusted Relative Risk (95% CI)	0.90 (0.64, 1.27)		0.60 (0.38, 0.97)		
p-value [1]	0.54		0.039		
Unadjusted interaction test for Treatment*Region [3]					0.17
Unadjusted Odds Ratio (95% CI)	0.78 (0.36, 1.70)		0.35 (0.14, 0.89)		
p-value [1]	0.54		0.028		
Unadjusted Absolute Risk Difference (95% CI)	-0.06 (-0.25, 0.13)		-0.26 (-0.48, -0.04)		
Adjusted Relative Risk (95% CI) [2]	0.82 (0.59, 1.14)		0.59 (0.38, 0.93)		
p-value [2]	0.24		0.022		
Adjusted interaction test for Treatment*Region [3]					0.22

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.3804: Analysis of RBC Transfusion Dependence Rate at Week 24 by Region
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
>=4 units transfused in the last 8 weeks	11 (20.8%)	19 (37.3%)	3 (9.1%)	10 (23.3%)	
Any Hgb assessment < 8g/dL in the last 8 weeks	14 (26.4%)	19 (37.3%)	6 (18.2%)	24 (55.8%)	
Last Participation date < Day 162 in DB phase	10 (18.9%)	5 (9.8%)	6 (18.2%)	3 (7.0%)	
Other	5 (9.4%)	9 (17.6%)	6 (18.2%)	17 (39.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.3803: Analysis of RBC Transfusion Dependence Rate at Week 24 by Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Not-Dependent, n(%)	24 (48.0%)	21 (37.5%)	21 (58.3%)	15 (39.5%)	
Transfusion Requiring, n(%)	4 (8.0%)	5 (8.9%)	1 (2.8%)	6 (15.8%)	
Transfusion Independent, n(%)	20 (40.0%)	16 (28.6%)	20 (55.6%)	9 (23.7%)	
Dependent, n(%)	26 (52.0%)	35 (62.5%)	15 (41.7%)	23 (60.5%)	
95% Exact CI	0.3742, 0.6634	0.4855, 0.7508	0.2551, 0.5924	0.4339, 0.7596	
Proportion Difference - Stratified CMH Method (95% CI)	-0.17 (-0.36, 0.03)		-0.14 (-0.38, 0.11)		
p-value	0.094		0.27		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.11 (-0.29, 0.08)		-0.19 (-0.42, 0.04)		
p-value	0.28		0.10		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.11 (-0.29, 0.09)		-0.19 (-0.41, 0.05)		
p-value	0.33		0.16		
Unadjusted Relative Risk (95% CI)	0.83 (0.60, 1.16)		0.69 (0.43, 1.09)		
p-value [1]	0.28		0.11		
Unadjusted interaction test for Treatment*Gender [3]					0.51
Unadjusted Odds Ratio (95% CI)	0.65 (0.30, 1.41)		0.47 (0.18, 1.18)		
p-value [1]	0.28		0.11		
Unadjusted Absolute Risk Difference (95% CI)	-0.11 (-0.29, 0.08)		-0.19 (-0.41, 0.04)		
Adjusted Relative Risk (95% CI) [2]	0.75 (0.54, 1.04)		0.76 (0.48, 1.20)		
p-value [2]	0.084		0.24		
Adjusted interaction test for Treatment*Gender [3]					0.95

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.3803: Analysis of RBC Transfusion Dependence Rate at Week 24 by Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
>=4 units transfused in the last 8 weeks	12 (24.0%)	20 (35.7%)	2 (5.6%)	9 (23.7%)	
Any Hgb assessment < 8g/dL in the last 8 weeks	16 (32.0%)	24 (42.9%)	4 (11.1%)	19 (50.0%)	
Last Participation date < Day 162 in DB phase	6 (12.0%)	6 (10.7%)	10 (27.8%)	2 (5.3%)	
Other	9 (18.0%)	14 (25.0%)	2 (5.6%)	12 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbctd24-gba.sas V.03.05 Output file: t-rbctd24-gba-sex.pdf 29AUG2023: 9:35

Table 2.3810: Analysis of RBC Transfusion Dependence Rate at Week 24 by Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	<Median (1837.09 cm^3)		>=Median (1837.09 cm^3)		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Not-Dependent, n(%)	28 (59.6%)	12 (27.9%)	17 (43.6%)	24 (47.1%)	
Transfusion Requiring, n(%)	2 (4.3%)	4 (9.3%)	3 (7.7%)	7 (13.7%)	
Transfusion Independent, n(%)	26 (55.3%)	8 (18.6%)	14 (35.9%)	17 (33.3%)	
Dependent, n(%)	19 (40.4%)	31 (72.1%)	22 (56.4%)	27 (52.9%)	
95% Exact CI	0.2637, 0.5573	0.5633, 0.8467	0.3962, 0.7219	0.3846, 0.6707	
Proportion Difference - Stratified CMH Method (95% CI)	-0.31 (-0.52, -0.09)		-0.04 (-0.26, 0.18)		
p-value	0.005		0.73		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.32 (-0.51, -0.12)		0.03 (-0.18, 0.24)		
p-value	0.002		0.75		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.32 (-0.50, -0.11)		0.03 (-0.17, 0.24)		
p-value	0.003		0.83		
Unadjusted Relative Risk (95% CI)	0.56 (0.38, 0.83)		1.07 (0.73, 1.56)		
p-value [1]	0.004		0.74		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.021
Unadjusted Odds Ratio (95% CI)	0.26 (0.11, 0.64)		1.15 (0.50, 2.66)		
p-value [1]	0.003		0.74		
Unadjusted Absolute Risk Difference (95% CI)	-0.32 (-0.51, -0.12)		0.03 (-0.17, 0.24)		
Adjusted Relative Risk (95% CI) [2]	0.56 (0.38, 0.84)		0.93 (0.64, 1.35)		
p-value [2]	0.005		0.71		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.059

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.3810: Analysis of RBC Transfusion Dependence Rate at Week 24 by Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	<Median (1837.09 cm^3)		>=Median (1837.09 cm^3)		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
>=4 units transfused in the last 8 weeks	8 (17.0%)	17 (39.5%)	6 (15.4%)	12 (23.5%)	
Any Hgb assessment < 8g/dL in the last 8 weeks	10 (21.3%)	23 (53.5%)	10 (25.6%)	20 (39.2%)	
Last Participation date < Day 162 in DB phase	7 (14.9%)	4 (9.3%)	9 (23.1%)	4 (7.8%)	
Other	5 (10.6%)	14 (32.6%)	6 (15.4%)	12 (23.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.3809: Analysis of RBC Transfusion Dependence Rate at Week 24 by Baseline TSS
Double-Blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Not-Dependent, n(%)	23 (52.3%)	23 (41.8%)	21 (51.2%)	13 (34.2%)	
Transfusion Requiring, n(%)	2 (4.5%)	6 (10.9%)	3 (7.3%)	5 (13.2%)	
Transfusion Independent, n(%)	21 (47.7%)	17 (30.9%)	18 (43.9%)	8 (21.1%)	
Dependent, n(%)	21 (47.7%)	32 (58.2%)	20 (48.8%)	25 (65.8%)	
95% Exact CI	0.3246, 0.6331	0.4411, 0.7135	0.3288, 0.6487	0.4865, 0.8037	
Proportion Difference - Stratified CMH Method (95% CI)	-0.14 (-0.33, 0.06)		-0.18 (-0.40, 0.03)		
p-value	0.17		0.097		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.10 (-0.30, 0.09)		-0.17 (-0.39, 0.05)		
p-value	0.30		0.13		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.10 (-0.30, 0.10)		-0.17 (-0.38, 0.05)		
p-value	0.32		0.17		
Unadjusted Relative Risk (95% CI)	0.82 (0.56, 1.20)		0.74 (0.50, 1.09)		
p-value [1]	0.31		0.13		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.72
Unadjusted Odds Ratio (95% CI)	0.66 (0.30, 1.46)		0.50 (0.20, 1.23)		
p-value [1]	0.30		0.13		
Unadjusted Absolute Risk Difference (95% CI)	-0.10 (-0.30, 0.09)		-0.17 (-0.38, 0.04)		
Adjusted Relative Risk (95% CI) [2]	0.77 (0.54, 1.11)		0.73 (0.50, 1.05)		
p-value [2]	0.16		0.091		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					0.84

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019
Source: t-sg-rbctd24-gba.sas V.03.05 Output file: t-rbctd24-gba-tss.pdf 29AUG2023: 9:36

Table 2.3809: Analysis of RBC Transfusion Dependence Rate at Week 24 by Baseline TSS
Double-Blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
>=4 units transfused in the last 8 weeks	9 (20.5%)	17 (30.9%)	5 (12.2%)	11 (28.9%)	
Any Hgb assessment < 8g/dL in the last 8 weeks	16 (36.4%)	24 (43.6%)	4 (9.8%)	18 (47.4%)	
Last Participation date < Day 162 in DB phase	3 (6.8%)	4 (7.3%)	13 (31.7%)	4 (10.5%)	
Other	8 (18.2%)	14 (25.5%)	3 (7.3%)	12 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 01JUL2019

Table 2.1802: Analysis of Time to First RBC Unit Transfused by Age
Double-blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Subjects with Event					
First RBC Unit Transfused, n(%)	12 (50.0%)	24 (66.7%)	36 (58.1%)	50 (86.2%)	
Censor					
Subjects Censored, n(%)	12 (50.0%)	12 (33.3%)	26 (41.9%)	8 (13.8%)	
Kaplan-Meier Estimate of Time to First RBC Unit Transfused (Weeks)					
25-percentile (95% CI)	2.64 (0.29, 5.86)	4.14 (1.86, 4.71)	2.00 (0.71, 4.29)	1.86 (0.86, 3.00)	
Median (95% CI)	22.71 (3.14, NE)	6.36 (4.71, 14.29)	9.86 (4.29, NE)	4.14 (3.29, 5.14)	
75-percentile (95% CI)	NE (NE, NE)	NE (10.29, NE)	NE (NE, NE)	8.43 (5.14, 16.43)	
Min, Max	0.29, 24.43	0.57, 24.57	0.29, 24.71	0.29, 25.14	
Stratified Log-Rank Test p-value	0.92		< 0.001		
Adjusted Hazard Ratio (95% CI)	0.93 (0.45, 1.93)		0.39 (0.24, 0.62)		
Unstratified Log-Rank Test p-value	0.40		0.004		
Unadjusted Hazard Ratio (95% CI)	0.74 (0.37, 1.49)		0.53 (0.35, 0.82)		
P-value for interaction test					0.074

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-tte-rbc-tran-sub.sas V.03.05 Output file: t-tte-rbc-tran-age.pdf 24AUG2023:11:02

Table 2.1804: Analysis of Time to First RBC Unit Transfused by Region
Double-blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Subjects with Event					
First RBC Unit Transfused, n(%)	35 (66.0%)	42 (82.4%)	13 (39.4%)	32 (74.4%)	
Censor					
Subjects Censored, n(%)	18 (34.0%)	9 (17.6%)	20 (60.6%)	11 (25.6%)	
Kaplan-Meier Estimate of Time to First RBC Unit Transfused (Weeks)					
25-percentile (95% CI)	1.29 (0.43, 2.43)	1.57 (0.86, 2.57)	4.29 (0.29, 11.43)	4.14 (2.00, 4.71)	
Median (95% CI)	6.14 (2.00, 17.29)	4.00 (2.29, 5.14)	NE (8.14, NE)	6.71 (4.43, 9.86)	
75-percentile (95% CI)	NE (17.29, NE)	9.29 (4.86, NE)	NE (NE, NE)	NE (8.43, NE)	
Min, Max	0.29, 24.57	0.29, 24.57	0.29, 24.71	0.29, 25.14	
Stratified Log-Rank Test p-value	0.009		0.023		
Adjusted Hazard Ratio (95% CI)	0.48 (0.30, 0.78)		0.46 (0.24, 0.89)		
Unstratified Log-Rank Test p-value	0.11		0.015		
Unadjusted Hazard Ratio (95% CI)	0.70 (0.44, 1.09)		0.46 (0.24, 0.88)		
P-value for interaction test					0.94

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-tte-rbc-tran-sub.sas V.03.05 Output file: t-tte-rbc-tran-geo.pdf 24AUG2023:11:02

Table 2.1807: Analysis of Time to First RBC Unit Transfused by Baseline Hemoglobin Level
Double-blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Subjects with Event					
First RBC Unit Transfused, n(%)	21 (75.0%)	19 (90.5%)	27 (46.6%)	55 (75.3%)	
Censor					
Subjects Censored, n(%)	7 (25.0%)	2 (9.5%)	31 (53.4%)	18 (24.7%)	
Kaplan-Meier Estimate of Time to First RBC Unit Transfused (Weeks)					
25-percentile (95% CI)	0.93 (0.29, 2.14)	1.29 (0.29, 2.14)	4.29 (1.00, 10.00)	3.29 (1.86, 4.14)	
Median (95% CI)	3.14 (1.43, 5.86)	3.29 (1.29, 4.71)	NE (10.00, NE)	6.14 (4.29, 7.71)	
75-percentile (95% CI)	8.14 (4.29, NE)	6.00 (3.86, NE)	NE (NE, NE)	16.43 (8.43, NE)	
Min, Max	0.29, 24.57	0.29, 24.14	0.29, 24.71	0.29, 25.14	
Stratified Log-Rank Test p-value	0.50		< 0.001		
Adjusted Hazard Ratio (95% CI)	0.84 (0.45, 1.57)		0.45 (0.28, 0.72)		
Unstratified Log-Rank Test p-value	0.50		0.002		
Unadjusted Hazard Ratio (95% CI)	0.80 (0.43, 1.49)		0.49 (0.31, 0.78)		
P-value for interaction test					0.18

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-tte-rbc-tran-sub.sas V.03.05 Output file: t-tte-rbc-tran-hgb.pdf 24AUG2023:11:02

Table 2.1806: Analysis of Time to First RBC Unit Transfused by Baseline IPSS Two-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Subjects with Event					
First RBC Unit Transfused, n(%)	12 (42.9%)	17 (70.8%)	36 (62.1%)	57 (81.4%)	
Censor					
Subjects Censored, n(%)	16 (57.1%)	7 (29.2%)	22 (37.9%)	13 (18.6%)	
Kaplan-Meier Estimate of Time to First RBC Unit Transfused (Weeks)					
25-percentile (95% CI)	2.64 (0.29, 10.14)	3.57 (1.29, 4.57)	2.00 (0.71, 4.29)	2.14 (0.86, 3.29)	
Median (95% CI)	NE (4.29, NE)	6.14 (3.86, 10.29)	9.86 (4.29, 24.14)	4.71 (3.57, 6.14)	
75-percentile (95% CI)	NE (NE, NE)	NE (6.43, NE)	NE (24.14, NE)	14.14 (6.71, NE)	
Min, Max	0.29, 24.43	1.29, 24.57	0.29, 24.71	0.29, 25.14	
Stratified Log-Rank Test p-value	0.074		0.023		
Adjusted Hazard Ratio (95% CI)	0.44 (0.19, 0.98)		0.62 (0.40, 0.94)		
Unstratified Log-Rank Test p-value	0.15		0.045		
Unadjusted Hazard Ratio (95% CI)	0.59 (0.28, 1.24)		0.65 (0.43, 0.99)		
P-value for interaction test					0.48

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-tte-rbc-tran-sub.sas V.03.05 Output file: t-tte-rbc-tran-ipss2.pdf 24AUG2023:11:02

Table 2.1805: Analysis of Time to First RBC Unit Transfused by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Subjects with Event				
First RBC Unit Transfused, n(%)	0	3 (75.0%)	12 (46.2%)	14 (70.0%)
Censor				
Subjects Censored, n(%)	2 (100.0%)	1 (25.0%)	14 (53.8%)	6 (30.0%)
Kaplan-Meier Estimate of Time to First RBC Unit Transfused (Weeks)				
25-percentile (95% CI)	NE (NE, NE)	4.21 (3.86, 4.71)	2.14 (0.29, 8.14)	2.79 (1.29, 6.00)
Median (95% CI)	NE (NE, NE)	4.64 (3.86, NE)	NE (3.14, NE)	6.36 (2.29, NE)
75-percentile (95% CI)	NE (NE, NE)	NE (3.86, NE)	NE (NE, NE)	NE (6.43, NE)
Min, Max	23.71, 24.14	3.86, 24.43	0.29, 24.43	1.29, 24.57
Stratified Log-Rank Test p-value	NA		NA	
Adjusted Hazard Ratio (95% CI)	NA		NA	
Unstratified Log-Rank Test p-value	NA		NA	
Unadjusted Hazard Ratio (95% CI)	NA		NA	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-tte-rbc-tran-sub.sas V.03.05 Output file: t-tte-rbc-tran-ipss3.pdf 24AUG2023:11:02

Table 2.1805: Analysis of Time to First RBC Unit Transfused by Baseline IPSS Three-Level Risk
Double-blind Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=58)	High Risk RUX (N=70)	p-value
Subjects with Event			
First RBC Unit Transfused, n(%)	36 (62.1%)	57 (81.4%)	
Censor			
Subjects Censored, n(%)	22 (37.9%)	13 (18.6%)	
Kaplan-Meier Estimate of Time to First RBC Unit Transfused (Weeks)			
25-percentile (95% CI)	2.00 (0.71, 4.29)	2.14 (0.86, 3.29)	
Median (95% CI)	9.86 (4.29, 24.14)	4.71 (3.57, 6.14)	
75-percentile (95% CI)	NE (24.14, NE)	14.14 (6.71, NE)	
Min, Max	0.29, 24.71	0.29, 25.14	
Stratified Log-Rank Test p-value	NA		
Adjusted Hazard Ratio (95% CI)	NA		
Unstratified Log-Rank Test p-value	NA		
Unadjusted Hazard Ratio (95% CI)	NA		
P-value for interaction test			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-tte-rbc-tran-sub.sas V.03.05 Output file: t-tte-rbc-tran-ipss3.pdf 24AUG2023:11:02

Table 2.1808: Analysis of Time to First RBC Unit Transfused by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

	Post-ET Myelofibrosis		Post-PV Myelofibrosis	
	MMB (N=16)	RUX (N=28)	MMB (N=11)	RUX (N=12)
Subjects with Event				
First RBC Unit Transfused, n(%)	11 (68.8%)	21 (75.0%)	5 (45.5%)	11 (91.7%)
Censor				
Subjects Censored, n(%)	5 (31.3%)	7 (25.0%)	6 (54.5%)	1 (8.3%)
Kaplan-Meier Estimate of Time to First RBC Unit Transfused (Weeks)				
25-percentile (95% CI)	0.86 (0.29, 5.29)	2.00 (0.29, 4.14)	0.71 (0.29, NE)	0.64 (0.29, 3.57)
Median (95% CI)	6.50 (0.71, NE)	4.79 (2.14, 9.29)	NE (0.29, NE)	3.79 (0.43, 6.71)
75-percentile (95% CI)	NE (5.29, NE)	NE (6.00, NE)	NE (2.43, NE)	6.43 (3.57, NE)
Min, Max	0.29, 24.71	0.29, 24.71	0.29, 24.57	0.29, 24.57
Stratified Log-Rank Test p-value	0.80		0.19	
Adjusted Hazard Ratio (95% CI)	1.04 (0.46, 2.38)		0.39 (0.12, 1.30)	
Unstratified Log-Rank Test p-value	0.76		0.11	
Unadjusted Hazard Ratio (95% CI)	0.89 (0.43, 1.86)		0.44 (0.15, 1.28)	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-tte-rbc-tran-sub.sas V.03.05 Output file: t-tte-rbc-tran-mf.pdf 24AUG2023:11:02

Table 2.1808: Analysis of Time to First RBC Unit Transfused by Baseline MF Disease Status
Double-blind Phase
ITT-Anemic Analysis Set

(Continued)	Primary Myelofibrosis MMB (N=59)	Primary Myelofibrosis RUX (N=54)	p-value
Subjects with Event			
First RBC Unit Transfused, n(%)	32 (54.2%)	42 (77.8%)	
Censor			
Subjects Censored, n(%)	27 (45.8%)	12 (22.2%)	
Kaplan-Meier Estimate of Time to First RBC Unit Transfused (Weeks)			
25-percentile (95% CI)	2.14 (1.14, 4.29)	3.29 (1.86, 4.14)	
Median (95% CI)	11.43 (4.29, NE)	5.14 (4.14, 6.71)	
75-percentile (95% CI)	NE (NE, NE)	14.14 (6.71, NE)	
Min, Max	0.29, 24.43	0.29, 25.14	
Stratified Log-Rank Test p-value	0.042		
Adjusted Hazard Ratio (95% CI)	0.54 (0.34, 0.88)		
Unstratified Log-Rank Test p-value	0.034		
Unadjusted Hazard Ratio (95% CI)	0.61 (0.38, 0.97)		
P-value for interaction test			0.16

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-tte-rbc-tran-sub.sas V.03.05 Output file: t-tte-rbc-tran-mf.pdf 24AUG2023:11:02

Table 2.1803: Analysis of Time to First RBC Unit Transfused by Gender
Double-blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Subjects with Event					
First RBC Unit Transfused, n(%)	35 (70.0%)	47 (83.9%)	13 (36.1%)	27 (71.1%)	
Censor					
Subjects Censored, n(%)	15 (30.0%)	9 (16.1%)	23 (63.9%)	11 (28.9%)	
Kaplan-Meier Estimate of Time to First RBC Unit Transfused (Weeks)					
25-percentile (95% CI)	1.14 (0.43, 2.14)	2.14 (1.14, 3.29)	4.29 (1.29, NE)	3.57 (0.86, 4.29)	
Median (95% CI)	6.00 (2.00, 12.00)	4.64 (3.29, 6.00)	NE (9.86, NE)	6.29 (4.14, 10.29)	
75-percentile (95% CI)	NE (11.43, NE)	9.14 (6.14, NE)	NE (NE, NE)	NE (8.43, NE)	
Min, Max	0.29, 24.71	0.29, 25.14	0.29, 24.29	0.29, 24.71	
Stratified Log-Rank Test p-value	0.025		0.073		
Adjusted Hazard Ratio (95% CI)	0.57 (0.36, 0.90)		0.49 (0.25, 0.96)		
Unstratified Log-Rank Test p-value	0.19		0.013		
Unadjusted Hazard Ratio (95% CI)	0.75 (0.48, 1.16)		0.44 (0.23, 0.86)		
P-value for interaction test					0.69

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-tte-rbc-tran-sub.sas V.03.05 Output file: t-tte-rbc-tran-sex.pdf 24AUG2023:11:02

Table 2.1810: Analysis of Time to First RBC Unit Transfused by Baseline Spleen Volume
Double-blind Phase
ITT-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Subjects with Event					
First RBC Unit Transfused, n(%)	23 (48.9%)	34 (79.1%)	25 (64.1%)	40 (78.4%)	
Censor					
Subjects Censored, n(%)	24 (51.1%)	9 (20.9%)	14 (35.9%)	11 (21.6%)	
Kaplan-Meier Estimate of Time to First RBC Unit Transfused (Weeks)					
25-percentile (95% CI)	2.00 (0.71, 6.14)	2.57 (1.14, 3.57)	1.14 (0.43, 4.29)	2.29 (0.86, 4.43)	
Median (95% CI)	24.14 (5.86, NE)	4.14 (3.29, 6.14)	7.71 (2.43, 12.29)	5.14 (4.14, 9.86)	
75-percentile (95% CI)	NE (NE, NE)	8.43 (6.14, NE)	NE (11.43, NE)	15.86 (8.14, NE)	
Min, Max	0.29, 24.71	0.29, 25.14	0.29, 24.57	0.29, 24.57	
Stratified Log-Rank Test p-value	0.001		0.27		
Adjusted Hazard Ratio (95% CI)	0.33 (0.18, 0.61)		0.77 (0.46, 1.30)		
Unstratified Log-Rank Test p-value	0.009		0.45		
Unadjusted Hazard Ratio (95% CI)	0.50 (0.29, 0.85)		0.83 (0.50, 1.37)		
P-value for interaction test					0.076

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-tte-rbc-tran-sub.sas V.03.05 Output file: t-tte-rbc-tran-svb.pdf 24AUG2023:11:02

Table 2.1809: Analysis of Time to First RBC Unit Transfused by Baseline TSS
Double-blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Subjects with Event					
First RBC Unit Transfused, n(%)	25 (56.8%)	43 (78.2%)	22 (53.7%)	30 (78.9%)	
Censor					
Subjects Censored, n(%)	19 (43.2%)	12 (21.8%)	19 (46.3%)	8 (21.1%)	
Kaplan-Meier Estimate of Time to First RBC Unit Transfused (Weeks)					
25-percentile (95% CI)	2.14 (0.43, 6.14)	2.71 (1.57, 4.00)	1.29 (0.43, 4.29)	2.14 (0.71, 4.00)	
Median (95% CI)	11.43 (5.29, NE)	4.71 (4.00, 6.43)	7.71 (3.14, NE)	4.86 (3.29, 9.29)	
75-percentile (95% CI)	NE (24.14, NE)	14.29 (6.43, NE)	NE (NE, NE)	14.29 (6.71, NE)	
Min, Max	0.29, 24.43	0.29, 25.14	0.29, 24.71	0.43, 24.71	
Stratified Log-Rank Test p-value	0.015		0.10		
Adjusted Hazard Ratio (95% CI)	0.54 (0.33, 0.89)		0.58 (0.33, 1.02)		
Unstratified Log-Rank Test p-value	0.049		0.12		
Unadjusted Hazard Ratio (95% CI)	0.61 (0.37, 1.00)		0.65 (0.38, 1.14)		
P-value for interaction test					0.77

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline platelet count (<100,100-200,>200 10^9/L). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline platelet count (<100,100-200,>200 10^9/L) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-tte-rbc-tran-sub.sas V.03.05 Output file: t-tte-rbc-tran-tss.pdf 24AUG2023:11:02

Table 2.6502: Analysis of Patient Global Impression of Change at Week 24 by Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	RUX (N = 36)	MMB (N = 62)	RUX (N = 58)	p-value
Week 24 at Double-Blind Phase, n(%)					
Improvement, n(%)	15 (62.5%)	28 (77.8%)	40 (64.5%)	42 (72.4%)	
Very much improved	0	3 (8.3%)	6 (9.7%)	3 (5.2%)	
Much improved	12 (50.0%)	14 (38.9%)	23 (37.1%)	26 (44.8%)	
Minimally improved	3 (12.5%)	11 (30.6%)	11 (17.7%)	13 (22.4%)	
95% Exact CI	0.4059, 0.8120	0.6085, 0.8988	0.5134, 0.7626	0.5910, 0.8334	
Proportion Difference - Stratified CMH Method (95% CI)	-0.21 (-0.48, 0.07)		-0.10 (-0.28, 0.08)		
p-value	0.14		0.27		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.15 (-0.40, 0.09)		-0.08 (-0.25, 0.09)		
p-value	0.22		0.36		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.15 (-0.40, 0.11)		-0.08 (-0.25, 0.10)		
p-value	0.25		0.43		
Unadjusted Inverse Relative Risk (95% CI)	1.24 (0.87, 1.78)		1.12 (0.88, 1.43)		
p-value [1]	0.23		0.35		
Unadjusted interaction test for Treatment*Age Group [3]					0.64
Unadjusted Inverse Odds Ratio (95% CI)	2.10 (0.67, 6.57)		1.44 (0.66, 3.14)		
p-value [1]	0.20		0.35		
Unadjusted Absolute Risk Difference (95% CI)	-0.15 (-0.39, 0.08)		-0.08 (-0.24, 0.09)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.34 (0.92, 1.95)		1.16 (0.90, 1.48)		
p-value [2]	0.12		0.24		
Adjusted interaction test for Treatment*Age Group [3]					0.64

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.6502: Analysis of Patient Global Impression of Change at Week 24 by Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	RUX (N = 36)	MMB (N = 62)	RUX (N = 58)	p-value
Worsening, n(%)	3 (12.5%)	1 (2.8%)	2 (3.2%)	4 (6.9%)	
Minimally worse	1 (4.2%)	1 (2.8%)	2 (3.2%)	2 (3.4%)	
Much worse	2 (8.3%)	0	0	2 (3.4%)	
Very much worse	0	0	0	0	
95% Exact CI	0.0266, 0.3236	0.0007, 0.1453	0.0039, 0.1117	0.0191, 0.1673	
Proportion Difference - Stratified CMH Method (95% CI)	0.09 (-0.14, 0.31)		-0.02 (-0.13, 0.09)		
p-value	0.45		0.68		
Proportion Difference - Unstratified CMH Method (95% CI)	0.10 (-0.06, 0.25)		-0.04 (-0.12, 0.05)		
p-value	0.22		0.39		
Proportion Difference - Unstratified Exact Method (95% CI)	0.10 (-0.17, 0.35)		-0.04 (-0.22, 0.14)		
p-value	0.29		0.43		
Unadjusted Relative Risk (95% CI)	4.50 (0.50, 40.75)		0.47 (0.09, 2.46)		
p-value [1]	0.18		0.37		
Unadjusted interaction test for Treatment*Age Group [3]					NA
Unadjusted Odds Ratio (95% CI)	5.00 (0.49, 51.23)		0.45 (0.08, 2.56)		
p-value [1]	0.18		0.37		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.05, 0.24)		-0.04 (-0.12, 0.04)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Age Group [3]					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.6502: Analysis of Patient Global Impression of Change at Week 24 by Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	RUX (N = 36)	MMB (N = 62)	RUX (N = 58)	p-value
Missing Assessment	4 (16.7%)	5 (13.9%)	17 (27.4%)	9 (15.5%)	
No change	2 (8.3%)	2 (5.6%)	3 (4.8%)	3 (5.2%)	
Return Rate (%)	83%	86%	73%	84%	
Number of Subjects in Risk	20	33	50	53	
Return Rate in Risk (%)	100%	94%	90%	92%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-chg-pgic.sas V.03.05 Output file: t-subgrp-chg-pgic-db-gba-age.pdf 29AUG2023: 9:47

Table 2.6504: Analysis of Patient Global Impression of Change at Week 24 by Region
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N = 53)	RUX (N = 51)	MMB (N = 33)	RUX (N = 43)	p-value
Week 24 at Double-Blind Phase, n(%)					
Improvement, n(%)	31 (58.5%)	34 (66.7%)	24 (72.7%)	36 (83.7%)	
Very much improved	5 (9.4%)	4 (7.8%)	1 (3.0%)	2 (4.7%)	
Much improved	19 (35.8%)	19 (37.3%)	16 (48.5%)	21 (48.8%)	
Minimally improved	7 (13.2%)	11 (21.6%)	7 (21.2%)	13 (30.2%)	
95% Exact CI	0.4413, 0.7186	0.5208, 0.7924	0.5448, 0.8670	0.6930, 0.9319	
Proportion Difference - Stratified CMH Method (95% CI)	-0.08 (-0.28, 0.12)		-0.14 (-0.34, 0.07)		
p-value	0.44		0.19		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.08 (-0.27, 0.11)		-0.11 (-0.30, 0.08)		
p-value	0.39		0.26		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.08 (-0.27, 0.11)		-0.11 (-0.33, 0.12)		
p-value	0.42		0.27		
Unadjusted Inverse Relative Risk (95% CI)	1.14 (0.85, 1.54)		1.15 (0.90, 1.47)		
p-value [1]	0.39		0.26		
Unadjusted interaction test for Treatment*Region [3]					0.96
Unadjusted Inverse Odds Ratio (95% CI)	1.42 (0.64, 3.15)		1.93 (0.63, 5.88)		
p-value [1]	0.39		0.25		
Unadjusted Absolute Risk Difference (95% CI)	-0.08 (-0.27, 0.10)		-0.11 (-0.30, 0.08)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.14 (0.84, 1.54)		NE		
p-value [2]	0.41		NE		
Adjusted interaction test for Treatment*Region [3]					0.95

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-chg-pgic.sas V.03.05 Output file: t-subgrp-chg-pgic-db-gba-geo.pdf 29AUG2023: 9:47

Table 2.6504: Analysis of Patient Global Impression of Change at Week 24 by Region
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N = 53)	RUX (N = 51)	MMB (N = 33)	RUX (N = 43)	p-value
Worsening, n(%)	5 (9.4%)	4 (7.8%)	0	1 (2.3%)	
Minimally worse	3 (5.7%)	2 (3.9%)	0	1 (2.3%)	
Much worse	2 (3.8%)	2 (3.9%)	0	0	
Very much worse	0	0	0	0	
95% Exact CI	0.0313, 0.2066	0.0218, 0.1888	0.0000, 0.1058	0.0006, 0.1229	
Proportion Difference - Stratified CMH Method (95% CI)	0.02 (-0.12, 0.16)		-0.02 (-0.15, 0.10)		
p-value	0.81		0.72		
Proportion Difference - Unstratified CMH Method (95% CI)	0.02 (-0.10, 0.13)		-0.02 (-0.09, 0.05)		
p-value	0.78		0.51		
Proportion Difference - Unstratified Exact Method (95% CI)	0.02 (-0.18, 0.20)		-0.02 (-0.25, 0.20)		
p-value	1.00		1.00		
Unadjusted Relative Risk (95% CI)	1.20 (0.34, 4.23)		0.43 (0.02, 10.26)		
p-value [1]	0.77		0.60		
Unadjusted interaction test for Treatment*Region [3]					NA
Unadjusted Odds Ratio (95% CI)	1.22 (0.31, 4.84)		0.42 (0.02, 10.72)		
p-value [1]	0.77		0.60		
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.09, 0.12)		-0.02 (-0.09, 0.05)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Region [3]					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-chg-pgic.sas V.03.05 Output file: t-subgrp-chg-pgic-db-gba-geo.pdf 29AUG2023: 9:47

Table 2.6504: Analysis of Patient Global Impression of Change at Week 24 by Region
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N = 53)	RUX (N = 51)	MMB (N = 33)	RUX (N = 43)	p-value
Missing Assessment	15 (28.3%)	11 (21.6%)	6 (18.2%)	3 (7.0%)	
No change	2 (3.8%)	2 (3.9%)	3 (9.1%)	3 (7.0%)	
Return Rate (%)	72%	78%	82%	93%	
Number of Subjects in Risk	43	46	27	40	
Return Rate in Risk (%)	88%	87%	100%	100%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-chg-pgic.sas V.03.05 Output file: t-subgrp-chg-pgic-db-gba-geo.pdf 29AUG2023: 9:47

Table 2.6507: Analysis of Patient Global Impression of Change at Week 24 by Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 28)	RUX (N = 21)	MMB (N = 58)	RUX (N = 73)	p-value
Week 24 at Double-Blind Phase, n(%)					
Improvement, n(%)	18 (64.3%)	15 (71.4%)	37 (63.8%)	55 (75.3%)	
Very much improved	5 (17.9%)	1 (4.8%)	1 (1.7%)	5 (6.8%)	
Much improved	8 (28.6%)	8 (38.1%)	27 (46.6%)	32 (43.8%)	
Minimally improved	5 (17.9%)	6 (28.6%)	9 (15.5%)	18 (24.7%)	
95% Exact CI	0.4407, 0.8136	0.4782, 0.8872	0.5012, 0.7601	0.6386, 0.8468	
Proportion Difference - Stratified CMH Method (95% CI)	-0.07 (-0.34, 0.20)		-0.14 (-0.30, 0.03)		
p-value	0.62		0.11		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.07 (-0.34, 0.20)		-0.12 (-0.28, 0.04)		
p-value	0.60		0.16		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.07 (-0.35, 0.21)		-0.12 (-0.28, 0.06)		
p-value	0.76		0.18		
Unadjusted Inverse Relative Risk (95% CI)	1.11 (0.75, 1.64)		1.18 (0.93, 1.49)		
p-value [1]	0.59		0.16		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.79
Unadjusted Inverse Odds Ratio (95% CI)	1.39 (0.41, 4.72)		1.73 (0.82, 3.69)		
p-value [1]	0.60		0.15		
Unadjusted Absolute Risk Difference (95% CI)	-0.07 (-0.33, 0.19)		-0.12 (-0.27, 0.04)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.11 (0.76, 1.63)		1.22 (0.96, 1.53)		
p-value [2]	0.60		0.099		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-chg-pgic.sas V.03.05 Output file: t-subgrp-chg-pgic-db-gba-hgb.pdf 29AUG2023: 9:47

Table 2.6507: Analysis of Patient Global Impression of Change at Week 24 by Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 28)	RUX (N = 21)	MMB (N = 58)	RUX (N = 73)	p-value
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.68

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.6507: Analysis of Patient Global Impression of Change at Week 24 by Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 28)	RUX (N = 21)	MMB (N = 58)	RUX (N = 73)	p-value
Worsening, n(%)	2 (7.1%)	1 (4.8%)	3 (5.2%)	4 (5.5%)	
Minimally worse	1 (3.6%)	0	2 (3.4%)	3 (4.1%)	
Much worse	1 (3.6%)	1 (4.8%)	1 (1.7%)	1 (1.4%)	
Very much worse	0	0	0	0	
95% Exact CI	0.0088, 0.2350	0.0012, 0.2382	0.0108, 0.1438	0.0151, 0.1344	
Proportion Difference - Stratified CMH Method (95% CI)	0.02 (-0.16, 0.20)		0.00 (-0.10, 0.10)		
p-value	0.83		0.99		
Proportion Difference - Unstratified CMH Method (95% CI)	0.02 (-0.13, 0.18)		0.00 (-0.09, 0.08)		
p-value	0.76		0.94		
Proportion Difference - Unstratified Exact Method (95% CI)	0.02 (-0.26, 0.30)		0.00 (-0.17, 0.17)		
p-value	1.00		1.00		
Unadjusted Relative Risk (95% CI)	1.50 (0.15, 15.46)		0.94 (0.22, 4.05)		
p-value [1]	0.73		0.94		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Unadjusted Odds Ratio (95% CI)	1.54 (0.13, 18.19)		0.94 (0.20, 4.38)		
p-value [1]	0.73		0.94		
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.11, 0.16)		0.00 (-0.08, 0.07)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-chg-pgic.sas V.03.05 Output file: t-subgrp-chg-pgic-db-gba-hgb.pdf 29AUG2023: 9:47

Table 2.6507: Analysis of Patient Global Impression of Change at Week 24 by Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 28)	RUX (N = 21)	MMB (N = 58)	RUX (N = 73)	p-value
Missing Assessment	7 (25.0%)	5 (23.8%)	14 (24.1%)	9 (12.3%)	
No change	1 (3.6%)	0	4 (6.9%)	5 (6.8%)	
Return Rate (%)	75%	76%	76%	88%	
Number of Subjects in Risk	22	17	48	69	
Return Rate in Risk (%)	95%	94%	92%	93%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-chg-pgic.sas V.03.05 Output file: t-subgrp-chg-pgic-db-gba-hgb.pdf 29AUG2023: 9:47

Table 2.6506: Analysis of Patient Global Impression of Change at Week 24 by Baseline IPSS Two-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 28)	RUX (N = 24)	MMB (N = 58)	RUX (N = 70)	p-value
Week 24 at Double-Blind Phase, n(%)					
Improvement, n(%)	18 (64.3%)	18 (75.0%)	37 (63.8%)	52 (74.3%)	
Very much improved	1 (3.6%)	2 (8.3%)	5 (8.6%)	4 (5.7%)	
Much improved	12 (42.9%)	10 (41.7%)	23 (39.7%)	30 (42.9%)	
Minimally improved	5 (17.9%)	6 (25.0%)	9 (15.5%)	18 (25.7%)	
95% Exact CI	0.4407, 0.8136	0.5329, 0.9023	0.5012, 0.7601	0.6244, 0.8399	
Proportion Difference - Stratified CMH Method (95% CI)	-0.12 (-0.42, 0.17)		-0.13 (-0.30, 0.03)		
p-value	0.41		0.12		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.11 (-0.36, 0.15)		-0.10 (-0.27, 0.06)		
p-value	0.41		0.21		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.11 (-0.37, 0.17)		-0.10 (-0.27, 0.07)		
p-value	0.55		0.25		
Unadjusted Inverse Relative Risk (95% CI)	1.17 (0.81, 1.67)		1.16 (0.92, 1.48)		
p-value [1]	0.40		0.21		
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.99
Unadjusted Inverse Odds Ratio (95% CI)	1.67 (0.50, 5.56)		1.64 (0.77, 3.50)		
p-value [1]	0.41		0.20		
Unadjusted Absolute Risk Difference (95% CI)	-0.11 (-0.36, 0.14)		-0.10 (-0.27, 0.06)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.20 (0.83, 1.73)		1.21 (0.96, 1.54)		
p-value [2]	0.34		0.11		
Adjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.96

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-chg-pgic.sas V.03.05 Output file: t-subgrp-chg-pgic-db-gba-ip2.pdf 29AUG2023: 9:47

Table 2.6506: Analysis of Patient Global Impression of Change at Week 24 by Baseline IPSS Two-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 28)	RUX (N = 24)	MMB (N = 58)	RUX (N = 70)	p-value
Worsening, n(%)	2 (7.1%)	2 (8.3%)	3 (5.2%)	3 (4.3%)	
Minimally worse	1 (3.6%)	1 (4.2%)	2 (3.4%)	2 (2.9%)	
Much worse	1 (3.6%)	1 (4.2%)	1 (1.7%)	1 (1.4%)	
Very much worse	0	0	0	0	
95% Exact CI	0.0088, 0.2350	0.0103, 0.2700	0.0108, 0.1438	0.0089, 0.1202	
Proportion Difference - Stratified CMH Method (95% CI)	-0.04 (-0.28, 0.20)		0.02 (-0.08, 0.12)		
p-value	0.76		0.75		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.01 (-0.17, 0.15)		0.01 (-0.07, 0.09)		
p-value	0.89		0.83		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.01 (-0.28, 0.26)		0.01 (-0.16, 0.18)		
p-value	1.00		1.00		
Unadjusted Relative Risk (95% CI)	0.86 (0.13, 5.63)		1.21 (0.25, 5.76)		
p-value [1]	0.87		0.81		
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [3]					NA
Unadjusted Odds Ratio (95% CI)	0.85 (0.11, 6.51)		1.22 (0.24, 6.28)		
p-value [1]	0.87		0.81		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.16, 0.13)		0.01 (-0.07, 0.08)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*IPSS 2-Level Risk [3]					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.6506: Analysis of Patient Global Impression of Change at Week 24 by Baseline IPSS Two-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 28)	RUX (N = 24)	MMB (N = 58)	RUX (N = 70)	p-value
Missing Assessment	6 (21.4%)	2 (8.3%)	15 (25.9%)	12 (17.1%)	
No change	2 (7.1%)	2 (8.3%)	3 (5.2%)	3 (4.3%)	
Return Rate (%)	79%	92%	74%	83%	
Number of Subjects in Risk	24	22	46	64	
Return Rate in Risk (%)	92%	100%	93%	91%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-chg-pgic.sas V.03.05 Output file: t-subgrp-chg-pgic-db-gba-ip2.pdf 29AUG2023: 9:47

Table 2.6505: Analysis of Patient Global Impression of Change at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 2)	RUX (N = 4)	MMB (N = 26)	RUX (N = 20)
Week 24 at Double-Blind Phase, n(%)				
Improvement, n(%)	2 (100.0%)	3 (75.0%)	16 (61.5%)	15 (75.0%)
Very much improved	0	0	1 (3.8%)	2 (10.0%)
Much improved	2 (100.0%)	2 (50.0%)	10 (38.5%)	8 (40.0%)
Minimally improved	0	1 (25.0%)	5 (19.2%)	5 (25.0%)
95% Exact CI	0.1581, 1.0000	0.1941, 0.9937	0.4057, 0.7977	0.5090, 0.9134
Proportion Difference - Stratified CMH Method (95% CI)	0.00 (-1.03, 1.03)		-0.20 (-0.49, 0.09)	
p-value	1.00		0.18	
Proportion Difference - Unstratified CMH Method (95% CI)	0.25 (-0.65, 1.15)		-0.13 (-0.41, 0.14)	
p-value	0.58		0.34	
Proportion Difference - Unstratified Exact Method (95% CI)	0.25 (-0.64, 0.89)		-0.13 (-0.41, 0.16)	
p-value	1.00		0.36	
Unadjusted Inverse Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-chg-pgic.sas V.03.05 Output file: t-subgrp-chg-pgic-db-gba-ip3.pdf 29AUG2023: 9:48

Table 2.6505: Analysis of Patient Global Impression of Change at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 58)	RUX (N = 70)	p-value
Week 24 at Double-Blind Phase, n(%)			
Improvement, n(%)	37 (63.8%)	52 (74.3%)	
Very much improved	5 (8.6%)	4 (5.7%)	
Much improved	23 (39.7%)	30 (42.9%)	
Minimally improved	9 (15.5%)	18 (25.7%)	
95% Exact CI	0.5012, 0.7601	0.6244, 0.8399	
Proportion Difference - Stratified CMH Method (95% CI)	-0.13 (-0.30, 0.03)		
p-value	0.12		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.10 (-0.27, 0.06)		
p-value	0.21		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.10 (-0.27, 0.07)		
p-value	0.25		
Unadjusted Inverse Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-chg-pgic.sas V.03.05 Output file: t-subgrp-chg-pgic-db-gba-ip3.pdf 29AUG2023: 9:48

Table 2.6505: Analysis of Patient Global Impression of Change at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 2)	RUX (N = 4)	MMB (N = 26)	RUX (N = 20)
Worsening, n(%)	0	1 (25.0%)	2 (7.7%)	1 (5.0%)
Minimally worse	0	0	1 (3.8%)	1 (5.0%)
Much worse	0	1 (25.0%)	1 (3.8%)	0
Very much worse	0	0	0	0
95% Exact CI	0.0000, 0.8419	0.0063, 0.8059	0.0095, 0.2513	0.0013, 0.2487
Proportion Difference - Stratified CMH Method (95% CI)	0.00 (-1.03, 1.03)		0.00 (-0.23, 0.23)	
p-value	1.00		1.00	
Proportion Difference - Unstratified CMH Method (95% CI)	-0.25 (-1.15, 0.65)		0.03 (-0.14, 0.19)	
p-value	0.58		0.74	
Proportion Difference - Unstratified Exact Method (95% CI)	-0.25 (-0.89, 0.64)		0.03 (-0.26, 0.31)	
p-value	1.00		1.00	
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.6505: Analysis of Patient Global Impression of Change at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 58)	RUX (N = 70)	p-value
Worsening, n(%)	3 (5.2%)	3 (4.3%)	
Minimally worse	2 (3.4%)	2 (2.9%)	
Much worse	1 (1.7%)	1 (1.4%)	
Very much worse	0	0	
95% Exact CI	0.0108, 0.1438	0.0089, 0.1202	
Proportion Difference - Stratified CMH Method (95% CI)	0.02 (-0.08, 0.12)		
p-value	0.75		
Proportion Difference - Unstratified CMH Method (95% CI)	0.01 (-0.07, 0.09)		
p-value	0.83		
Proportion Difference - Unstratified Exact Method (95% CI)	0.01 (-0.16, 0.18)		
p-value	1.00		
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.6505: Analysis of Patient Global Impression of Change at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 2)	RUX (N = 4)	MMB (N = 26)	RUX (N = 20)
Missing Assessment	0	0	6 (23.1%)	2 (10.0%)
No change	0	0	2 (7.7%)	2 (10.0%)
Return Rate (%)	100%	100%	77%	90%
Number of Subjects in Risk	2	4	22	18
Return Rate in Risk (%)	100%	100%	91%	100%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.6505: Analysis of Patient Global Impression of Change at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 58)	RUX (N = 70)	p-value
Missing Assessment	15 (25.9%)	12 (17.1%)	
No change	3 (5.2%)	3 (4.3%)	
Return Rate (%)	74%	83%	
Number of Subjects in Risk	46	64	
Return Rate in Risk (%)	93%	91%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
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Table 2.6508: Analysis of Patient Global Impression of Change at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-OL Myelofibrosis	
	MMB (N = 59)	RUX (N = 54)	MMB (N = 16)	RUX (N = 28)
Week 24 at Double-Blind Phase, n(%)				
Improvement, n(%)	41 (69.5%)	43 (79.6%)	8 (50.0%)	20 (71.4%)
Very much improved	4 (6.8%)	3 (5.6%)	1 (6.3%)	2 (7.1%)
Much improved	26 (44.1%)	27 (50.0%)	5 (31.3%)	9 (32.1%)
Minimally improved	11 (18.6%)	13 (24.1%)	2 (12.5%)	9 (32.1%)
95% Exact CI	0.5613, 0.8081	0.6647, 0.8937	0.2465, 0.7535	0.5133, 0.8678
Proportion Difference - Stratified CMH Method (95% CI)	-0.14 (-0.30, 0.03)		-0.22 (-0.55, 0.11)	
p-value	0.10		0.19	
Proportion Difference - Unstratified CMH Method (95% CI)	-0.10 (-0.26, 0.06)		-0.21 (-0.52, 0.09)	
p-value	0.22		0.17	
Proportion Difference - Unstratified Exact Method (95% CI)	-0.10 (-0.28, 0.08)		-0.21 (-0.50, 0.10)	
p-value	0.28		0.20	
Unadjusted Inverse Relative Risk (95% CI)	1.15 (0.92, 1.42)		1.43 (0.83, 2.46)	
p-value [1]	0.22		0.20	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	1.72 (0.72, 4.07)		2.50 (0.70, 8.97)	
p-value [1]	0.22		0.16	
Unadjusted Absolute Risk Difference (95% CI)	-0.10 (-0.26, 0.06)		-0.21 (-0.51, 0.08)	
Adjusted Inverse Relative Risk (95% CI) [2]	1.20 (0.97, 1.49)		1.44 (0.82, 2.54)	
p-value [2]	0.089		0.20	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 01JUL2019
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Table 2.6508: Analysis of Patient Global Impression of Change at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 11)	RUX (N = 12)	p-value
Week 24 at Double-Blind Phase, n(%)			
Improvement, n(%)	6 (54.5%)	7 (58.3%)	
Very much improved	1 (9.1%)	1 (8.3%)	
Much improved	4 (36.4%)	4 (33.3%)	
Minimally improved	1 (9.1%)	2 (16.7%)	
95% Exact CI	0.2338, 0.8325	0.2767, 0.8483	
Proportion Difference - Stratified CMH Method (95% CI)	-0.23 (-0.69, 0.23)		
p-value	0.33		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.04 (-0.46, 0.39)		
p-value	0.86		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.04 (-0.44, 0.38)		
p-value	1.00		
Unadjusted Inverse Relative Risk (95% CI)	1.07 (0.52, 2.20)		
p-value [1]	0.86		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.72
Unadjusted Inverse Odds Ratio (95% CI)	1.17 (0.22, 6.08)		
p-value [1]	0.85		
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.44, 0.37)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.83

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 01JUL2019
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Table 2.6508: Analysis of Patient Global Impression of Change at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-OL Myelofibrosis	
	MMB (N = 59)	RUX (N = 54)	MMB (N = 16)	RUX (N = 28)
Worsening, n(%)	2 (3.4%)	2 (3.7%)	3 (18.8%)	3 (10.7%)
Minimally worse	1 (1.7%)	1 (1.9%)	2 (12.5%)	2 (7.1%)
Much worse	1 (1.7%)	1 (1.9%)	1 (6.3%)	1 (3.6%)
Very much worse	0	0	0	0
95% Exact CI	0.0041, 0.1171	0.0045, 0.1275	0.0405, 0.4565	0.0227, 0.2823
Proportion Difference - Stratified CMH Method (95% CI)	0.01 (-0.09, 0.11)		0.04 (-0.22, 0.30)	
p-value	0.85		0.78	
Proportion Difference - Unstratified CMH Method (95% CI)	0.00 (-0.08, 0.07)		0.08 (-0.16, 0.32)	
p-value	0.94		0.51	
Proportion Difference - Unstratified Exact Method (95% CI)	0.00 (-0.19, 0.18)		0.08 (-0.23, 0.38)	
p-value	1.00		0.65	
Unadjusted Relative Risk (95% CI)	0.92 (0.13, 6.27)		1.75 (0.40, 7.67)	
p-value [1]	0.93		0.46	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Odds Ratio (95% CI)	0.91 (0.12, 6.71)		1.92 (0.34, 10.90)	
p-value [1]	0.93		0.46	
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.07, 0.07)		0.08 (-0.14, 0.30)	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 01JUL2019
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Table 2.6508: Analysis of Patient Global Impression of Change at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 11)	RUX (N = 12)	p-value
Worsening, n(%)	0	0	
Minimally worse	0	0	
Much worse	0	0	
Very much worse	0	0	
95% Exact CI	0.0000, 0.2849	0.0000, 0.2646	
Proportion Difference - Stratified CMH Method (95% CI)	0.00 (-0.37, 0.37)		
p-value	1.00		
Proportion Difference - Unstratified CMH Method (95% CI)	0.00 (-0.17, 0.17)		
p-value	1.00		
Proportion Difference - Unstratified Exact Method (95% CI)	NA		
p-value	NA		
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 01JUL2019
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Table 2.6508: Analysis of Patient Global Impression of Change at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-OL Myelofibrosis	
	MMB (N = 59)	RUX (N = 54)	MMB (N = 16)	RUX (N = 28)
Missing Assessment	14 (23.7%)	5 (9.3%)	3 (18.8%)	5 (17.9%)
No change	2 (3.4%)	4 (7.4%)	2 (12.5%)	0
Return Rate (%)	76%	91%	81%	82%
Number of Subjects in Risk	49	50	13	26
Return Rate in Risk (%)	92%	98%	100%	88%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 01JUL2019
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Table 2.6508: Analysis of Patient Global Impression of Change at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 11)	RUX (N = 12)	p-value
Missing Assessment	4 (36.4%)	4 (33.3%)	
No change	1 (9.1%)	1 (8.3%)	
Return Rate (%)	64%	67%	
Number of Subjects in Risk	8	10	
Return Rate in Risk (%)	88%	80%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 01JUL2019
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Table 2.6503: Analysis of Patient Global Impression of Change at Week 24 by Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 50)	RUX (N = 56)	MMB (N = 36)	RUX (N = 38)	p-value
Week 24 at Double-Blind Phase, n(%)					
Improvement, n(%)	34 (68.0%)	38 (67.9%)	21 (58.3%)	32 (84.2%)	
Very much improved	5 (10.0%)	3 (5.4%)	1 (2.8%)	3 (7.9%)	
Much improved	20 (40.0%)	20 (35.7%)	15 (41.7%)	20 (52.6%)	
Minimally improved	9 (18.0%)	15 (26.8%)	5 (13.9%)	9 (23.7%)	
95% Exact CI	0.5330, 0.8048	0.5404, 0.7971	0.4076, 0.7449	0.6875, 0.9398	
Proportion Difference - Stratified CMH Method (95% CI)	-0.02 (-0.20, 0.17)		-0.26 (-0.49, -0.03)		
p-value	0.86		0.028		
Proportion Difference - Unstratified CMH Method (95% CI)	0.00 (-0.18, 0.18)		-0.26 (-0.46, -0.06)		
p-value	0.99		0.012		
Proportion Difference - Unstratified Exact Method (95% CI)	0.00 (-0.19, 0.19)		-0.26 (-0.47, -0.03)		
p-value	1.00		0.020		
Unadjusted Inverse Relative Risk (95% CI)	1.00 (0.77, 1.30)		1.44 (1.06, 1.97)		
p-value [1]	0.99		0.020		
Unadjusted interaction test for Treatment*Gender [3]					0.069
Unadjusted Inverse Odds Ratio (95% CI)	0.99 (0.44, 2.25)		3.81 (1.27, 11.39)		
p-value [1]	0.99		0.017		
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.18, 0.18)		-0.26 (-0.46, -0.06)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.03 (0.79, 1.33)		1.44 (1.06, 1.96)		
p-value [2]	0.85		0.020		
Adjusted interaction test for Treatment*Gender [3]					0.086

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

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Table 2.6503: Analysis of Patient Global Impression of Change at Week 24 by Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 50)	RUX (N = 56)	MMB (N = 36)	RUX (N = 38)	p-value
Worsening, n(%)	1 (2.0%)	5 (8.9%)	4 (11.1%)	0	
Minimally worse	1 (2.0%)	3 (5.4%)	2 (5.6%)	0	
Much worse	0	2 (3.6%)	2 (5.6%)	0	
Very much worse	0	0	0	0	
95% Exact CI	0.0005, 0.1065	0.0296, 0.1962	0.0311, 0.2606	0.0000, 0.0925	
Proportion Difference - Stratified CMH Method (95% CI)	-0.07 (-0.19, 0.04)		0.11 (-0.05, 0.27)		
p-value	0.20		0.19		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.07 (-0.16, 0.02)		0.11 (0.00, 0.23)		
p-value	0.14		0.057		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.07 (-0.26, 0.12)		0.11 (-0.12, 0.34)		
p-value	0.21		0.051		
Unadjusted Relative Risk (95% CI)	0.22 (0.03, 1.85)		9.49 (0.53, 170.18)		
p-value [1]	0.17		0.13		
Unadjusted interaction test for Treatment*Gender [3]					NA
Unadjusted Odds Ratio (95% CI)	0.21 (0.02, 1.85)		10.66 (0.55, 205.51)		
p-value [1]	0.16		0.12		
Unadjusted Absolute Risk Difference (95% CI)	-0.07 (-0.15, 0.01)		0.11 (0.00, 0.22)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Gender [3]					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.6503: Analysis of Patient Global Impression of Change at Week 24 by Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 50)	RUX (N = 56)	MMB (N = 36)	RUX (N = 38)	p-value
Missing Assessment	11 (22.0%)	10 (17.9%)	10 (27.8%)	4 (10.5%)	
No change	4 (8.0%)	3 (5.4%)	1 (2.8%)	2 (5.3%)	
Return Rate (%)	78%	82%	72%	89%	
Number of Subjects in Risk	44	50	26	36	
Return Rate in Risk (%)	89%	92%	100%	94%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
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Table 2.6510: Analysis of Patient Global Impression of Change at Week 24 by Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N = 47)	RUX (N = 43)	MMB (N = 39)	RUX (N = 51)	p-value
Week 24 at Double-Blind Phase, n(%)					
Improvement, n(%)	31 (66.0%)	34 (79.1%)	24 (61.5%)	36 (70.6%)	
Very much improved	3 (6.4%)	3 (7.0%)	3 (7.7%)	3 (5.9%)	
Much improved	21 (44.7%)	18 (41.9%)	14 (35.9%)	22 (43.1%)	
Minimally improved	7 (14.9%)	13 (30.2%)	7 (17.9%)	11 (21.6%)	
95% Exact CI	0.5069, 0.7914	0.6396, 0.8996	0.4462, 0.7664	0.5617, 0.8251	
Proportion Difference - Stratified CMH Method (95% CI)	-0.14 (-0.36, 0.07)		-0.13 (-0.34, 0.08)		
p-value	0.18		0.22		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.13 (-0.32, 0.05)		-0.09 (-0.29, 0.11)		
p-value	0.17		0.38		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.13 (-0.33, 0.08)		-0.09 (-0.29, 0.12)		
p-value	0.24		0.38		
Unadjusted Inverse Relative Risk (95% CI)	1.20 (0.93, 1.55)		1.15 (0.85, 1.56)		
p-value [1]	0.17		0.38		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.83
Unadjusted Inverse Odds Ratio (95% CI)	1.95 (0.75, 5.05)		1.50 (0.62, 3.63)		
p-value [1]	0.17		0.37		
Unadjusted Absolute Risk Difference (95% CI)	-0.13 (-0.31, 0.05)		-0.09 (-0.29, 0.11)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.22 (0.94, 1.59)		1.22 (0.90, 1.64)		
p-value [2]	0.14		0.20		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

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Table 2.6510: Analysis of Patient Global Impression of Change at Week 24 by Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N = 47)	RUX (N = 43)	MMB (N = 39)	RUX (N = 51)	p-value
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.81

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-chg-pgic.sas V.03.05 Output file: t-subgrp-chg-pgic-db-gba-svb.pdf 29AUG2023: 9:48

Table 2.6510: Analysis of Patient Global Impression of Change at Week 24 by Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N = 47)	RUX (N = 43)	MMB (N = 39)	RUX (N = 51)	p-value
Worsening, n(%)	2 (4.3%)	0	3 (7.7%)	5 (9.8%)	
Minimally worse	0	0	3 (7.7%)	3 (5.9%)	
Much worse	2 (4.3%)	0	0	2 (3.9%)	
Very much worse	0	0	0	0	
95% Exact CI	0.0052, 0.1454	0.0000, 0.0822	0.0162, 0.2087	0.0326, 0.2141	
Proportion Difference - Stratified CMH Method (95% CI)	0.05 (-0.08, 0.18)		-0.05 (-0.21, 0.12)		
p-value	0.48		0.58		
Proportion Difference - Unstratified CMH Method (95% CI)	0.04 (-0.03, 0.11)		-0.02 (-0.14, 0.10)		
p-value	0.25		0.74		
Proportion Difference - Unstratified Exact Method (95% CI)	0.04 (-0.17, 0.25)		-0.02 (-0.23, 0.19)		
p-value	0.50		1.00		
Unadjusted Relative Risk (95% CI)	4.58 (0.23, 92.87)		0.78 (0.20, 3.09)		
p-value [1]	0.32		0.73		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Odds Ratio (95% CI)	4.78 (0.22, 102.43)		0.77 (0.17, 3.42)		
p-value [1]	0.32		0.73		
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.03, 0.11)		-0.02 (-0.14, 0.10)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-chg-pgic.sas V.03.05 Output file: t-subgrp-chg-pgic-db-gba-svb.pdf 29AUG2023: 9:48

Table 2.6510: Analysis of Patient Global Impression of Change at Week 24 by Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N = 47)	RUX (N = 43)	MMB (N = 39)	RUX (N = 51)	p-value
Missing Assessment	10 (21.3%)	5 (11.6%)	11 (28.2%)	9 (17.6%)	
No change	4 (8.5%)	4 (9.3%)	1 (2.6%)	1 (2.0%)	
Return Rate (%)	79%	88%	72%	82%	
Number of Subjects in Risk	40	39	30	47	
Return Rate in Risk (%)	93%	97%	93%	89%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-chg-pgic.sas V.03.05 Output file: t-subgrp-chg-pgic-db-gba-svb.pdf 29AUG2023: 9:48

Table 2.6509: Analysis of Patient Global Impression of Change at Week 24 by Baseline TSS
Double-Blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 44)	RUX (N = 55)	MMB (N = 41)	RUX (N = 38)	p-value
Week 24 at Double-Blind Phase, n(%)					
Improvement, n(%)	30 (68.2%)	45 (81.8%)	24 (58.5%)	24 (63.2%)	
Very much improved	2 (4.5%)	4 (7.3%)	4 (9.8%)	2 (5.3%)	
Much improved	20 (45.5%)	24 (43.6%)	14 (34.1%)	15 (39.5%)	
Minimally improved	8 (18.2%)	17 (30.9%)	6 (14.6%)	7 (18.4%)	
95% Exact CI	0.5242, 0.8139	0.6910, 0.9092	0.4211, 0.7368	0.4599, 0.7819	
Proportion Difference - Stratified CMH Method (95% CI)	-0.15 (-0.34, 0.03)		-0.06 (-0.29, 0.16)		
p-value	0.10		0.58		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.14 (-0.31, 0.04)		-0.05 (-0.26, 0.17)		
p-value	0.12		0.68		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.14 (-0.33, 0.06)		-0.05 (-0.27, 0.17)		
p-value	0.16		0.82		
Unadjusted Inverse Relative Risk (95% CI)	1.20 (0.95, 1.52)		1.08 (0.76, 1.54)		
p-value [1]	0.13		0.67		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.62
Unadjusted Inverse Odds Ratio (95% CI)	2.10 (0.83, 5.34)		1.21 (0.49, 3.00)		
p-value [1]	0.12		0.67		
Unadjusted Absolute Risk Difference (95% CI)	-0.14 (-0.31, 0.03)		-0.05 (-0.26, 0.17)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		1.11 (0.79, 1.56)		
p-value [2]	NE		0.54		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					0.62

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-chg-pgic.sas V.03.05 Output file: t-subgrp-chg-pgic-db-gba-tss.pdf 29AUG2023: 9:48

Table 2.6509: Analysis of Patient Global Impression of Change at Week 24 by Baseline TSS
Double-Blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 44)	RUX (N = 55)	MMB (N = 41)	RUX (N = 38)	p-value
Worsening, n(%)	2 (4.5%)	2 (3.6%)	3 (7.3%)	3 (7.9%)	
Minimally worse	2 (4.5%)	2 (3.6%)	1 (2.4%)	1 (2.6%)	
Much worse	0	0	2 (4.9%)	2 (5.3%)	
Very much worse	0	0	0	0	
95% Exact CI	0.0056, 0.1547	0.0044, 0.1253	0.0154, 0.1992	0.0166, 0.2138	
Proportion Difference - Stratified CMH Method (95% CI)	0.01 (-0.11, 0.12)		0.00 (-0.16, 0.16)		
p-value	0.89		1.00		
Proportion Difference - Unstratified CMH Method (95% CI)	0.01 (-0.08, 0.10)		-0.01 (-0.13, 0.12)		
p-value	0.84		0.93		
Proportion Difference - Unstratified Exact Method (95% CI)	0.01 (-0.19, 0.21)		-0.01 (-0.22, 0.22)		
p-value	1.00		1.00		
Unadjusted Relative Risk (95% CI)	1.25 (0.18, 8.52)		0.93 (0.20, 4.32)		
p-value [1]	0.82		0.92		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Unadjusted Odds Ratio (95% CI)	1.26 (0.17, 9.34)		0.92 (0.17, 4.87)		
p-value [1]	0.82		0.92		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.07, 0.09)		-0.01 (-0.12, 0.11)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.6509: Analysis of Patient Global Impression of Change at Week 24 by Baseline TSS
Double-Blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 44)	RUX (N = 55)	MMB (N = 41)	RUX (N = 38)	p-value
Missing Assessment	7 (15.9%)	5 (9.1%)	14 (34.1%)	9 (23.7%)	
No change	5 (11.4%)	3 (5.5%)	0	2 (5.3%)	
Return Rate (%)	84%	91%	66%	76%	
Number of Subjects in Risk	41	51	28	34	
Return Rate in Risk (%)	90%	98%	96%	85%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
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Table 2.6902: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	RUX (N = 36)	MMB (N = 62)	RUX (N = 58)	p-value
EQ-5D-5L VAS Response Rate at Week 4					
Responder, n(%)	0	4 (11.1%)	6 (9.7%)	8 (13.8%)	
Non-Responder, n(%)	24 (100.0%)	32 (88.9%)	56 (90.3%)	50 (86.2%)	
Non-missing	18 (75.0%)	24 (66.7%)	45 (72.6%)	39 (67.2%)	
Missing	6 (25.0%)	8 (22.2%)	11 (17.7%)	11 (19.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-vas-gba-improv.sas V.03.05 Output file: t-subgrp-vas-det-gba-age.pdf 29AUG2023: 9:47

Table 2.6902: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	RUX (N = 36)	MMB (N = 62)	RUX (N = 58)	p-value
EQ-5D-5L VAS Response Rate at Week 8					
Responder, n(%)	2 (8.3%)	3 (8.3%)	7 (11.3%)	3 (5.2%)	
Non-Responder, n(%)	22 (91.7%)	33 (91.7%)	55 (88.7%)	55 (94.8%)	
Non-missing	14 (58.3%)	23 (63.9%)	41 (66.1%)	43 (74.1%)	
Missing	8 (33.3%)	10 (27.8%)	14 (22.6%)	12 (20.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
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Table 2.6902: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	RUX (N = 36)	MMB (N = 62)	RUX (N = 58)	p-value
EQ-5D-5L VAS Response Rate at Week 12					
Responder, n(%)	3 (12.5%)	3 (8.3%)	6 (9.7%)	5 (8.6%)	
Non-Responder, n(%)	21 (87.5%)	33 (91.7%)	56 (90.3%)	53 (91.4%)	
Non-missing	14 (58.3%)	25 (69.4%)	41 (66.1%)	41 (70.7%)	
Missing	7 (29.2%)	8 (22.2%)	15 (24.2%)	12 (20.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-vas-gba-improv.sas V.03.05 Output file: t-subgrp-vas-det-gba-age.pdf 29AUG2023: 9:47

Table 2.6902: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	RUX (N = 36)	MMB (N = 62)	RUX (N = 58)	p-value
EQ-5D-5L VAS Response Rate at Week 16					
Responder, n(%)	4 (16.7%)	3 (8.3%)	9 (14.5%)	4 (6.9%)	
Non-Responder, n(%)	20 (83.3%)	33 (91.7%)	53 (85.5%)	54 (93.1%)	
Non-missing	13 (54.2%)	23 (63.9%)	34 (54.8%)	41 (70.7%)	
Missing	7 (29.2%)	10 (27.8%)	19 (30.6%)	13 (22.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
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Table 2.6902: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	RUX (N = 36)	MMB (N = 62)	RUX (N = 58)	p-value
EQ-5D-5L VAS Response Rate at Week 20					
Responder, n(%)	3 (12.5%)	2 (5.6%)	5 (8.1%)	4 (6.9%)	
Non-Responder, n(%)	21 (87.5%)	34 (94.4%)	57 (91.9%)	54 (93.1%)	
Non-missing	13 (54.2%)	23 (63.9%)	37 (59.7%)	40 (69.0%)	
Missing	8 (33.3%)	11 (30.6%)	20 (32.3%)	14 (24.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-vas-gba-improv.sas V.03.05 Output file: t-subgrp-vas-det-gba-age.pdf 29AUG2023: 9:47

Table 2.6902: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	RUX (N = 36)	MMB (N = 62)	RUX (N = 58)	p-value
EQ-5D-5L VAS Response Rate at Week 24					
Responder, n(%)	1 (4.2%)	3 (8.3%)	5 (8.1%)	5 (8.6%)	
Unadjusted Relative Risk (95% CI)	0.50 (0.06, 4.53)		0.94 (0.29, 3.07)		
p-value [1]	0.54		0.91		
Unadjusted interaction test for Treatment*Age Group [3]					0.60
Unadjusted Odds Ratio (95% CI)	0.48 (0.05, 4.89)		0.93 (0.25, 3.39)		
p-value [1]	0.53		0.91		
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.16, 0.08)		-0.01 (-0.10, 0.09)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Age Group [3]					NE
Non-Responder, n(%)	23 (95.8%)	33 (91.7%)	57 (91.9%)	53 (91.4%)	
Non-missing	14 (58.3%)	22 (61.1%)	38 (61.3%)	38 (65.5%)	
Missing	9 (37.5%)	11 (30.6%)	19 (30.6%)	15 (25.9%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-vas-gba-improv.sas V.03.05 Output file: t-subgrp-vas-det-gba-age.pdf 29AUG2023: 9:47

Table 2.6904: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Region
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N = 53)	RUX (N = 51)	MMB (N = 33)	RUX (N = 43)	p-value
EQ-5D-5L VAS Response Rate at Week 4					
Responder, n(%)	3 (5.7%)	6 (11.8%)	3 (9.1%)	6 (14.0%)	
Non-Responder, n(%)	50 (94.3%)	45 (88.2%)	30 (90.9%)	37 (86.0%)	
Non-missing	35 (66.0%)	31 (60.8%)	28 (84.8%)	32 (74.4%)	
Missing	15 (28.3%)	14 (27.5%)	2 (6.1%)	5 (11.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-vas-gba-improv.sas V.03.05 Output file: t-subgrp-vas-det-gba-geo.pdf 29AUG2023: 9:47

Table 2.6904: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Region
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N = 53)	RUX (N = 51)	MMB (N = 33)	RUX (N = 43)	p-value
EQ-5D-5L VAS Response Rate at Week 8					
Responder, n(%)	4 (7.5%)	2 (3.9%)	5 (15.2%)	4 (9.3%)	
Non-Responder, n(%)	49 (92.5%)	49 (96.1%)	28 (84.8%)	39 (90.7%)	
Non-missing	32 (60.4%)	34 (66.7%)	23 (69.7%)	32 (74.4%)	
Missing	17 (32.1%)	15 (29.4%)	5 (15.2%)	7 (16.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-vas-gba-improv.sas V.03.05 Output file: t-subgrp-vas-det-gba-geo.pdf 29AUG2023: 9:47

Table 2.6904: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Region
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N = 53)	RUX (N = 51)	MMB (N = 33)	RUX (N = 43)	p-value
EQ-5D-5L VAS Response Rate at Week 12					
Responder, n(%)	4 (7.5%)	3 (5.9%)	5 (15.2%)	5 (11.6%)	
Non-Responder, n(%)	49 (92.5%)	48 (94.1%)	28 (84.8%)	38 (88.4%)	
Non-missing	31 (58.5%)	33 (64.7%)	24 (72.7%)	33 (76.7%)	
Missing	18 (34.0%)	15 (29.4%)	4 (12.1%)	5 (11.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

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Table 2.6904: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Region
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N = 53)	RUX (N = 51)	MMB (N = 33)	RUX (N = 43)	p-value
EQ-5D-5L VAS Response Rate at Week 16					
Responder, n(%)	6 (11.3%)	3 (5.9%)	7 (21.2%)	4 (9.3%)	
Non-Responder, n(%)	47 (88.7%)	48 (94.1%)	26 (78.8%)	39 (90.7%)	
Non-missing	27 (50.9%)	31 (60.8%)	20 (60.6%)	33 (76.7%)	
Missing	20 (37.7%)	17 (33.3%)	6 (18.2%)	6 (14.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

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Table 2.6904: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Region
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N = 53)	RUX (N = 51)	MMB (N = 33)	RUX (N = 43)	p-value
EQ-5D-5L VAS Response Rate at Week 20					
Responder, n(%)	3 (5.7%)	0	5 (15.2%)	6 (14.0%)	
Non-Responder, n(%)	50 (94.3%)	51 (100.0%)	28 (84.8%)	37 (86.0%)	
Non-missing	27 (50.9%)	32 (62.7%)	23 (69.7%)	31 (72.1%)	
Missing	23 (43.4%)	19 (37.3%)	5 (15.2%)	6 (14.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

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Table 2.6904: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Region
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N = 53)	RUX (N = 51)	MMB (N = 33)	RUX (N = 43)	p-value
EQ-5D-5L VAS Response Rate at Week 24					
Responder, n(%)	4 (7.5%)	1 (2.0%)	2 (6.1%)	7 (16.3%)	
Unadjusted Relative Risk (95% CI)	3.85 (0.45, 33.29)		0.37 (0.08, 1.68)		
p-value [1]	0.22		0.20		
Unadjusted interaction test for Treatment*Region [3]					NA
Unadjusted Odds Ratio (95% CI)	4.08 (0.44, 37.83)		0.33 (0.06, 1.72)		
p-value [1]	0.22		0.19		
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.02, 0.14)		-0.10 (-0.24, 0.03)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Region [3]					NA
Non-Responder, n(%)	49 (92.5%)	50 (98.0%)	31 (93.9%)	36 (83.7%)	
Non-missing	27 (50.9%)	32 (62.7%)	25 (75.8%)	28 (65.1%)	
Missing	22 (41.5%)	18 (35.3%)	6 (18.2%)	8 (18.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

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Table 2.6907: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 28)	RUX (N = 21)	MMB (N = 58)	RUX (N = 73)	p-value
EQ-5D-5L VAS Response Rate at Week 4					
Responder, n(%)	3 (10.7%)	3 (14.3%)	3 (5.2%)	9 (12.3%)	
Non-Responder, n(%)	25 (89.3%)	18 (85.7%)	55 (94.8%)	64 (87.7%)	
Non-missing	19 (67.9%)	16 (76.2%)	44 (75.9%)	47 (64.4%)	
Missing	6 (21.4%)	2 (9.5%)	11 (19.0%)	17 (23.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

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Table 2.6907: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 28)	RUX (N = 21)	MMB (N = 58)	RUX (N = 73)	p-value
EQ-5D-5L VAS Response Rate at Week 8					
Responder, n(%)	3 (10.7%)	2 (9.5%)	6 (10.3%)	4 (5.5%)	
Non-Responder, n(%)	25 (89.3%)	19 (90.5%)	52 (89.7%)	69 (94.5%)	
Non-missing	16 (57.1%)	17 (81.0%)	39 (67.2%)	49 (67.1%)	
Missing	9 (32.1%)	2 (9.5%)	13 (22.4%)	20 (27.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

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Table 2.6907: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 28)	RUX (N = 21)	MMB (N = 58)	RUX (N = 73)	p-value
EQ-5D-5L VAS Response Rate at Week 12					
Responder, n(%)	3 (10.7%)	1 (4.8%)	6 (10.3%)	7 (9.6%)	
Non-Responder, n(%)	25 (89.3%)	20 (95.2%)	52 (89.7%)	66 (90.4%)	
Non-missing	15 (53.6%)	16 (76.2%)	40 (69.0%)	50 (68.5%)	
Missing	10 (35.7%)	4 (19.0%)	12 (20.7%)	16 (21.9%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

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Table 2.6907: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 28)	RUX (N = 21)	MMB (N = 58)	RUX (N = 73)	p-value
EQ-5D-5L VAS Response Rate at Week 16					
Responder, n(%)	6 (21.4%)	1 (4.8%)	7 (12.1%)	6 (8.2%)	
Non-Responder, n(%)	22 (78.6%)	20 (95.2%)	51 (87.9%)	67 (91.8%)	
Non-missing	10 (35.7%)	16 (76.2%)	37 (63.8%)	48 (65.8%)	
Missing	12 (42.9%)	4 (19.0%)	14 (24.1%)	19 (26.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

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Table 2.6907: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 28)	RUX (N = 21)	MMB (N = 58)	RUX (N = 73)	p-value
EQ-5D-5L VAS Response Rate at Week 20					
Responder, n(%)	3 (10.7%)	1 (4.8%)	5 (8.6%)	5 (6.8%)	
Non-Responder, n(%)	25 (89.3%)	20 (95.2%)	53 (91.4%)	68 (93.2%)	
Non-missing	15 (53.6%)	16 (76.2%)	35 (60.3%)	47 (64.4%)	
Missing	10 (35.7%)	4 (19.0%)	18 (31.0%)	21 (28.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

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Table 2.6907: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 28)	RUX (N = 21)	MMB (N = 58)	RUX (N = 73)	p-value
EQ-5D-5L VAS Response Rate at Week 24					
Responder, n(%)	2 (7.1%)	2 (9.5%)	4 (6.9%)	6 (8.2%)	
Unadjusted Relative Risk (95% CI)	0.75 (0.11, 4.90)		0.84 (0.25, 2.83)		
p-value [1]	0.76		0.78		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.92
Unadjusted Odds Ratio (95% CI)	0.73 (0.09, 5.66)		0.83 (0.22, 3.08)		
p-value [1]	0.76		0.78		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.18, 0.13)		-0.01 (-0.10, 0.08)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE
Non-Responder, n(%)	26 (92.9%)	19 (90.5%)	54 (93.1%)	67 (91.8%)	
Non-missing	16 (57.1%)	14 (66.7%)	36 (62.1%)	46 (63.0%)	
Missing	10 (35.7%)	5 (23.8%)	18 (31.0%)	21 (28.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

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Table 2.6906: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline
IPSS Two-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 28)	RUX (N = 24)	MMB (N = 58)	RUX (N = 70)	p-value
EQ-5D-5L VAS Response Rate at Week 4					
Responder, n(%)	2 (7.1%)	3 (12.5%)	4 (6.9%)	9 (12.9%)	
Non-Responder, n(%)	26 (92.9%)	21 (87.5%)	54 (93.1%)	61 (87.1%)	
Non-missing	18 (64.3%)	16 (66.7%)	45 (77.6%)	47 (67.1%)	
Missing	8 (28.6%)	5 (20.8%)	9 (15.5%)	14 (20.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

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Table 2.6906: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline
IPSS Two-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 28)	RUX (N = 24)	MMB (N = 58)	RUX (N = 70)	p-value
EQ-5D-5L VAS Response Rate at Week 8					
Responder, n(%)	4 (14.3%)	2 (8.3%)	5 (8.6%)	4 (5.7%)	
Non-Responder, n(%)	24 (85.7%)	22 (91.7%)	53 (91.4%)	66 (94.3%)	
Non-missing	15 (53.6%)	16 (66.7%)	40 (69.0%)	50 (71.4%)	
Missing	9 (32.1%)	6 (25.0%)	13 (22.4%)	16 (22.9%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.6906: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline
IPSS Two-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 28)	RUX (N = 24)	MMB (N = 58)	RUX (N = 70)	p-value
EQ-5D-5L VAS Response Rate at Week 12					
Responder, n(%)	4 (14.3%)	3 (12.5%)	5 (8.6%)	5 (7.1%)	
Non-Responder, n(%)	24 (85.7%)	21 (87.5%)	53 (91.4%)	65 (92.9%)	
Non-missing	15 (53.6%)	16 (66.7%)	40 (69.0%)	50 (71.4%)	
Missing	9 (32.1%)	5 (20.8%)	13 (22.4%)	15 (21.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

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Table 2.6906: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline
IPSS Two-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 28)	RUX (N = 24)	MMB (N = 58)	RUX (N = 70)	p-value
EQ-5D-5L VAS Response Rate at Week 16					
Responder, n(%)	4 (14.3%)	3 (12.5%)	9 (15.5%)	4 (5.7%)	
Non-Responder, n(%)	24 (85.7%)	21 (87.5%)	49 (84.5%)	66 (94.3%)	
Non-missing	14 (50.0%)	14 (58.3%)	33 (56.9%)	50 (71.4%)	
Missing	10 (35.7%)	7 (29.2%)	16 (27.6%)	16 (22.9%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
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Table 2.6906: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline
IPSS Two-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 28)	RUX (N = 24)	MMB (N = 58)	RUX (N = 70)	p-value
EQ-5D-5L VAS Response Rate at Week 20					
Responder, n(%)	2 (7.1%)	1 (4.2%)	6 (10.3%)	5 (7.1%)	
Non-Responder, n(%)	26 (92.9%)	23 (95.8%)	52 (89.7%)	65 (92.9%)	
Non-missing	16 (57.1%)	15 (62.5%)	34 (58.6%)	48 (68.6%)	
Missing	10 (35.7%)	8 (33.3%)	18 (31.0%)	17 (24.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
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Table 2.6906: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline
IPSS Two-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 28)	RUX (N = 24)	MMB (N = 58)	RUX (N = 70)	p-value
EQ-5D-5L VAS Response Rate at Week 24					
Responder, n(%)	0	1 (4.2%)	6 (10.3%)	7 (10.0%)	
Unadjusted Relative Risk (95% CI)	0.29 (0.01, 6.74)		1.03 (0.37, 2.91)		
p-value [1]	0.44		0.95		
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [3]					NE
Unadjusted Odds Ratio (95% CI)	0.27 (0.01, 7.07)		1.04 (0.33, 3.28)		
p-value [1]	0.44		0.95		
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.15, 0.06)		0.00 (-0.10, 0.11)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*IPSS 2-Level Risk [3]					NE
Non-Responder, n(%)	28 (100.0%)	23 (95.8%)	52 (89.7%)	63 (90.0%)	
Non-missing	17 (60.7%)	16 (66.7%)	35 (60.3%)	44 (62.9%)	
Missing	11 (39.3%)	7 (29.2%)	17 (29.3%)	19 (27.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.6905: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline
IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 2)	RUX (N = 4)	MMB (N = 26)	RUX (N = 20)
EQ-5D-5L VAS Response Rate at Week 4				
Responder, n(%)	0	0	2 (7.7%)	3 (15.0%)
Non-Responder, n(%)	2 (100.0%)	4 (100.0%)	24 (92.3%)	17 (85.0%)
Non-missing	1 (50.0%)	3 (75.0%)	17 (65.4%)	13 (65.0%)
Missing	1 (50.0%)	1 (25.0%)	7 (26.9%)	4 (20.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-vas-gba-improv.sas V.03.05 Output file: t-subgrp-vas-det-gba-ip3.pdf 29AUG2023: 9:47

Table 2.6905: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline
IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 58)	RUX (N = 70)	p-value
EQ-5D-5L VAS Response Rate at Week 4			
Responder, n(%)	4 (6.9%)	9 (12.9%)	
Non-Responder, n(%)	54 (93.1%)	61 (87.1%)	
Non-missing	45 (77.6%)	47 (67.1%)	
Missing	9 (15.5%)	14 (20.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.6905: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline
IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 2)	RUX (N = 4)	MMB (N = 26)	RUX (N = 20)
EQ-5D-5L VAS Response Rate at Week 8				
Responder, n(%)	0	0	4 (15.4%)	2 (10.0%)
Non-Responder, n(%)	2 (100.0%)	4 (100.0%)	22 (84.6%)	18 (90.0%)
Non-missing	1 (50.0%)	3 (75.0%)	14 (53.8%)	13 (65.0%)
Missing	1 (50.0%)	1 (25.0%)	8 (30.8%)	5 (25.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.6905: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline
IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 58)	RUX (N = 70)	p-value
EQ-5D-5L VAS Response Rate at Week 8			
Responder, n(%)	5 (8.6%)	4 (5.7%)	
Non-Responder, n(%)	53 (91.4%)	66 (94.3%)	
Non-missing	40 (69.0%)	50 (71.4%)	
Missing	13 (22.4%)	16 (22.9%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.6905: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline
IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 2)	RUX (N = 4)	MMB (N = 26)	RUX (N = 20)
EQ-5D-5L VAS Response Rate at Week 12				
Responder, n(%)	0	1 (25.0%)	4 (15.4%)	2 (10.0%)
Non-Responder, n(%)	2 (100.0%)	3 (75.0%)	22 (84.6%)	18 (90.0%)
Non-missing	1 (50.0%)	2 (50.0%)	14 (53.8%)	14 (70.0%)
Missing	1 (50.0%)	1 (25.0%)	8 (30.8%)	4 (20.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.6905: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline
IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 58)	RUX (N = 70)	p-value
EQ-5D-5L VAS Response Rate at Week 12			
Responder, n(%)	5 (8.6%)	5 (7.1%)	
Non-Responder, n(%)	53 (91.4%)	65 (92.9%)	
Non-missing	40 (69.0%)	50 (71.4%)	
Missing	13 (22.4%)	15 (21.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.6905: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline
IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 2)	RUX (N = 4)	MMB (N = 26)	RUX (N = 20)
EQ-5D-5L VAS Response Rate at Week 16				
Responder, n(%)	0	1 (25.0%)	4 (15.4%)	2 (10.0%)
Non-Responder, n(%)	2 (100.0%)	3 (75.0%)	22 (84.6%)	18 (90.0%)
Non-missing	1 (50.0%)	2 (50.0%)	13 (50.0%)	12 (60.0%)
Missing	1 (50.0%)	1 (25.0%)	9 (34.6%)	6 (30.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.6905: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline
IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 58)	RUX (N = 70)	p-value
EQ-5D-5L VAS Response Rate at Week 16			
Responder, n(%)	9 (15.5%)	4 (5.7%)	
Non-Responder, n(%)	49 (84.5%)	66 (94.3%)	
Non-missing	33 (56.9%)	50 (71.4%)	
Missing	16 (27.6%)	16 (22.9%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.6905: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline
IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 2)	RUX (N = 4)	MMB (N = 26)	RUX (N = 20)
EQ-5D-5L VAS Response Rate at Week 20				
Responder, n(%)	0	1 (25.0%)	2 (7.7%)	0
Non-Responder, n(%)	2 (100.0%)	3 (75.0%)	24 (92.3%)	20 (100.0%)
Non-missing	1 (50.0%)	1 (25.0%)	15 (57.7%)	14 (70.0%)
Missing	1 (50.0%)	2 (50.0%)	9 (34.6%)	6 (30.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
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Table 2.6905: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline
IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 58)	RUX (N = 70)	p-value
EQ-5D-5L VAS Response Rate at Week 20			
Responder, n(%)	6 (10.3%)	5 (7.1%)	
Non-Responder, n(%)	52 (89.7%)	65 (92.9%)	
Non-missing	34 (58.6%)	48 (68.6%)	
Missing	18 (31.0%)	17 (24.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.6905: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline
IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 2)	RUX (N = 4)	MMB (N = 26)	RUX (N = 20)
EQ-5D-5L VAS Response Rate at Week 24				
Responder, n(%)	0	1 (25.0%)	0	0
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Non-Responder, n(%)	2 (100.0%)	3 (75.0%)	26 (100.0%)	20 (100.0%)
Non-missing	1 (50.0%)	2 (50.0%)	16 (61.5%)	14 (70.0%)
Missing	1 (50.0%)	1 (25.0%)	10 (38.5%)	6 (30.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-vas-gba-improv.sas V.03.05 Output file: t-subgrp-vas-det-gba-ip3.pdf 29AUG2023: 9:47

Table 2.6905: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 58)	RUX (N = 70)	p-value
EQ-5D-5L VAS Response Rate at Week 24			
Responder, n(%)	6 (10.3%)	7 (10.0%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	52 (89.7%)	63 (90.0%)	
Non-missing	35 (60.3%)	44 (62.9%)	
Missing	17 (29.3%)	19 (27.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-vas-gba-improv.sas V.03.05 Output file: t-subgrp-vas-det-gba-ip3.pdf 29AUG2023: 9:47

Table 2.6908: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline
MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 59)	RUX (N = 54)	MMB (N = 16)	RUX (N = 28)
EQ-5D-5L VAS Response Rate at Week 4				
Responder, n(%)	5 (8.5%)	6 (11.1%)	1 (6.3%)	3 (10.7%)
Non-Responder, n(%)	54 (91.5%)	48 (88.9%)	15 (93.8%)	25 (89.3%)
Non-missing	45 (76.3%)	43 (79.6%)	10 (62.5%)	16 (57.1%)
Missing	9 (15.3%)	5 (9.3%)	5 (31.3%)	9 (32.1%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
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Table 2.6908: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 11)	RUX (N = 12)	p-value
EQ-5D-5L VAS Response Rate at Week 4			
Responder, n(%)	0	3 (25.0%)	
Non-Responder, n(%)	11 (100.0%)	9 (75.0%)	
Non-missing	8 (72.7%)	4 (33.3%)	
Missing	3 (27.3%)	5 (41.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-vas-gba-improv.sas V.03.05 Output file: t-subgrp-vas-det-gba-mf.pdf 29AUG2023: 9:48

Table 2.6908: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline
MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 59)	RUX (N = 54)	MMB (N = 16)	RUX (N = 28)
EQ-5D-5L VAS Response Rate at Week 8				
Responder, n(%)	6 (10.2%)	1 (1.9%)	3 (18.8%)	2 (7.1%)
Non-Responder, n(%)	53 (89.8%)	53 (98.1%)	13 (81.3%)	26 (92.9%)
Non-missing	40 (67.8%)	45 (83.3%)	8 (50.0%)	17 (60.7%)
Missing	13 (22.0%)	8 (14.8%)	5 (31.3%)	9 (32.1%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.6908: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 11)	RUX (N = 12)	p-value
EQ-5D-5L VAS Response Rate at Week 8			
Responder, n(%)	0	3 (25.0%)	
Non-Responder, n(%)	11 (100.0%)	9 (75.0%)	
Non-missing	7 (63.6%)	4 (33.3%)	
Missing	4 (36.4%)	5 (41.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.6908: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 59)	RUX (N = 54)	MMB (N = 16)	RUX (N = 28)
EQ-5D-5L VAS Response Rate at Week 12				
Responder, n(%)	7 (11.9%)	5 (9.3%)	2 (12.5%)	0
Non-Responder, n(%)	52 (88.1%)	49 (90.7%)	14 (87.5%)	28 (100.0%)
Non-missing	40 (67.8%)	44 (81.5%)	8 (50.0%)	18 (64.3%)
Missing	12 (20.3%)	5 (9.3%)	6 (37.5%)	10 (35.7%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
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Table 2.6908: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 11)	RUX (N = 12)	p-value
EQ-5D-5L VAS Response Rate at Week 12			
Responder, n(%)	0	3 (25.0%)	
Non-Responder, n(%)	11 (100.0%)	9 (75.0%)	
Non-missing	7 (63.6%)	4 (33.3%)	
Missing	4 (36.4%)	5 (41.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.6908: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 59)	RUX (N = 54)	MMB (N = 16)	RUX (N = 28)
EQ-5D-5L VAS Response Rate at Week 16				
Responder, n(%)	9 (15.3%)	5 (9.3%)	4 (25.0%)	1 (3.6%)
Non-Responder, n(%)	50 (84.7%)	49 (90.7%)	12 (75.0%)	27 (96.4%)
Non-missing	35 (59.3%)	41 (75.9%)	6 (37.5%)	16 (57.1%)
Missing	15 (25.4%)	8 (14.8%)	6 (37.5%)	11 (39.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.6908: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 11)	RUX (N = 12)	p-value
EQ-5D-5L VAS Response Rate at Week 16			
Responder, n(%)	0	1 (8.3%)	
Non-Responder, n(%)	11 (100.0%)	11 (91.7%)	
Non-missing	6 (54.5%)	7 (58.3%)	
Missing	5 (45.5%)	4 (33.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

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Table 2.6908: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline
MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 59)	RUX (N = 54)	MMB (N = 16)	RUX (N = 28)
EQ-5D-5L VAS Response Rate at Week 20				
Responder, n(%)	5 (8.5%)	3 (5.6%)	3 (18.8%)	1 (3.6%)
Non-Responder, n(%)	54 (91.5%)	51 (94.4%)	13 (81.3%)	27 (96.4%)
Non-missing	36 (61.0%)	42 (77.8%)	6 (37.5%)	16 (57.1%)
Missing	18 (30.5%)	9 (16.7%)	7 (43.8%)	11 (39.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.6908: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 11)	RUX (N = 12)	p-value
EQ-5D-5L VAS Response Rate at Week 20			
Responder, n(%)	0	2 (16.7%)	
Non-Responder, n(%)	11 (100.0%)	10 (83.3%)	
Non-missing	8 (72.7%)	5 (41.7%)	
Missing	3 (27.3%)	5 (41.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.6908: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 59)	RUX (N = 54)	MMB (N = 16)	RUX (N = 28)
EQ-5D-5L VAS Response Rate at Week 24				
Responder, n(%)	4 (6.8%)	3 (5.6%)	2 (12.5%)	2 (7.1%)
Unadjusted Relative Risk (95% CI)	1.22 (0.29, 5.21)		1.75 (0.27, 11.26)	
p-value [1]	0.79		0.56	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Odds Ratio (95% CI)	1.24 (0.26, 5.79)		1.86 (0.24, 14.64)	
p-value [1]	0.79		0.56	
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.08, 0.10)		0.05 (-0.13, 0.24)	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	55 (93.2%)	51 (94.4%)	14 (87.5%)	26 (92.9%)
Non-missing	38 (64.4%)	41 (75.9%)	7 (43.8%)	15 (53.6%)
Missing	17 (28.8%)	10 (18.5%)	7 (43.8%)	11 (39.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

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Table 2.6908: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 11)	RUX (N = 12)	p-value
EQ-5D-5L VAS Response Rate at Week 24			
Responder, n(%)	0	3 (25.0%)	
Unadjusted Relative Risk (95% CI)	0.15 (0.01, 2.70)		
p-value [1]	0.20		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Unadjusted Odds Ratio (95% CI)	0.12 (0.01, 2.58)		
p-value [1]	0.17		
Unadjusted Absolute Risk Difference (95% CI)	-0.23 (-0.49, 0.04)		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Non-Responder, n(%)	11 (100.0%)	9 (75.0%)	
Non-missing	7 (63.6%)	4 (33.3%)	
Missing	4 (36.4%)	5 (41.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

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Table 2.6903: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 50)	RUX (N = 56)	MMB (N = 36)	RUX (N = 38)	p-value
EQ-5D-5L VAS Response Rate at Week 4					
Responder, n(%)	5 (10.0%)	7 (12.5%)	1 (2.8%)	5 (13.2%)	
Non-Responder, n(%)	45 (90.0%)	49 (87.5%)	35 (97.2%)	33 (86.8%)	
Non-missing	36 (72.0%)	41 (73.2%)	27 (75.0%)	22 (57.9%)	
Missing	9 (18.0%)	8 (14.3%)	8 (22.2%)	11 (28.9%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

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Table 2.6903: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 50)	RUX (N = 56)	MMB (N = 36)	RUX (N = 38)	p-value
EQ-5D-5L VAS Response Rate at Week 8					
Responder, n(%)	5 (10.0%)	4 (7.1%)	4 (11.1%)	2 (5.3%)	
Non-Responder, n(%)	45 (90.0%)	52 (92.9%)	32 (88.9%)	36 (94.7%)	
Non-missing	33 (66.0%)	42 (75.0%)	22 (61.1%)	24 (63.2%)	
Missing	12 (24.0%)	10 (17.9%)	10 (27.8%)	12 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
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Table 2.6903: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 50)	RUX (N = 56)	MMB (N = 36)	RUX (N = 38)	p-value
EQ-5D-5L VAS Response Rate at Week 12					
Responder, n(%)	5 (10.0%)	5 (8.9%)	4 (11.1%)	3 (7.9%)	
Non-Responder, n(%)	45 (90.0%)	51 (91.1%)	32 (88.9%)	35 (92.1%)	
Non-missing	34 (68.0%)	41 (73.2%)	21 (58.3%)	25 (65.8%)	
Missing	11 (22.0%)	10 (17.9%)	11 (30.6%)	10 (26.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

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Table 2.6903: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 50)	RUX (N = 56)	MMB (N = 36)	RUX (N = 38)	p-value
EQ-5D-5L VAS Response Rate at Week 16					
Responder, n(%)	6 (12.0%)	4 (7.1%)	7 (19.4%)	3 (7.9%)	
Non-Responder, n(%)	44 (88.0%)	52 (92.9%)	29 (80.6%)	35 (92.1%)	
Non-missing	29 (58.0%)	41 (73.2%)	18 (50.0%)	23 (60.5%)	
Missing	15 (30.0%)	11 (19.6%)	11 (30.6%)	12 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

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Table 2.6903: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 50)	RUX (N = 56)	MMB (N = 36)	RUX (N = 38)	p-value
EQ-5D-5L VAS Response Rate at Week 20					
Responder, n(%)	4 (8.0%)	3 (5.4%)	4 (11.1%)	3 (7.9%)	
Non-Responder, n(%)	46 (92.0%)	53 (94.6%)	32 (88.9%)	35 (92.1%)	
Non-missing	30 (60.0%)	41 (73.2%)	20 (55.6%)	22 (57.9%)	
Missing	16 (32.0%)	12 (21.4%)	12 (33.3%)	13 (34.2%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

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Table 2.6903: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 50)	RUX (N = 56)	MMB (N = 36)	RUX (N = 38)	p-value
EQ-5D-5L VAS Response Rate at Week 24					
Responder, n(%)	3 (6.0%)	5 (8.9%)	3 (8.3%)	3 (7.9%)	
Unadjusted Relative Risk (95% CI)	0.67 (0.17, 2.67)		1.06 (0.23, 4.89)		
p-value [1]	0.57		0.94		
Unadjusted interaction test for Treatment*Gender [3]					NA
Unadjusted Odds Ratio (95% CI)	0.65 (0.15, 2.88)		1.06 (0.20, 5.63)		
p-value [1]	0.57		0.94		
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.13, 0.07)		0.00 (-0.12, 0.13)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Gender [3]					NA
Non-Responder, n(%)	47 (94.0%)	51 (91.1%)	33 (91.7%)	35 (92.1%)	
Non-missing	32 (64.0%)	37 (66.1%)	20 (55.6%)	23 (60.5%)	
Missing	15 (30.0%)	14 (25.0%)	13 (36.1%)	12 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

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Table 2.6910: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N = 47)	RUX (N = 43)	MMB (N = 39)	RUX (N = 51)	p-value
EQ-5D-5L VAS Response Rate at Week 4					
Responder, n(%)	5 (10.6%)	8 (18.6%)	1 (2.6%)	4 (7.8%)	
Non-Responder, n(%)	42 (89.4%)	35 (81.4%)	38 (97.4%)	47 (92.2%)	
Non-missing	35 (74.5%)	26 (60.5%)	28 (71.8%)	37 (72.5%)	
Missing	7 (14.9%)	9 (20.9%)	10 (25.6%)	10 (19.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

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Table 2.6910: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N = 47)	RUX (N = 43)	MMB (N = 39)	RUX (N = 51)	p-value
EQ-5D-5L VAS Response Rate at Week 8					
Responder, n(%)	3 (6.4%)	4 (9.3%)	6 (15.4%)	2 (3.9%)	
Non-Responder, n(%)	44 (93.6%)	39 (90.7%)	33 (84.6%)	49 (96.1%)	
Non-missing	33 (70.2%)	28 (65.1%)	22 (56.4%)	38 (74.5%)	
Missing	11 (23.4%)	11 (25.6%)	11 (28.2%)	11 (21.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
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Table 2.6910: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N = 47)	RUX (N = 43)	MMB (N = 39)	RUX (N = 51)	p-value
EQ-5D-5L VAS Response Rate at Week 12					
Responder, n(%)	4 (8.5%)	6 (14.0%)	5 (12.8%)	2 (3.9%)	
Non-Responder, n(%)	43 (91.5%)	37 (86.0%)	34 (87.2%)	49 (96.1%)	
Non-missing	32 (68.1%)	27 (62.8%)	23 (59.0%)	39 (76.5%)	
Missing	11 (23.4%)	10 (23.3%)	11 (28.2%)	10 (19.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

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Table 2.6910: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N = 47)	RUX (N = 43)	MMB (N = 39)	RUX (N = 51)	p-value
EQ-5D-5L VAS Response Rate at Week 16					
Responder, n(%)	7 (14.9%)	5 (11.6%)	6 (15.4%)	2 (3.9%)	
Non-Responder, n(%)	40 (85.1%)	38 (88.4%)	33 (84.6%)	49 (96.1%)	
Non-missing	27 (57.4%)	26 (60.5%)	20 (51.3%)	38 (74.5%)	
Missing	13 (27.7%)	12 (27.9%)	13 (33.3%)	11 (21.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

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Table 2.6910: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N = 47)	RUX (N = 43)	MMB (N = 39)	RUX (N = 51)	p-value
EQ-5D-5L VAS Response Rate at Week 20					
Responder, n(%)	2 (4.3%)	5 (11.6%)	6 (15.4%)	1 (2.0%)	
Non-Responder, n(%)	45 (95.7%)	38 (88.4%)	33 (84.6%)	50 (98.0%)	
Non-missing	30 (63.8%)	27 (62.8%)	20 (51.3%)	36 (70.6%)	
Missing	15 (31.9%)	11 (25.6%)	13 (33.3%)	14 (27.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
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Table 2.6910: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N = 47)	RUX (N = 43)	MMB (N = 39)	RUX (N = 51)	p-value
EQ-5D-5L VAS Response Rate at Week 24					
Responder, n(%)	3 (6.4%)	6 (14.0%)	3 (7.7%)	2 (3.9%)	
Unadjusted Relative Risk (95% CI)	0.46 (0.12, 1.72)		1.96 (0.34, 11.18)		
p-value [1]	0.25		0.45		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Odds Ratio (95% CI)	0.42 (0.10, 1.80)		2.04 (0.32, 12.86)		
p-value [1]	0.24		0.45		
Unadjusted Absolute Risk Difference (95% CI)	-0.08 (-0.20, 0.05)		0.04 (-0.06, 0.14)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Non-Responder, n(%)	44 (93.6%)	37 (86.0%)	36 (92.3%)	49 (96.1%)	
Non-missing	32 (68.1%)	25 (58.1%)	20 (51.3%)	35 (68.6%)	
Missing	12 (25.5%)	12 (27.9%)	16 (41.0%)	14 (27.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
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Table 2.6909: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline TSS
Double-Blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 44)	RUX (N = 55)	MMB (N = 41)	RUX (N = 38)	p-value
EQ-5D-5L VAS Response Rate at Week 4					
Responder, n(%)	5 (11.4%)	9 (16.4%)	1 (2.4%)	3 (7.9%)	
Non-Responder, n(%)	39 (88.6%)	46 (83.6%)	40 (97.6%)	35 (92.1%)	
Non-missing	33 (75.0%)	37 (67.3%)	29 (70.7%)	25 (65.8%)	
Missing	6 (13.6%)	9 (16.4%)	11 (26.8%)	10 (26.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-vas-gba-improv.sas V.03.05 Output file: t-subgrp-vas-det-gba-tss.pdf 29AUG2023: 9:48

Table 2.6909: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline TSS
Double-Blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 44)	RUX (N = 55)	MMB (N = 41)	RUX (N = 38)	p-value
EQ-5D-5L VAS Response Rate at Week 8					
Responder, n(%)	5 (11.4%)	3 (5.5%)	4 (9.8%)	3 (7.9%)	
Non-Responder, n(%)	39 (88.6%)	52 (94.5%)	37 (90.2%)	35 (92.1%)	
Non-missing	30 (68.2%)	42 (76.4%)	24 (58.5%)	23 (60.5%)	
Missing	9 (20.5%)	10 (18.2%)	13 (31.7%)	12 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-vas-gba-improv.sas V.03.05 Output file: t-subgrp-vas-det-gba-tss.pdf 29AUG2023: 9:48

Table 2.6909: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline TSS
Double-Blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 44)	RUX (N = 55)	MMB (N = 41)	RUX (N = 38)	p-value
EQ-5D-5L VAS Response Rate at Week 12					
Responder, n(%)	7 (15.9%)	6 (10.9%)	2 (4.9%)	2 (5.3%)	
Non-Responder, n(%)	37 (84.1%)	49 (89.1%)	39 (95.1%)	36 (94.7%)	
Non-missing	29 (65.9%)	40 (72.7%)	25 (61.0%)	25 (65.8%)	
Missing	8 (18.2%)	9 (16.4%)	14 (34.1%)	11 (28.9%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-vas-gba-improv.sas V.03.05 Output file: t-subgrp-vas-det-gba-tss.pdf 29AUG2023: 9:48

Table 2.6909: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline TSS
Double-Blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 44)	RUX (N = 55)	MMB (N = 41)	RUX (N = 38)	p-value
EQ-5D-5L VAS Response Rate at Week 16					
Responder, n(%)	7 (15.9%)	5 (9.1%)	6 (14.6%)	2 (5.3%)	
Non-Responder, n(%)	37 (84.1%)	50 (90.9%)	35 (85.4%)	36 (94.7%)	
Non-missing	26 (59.1%)	37 (67.3%)	20 (48.8%)	26 (68.4%)	
Missing	11 (25.0%)	13 (23.6%)	15 (36.6%)	10 (26.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.6909: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline TSS
Double-Blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 44)	RUX (N = 55)	MMB (N = 41)	RUX (N = 38)	p-value
EQ-5D-5L VAS Response Rate at Week 20					
Responder, n(%)	3 (6.8%)	4 (7.3%)	5 (12.2%)	2 (5.3%)	
Non-Responder, n(%)	41 (93.2%)	51 (92.7%)	36 (87.8%)	36 (94.7%)	
Non-missing	30 (68.2%)	38 (69.1%)	19 (46.3%)	24 (63.2%)	
Missing	11 (25.0%)	13 (23.6%)	17 (41.5%)	12 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.6909: Analysis of Response Rate (deterioration, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline TSS
Double-Blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 44)	RUX (N = 55)	MMB (N = 41)	RUX (N = 38)	p-value
EQ-5D-5L VAS Response Rate at Week 24					
Responder, n(%)	3 (6.8%)	4 (7.3%)	3 (7.3%)	4 (10.5%)	
Unadjusted Relative Risk (95% CI)	0.94 (0.22, 3.97)		0.70 (0.17, 2.91)		
p-value [1]	0.93		0.62		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Unadjusted Odds Ratio (95% CI)	0.93 (0.20, 4.41)		0.67 (0.14, 3.22)		
p-value [1]	0.93		0.62		
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.11, 0.10)		-0.03 (-0.16, 0.09)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Non-Responder, n(%)	41 (93.2%)	51 (92.7%)	38 (92.7%)	34 (89.5%)	
Non-missing	32 (72.7%)	38 (69.1%)	19 (46.3%)	21 (55.3%)	
Missing	9 (20.5%)	13 (23.6%)	19 (46.3%)	13 (34.2%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.6802: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	RUX (N = 36)	MMB (N = 62)	RUX (N = 58)	p-value
EQ-5D-5L VAS Response Rate at Week 4					
Responder, n(%)	4 (16.7%)	6 (16.7%)	13 (21.0%)	19 (32.8%)	
Non-Responder, n(%)	20 (83.3%)	30 (83.3%)	49 (79.0%)	39 (67.2%)	
Non-missing	14 (58.3%)	22 (61.1%)	38 (61.3%)	28 (48.3%)	
Missing	6 (25.0%)	8 (22.2%)	11 (17.7%)	11 (19.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-vas-gba-improv.sas V.03.05 Output file: t-subgrp-vas-imp-gba-age.pdf 29AUG2023: 9:46

Table 2.6802: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	RUX (N = 36)	MMB (N = 62)	RUX (N = 58)	p-value
EQ-5D-5L VAS Response Rate at Week 8					
Responder, n(%)	4 (16.7%)	8 (22.2%)	18 (29.0%)	15 (25.9%)	
Non-Responder, n(%)	20 (83.3%)	28 (77.8%)	44 (71.0%)	43 (74.1%)	
Non-missing	12 (50.0%)	18 (50.0%)	30 (48.4%)	31 (53.4%)	
Missing	8 (33.3%)	10 (27.8%)	14 (22.6%)	12 (20.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-vas-gba-improv.sas V.03.05 Output file: t-subgrp-vas-imp-gba-age.pdf 29AUG2023: 9:46

Table 2.6802: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	RUX (N = 36)	MMB (N = 62)	RUX (N = 58)	p-value
EQ-5D-5L VAS Response Rate at Week 12					
Responder, n(%)	3 (12.5%)	7 (19.4%)	17 (27.4%)	15 (25.9%)	
Non-Responder, n(%)	21 (87.5%)	29 (80.6%)	45 (72.6%)	43 (74.1%)	
Non-missing	14 (58.3%)	21 (58.3%)	30 (48.4%)	31 (53.4%)	
Missing	7 (29.2%)	8 (22.2%)	15 (24.2%)	12 (20.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-vas-gba-improv.sas V.03.05 Output file: t-subgrp-vas-imp-gba-age.pdf 29AUG2023: 9:46

Table 2.6802: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	RUX (N = 36)	MMB (N = 62)	RUX (N = 58)	p-value
EQ-5D-5L VAS Response Rate at Week 16					
Responder, n(%)	0	7 (19.4%)	15 (24.2%)	13 (22.4%)	
Non-Responder, n(%)	24 (100.0%)	29 (80.6%)	47 (75.8%)	45 (77.6%)	
Non-missing	17 (70.8%)	19 (52.8%)	28 (45.2%)	32 (55.2%)	
Missing	7 (29.2%)	10 (27.8%)	19 (30.6%)	13 (22.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-vas-gba-improv.sas V.03.05 Output file: t-subgrp-vas-imp-gba-age.pdf 29AUG2023: 9:46

Table 2.6802: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	RUX (N = 36)	MMB (N = 62)	RUX (N = 58)	p-value
EQ-5D-5L VAS Response Rate at Week 20					
Responder, n(%)	2 (8.3%)	7 (19.4%)	14 (22.6%)	13 (22.4%)	
Non-Responder, n(%)	22 (91.7%)	29 (80.6%)	48 (77.4%)	45 (77.6%)	
Non-missing	14 (58.3%)	18 (50.0%)	28 (45.2%)	31 (53.4%)	
Missing	8 (33.3%)	11 (30.6%)	20 (32.3%)	14 (24.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-vas-gba-improv.sas V.03.05 Output file: t-subgrp-vas-imp-gba-age.pdf 29AUG2023: 9:46

Table 2.6802: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	RUX (N = 36)	MMB (N = 62)	RUX (N = 58)	p-value
EQ-5D-5L VAS Response Rate at Week 24					
Responder, n(%)	1 (4.2%)	6 (16.7%)	19 (30.6%)	15 (25.9%)	
Unadjusted Inverse Relative Risk (95% CI)	4.00 (0.51, 31.17)		0.84 (0.48, 1.50)		
p-value [1]	0.19		0.56		
Unadjusted interaction test for Treatment*Age Group [3]					0.080
Unadjusted Inverse Odds Ratio (95% CI)	4.60 (0.52, 40.92)		0.79 (0.36, 1.75)		
p-value [1]	0.17		0.56		
Unadjusted Absolute Risk Difference (95% CI)	-0.13 (-0.27, 0.02)		0.05 (-0.11, 0.21)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Age Group [3]					NE
Non-Responder, n(%)	23 (95.8%)	30 (83.3%)	43 (69.4%)	43 (74.1%)	
Non-missing	14 (58.3%)	19 (52.8%)	24 (38.7%)	28 (48.3%)	
Missing	9 (37.5%)	11 (30.6%)	19 (30.6%)	15 (25.9%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.6804: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Region
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N = 53)	RUX (N = 51)	MMB (N = 33)	RUX (N = 43)	p-value
EQ-5D-5L VAS Response Rate at Week 4					
Responder, n(%)	9 (17.0%)	16 (31.4%)	8 (24.2%)	9 (20.9%)	
Non-Responder, n(%)	44 (83.0%)	35 (68.6%)	25 (75.8%)	34 (79.1%)	
Non-missing	29 (54.7%)	21 (41.2%)	23 (69.7%)	29 (67.4%)	
Missing	15 (28.3%)	14 (27.5%)	2 (6.1%)	5 (11.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-vas-gba-improv.sas V.03.05 Output file: t-subgrp-vas-imp-gba-geo.pdf 29AUG2023: 9:46

Table 2.6804: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Region
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N = 53)	RUX (N = 51)	MMB (N = 33)	RUX (N = 43)	p-value
EQ-5D-5L VAS Response Rate at Week 8					
Responder, n(%)	14 (26.4%)	13 (25.5%)	8 (24.2%)	10 (23.3%)	
Non-Responder, n(%)	39 (73.6%)	38 (74.5%)	25 (75.8%)	33 (76.7%)	
Non-missing	22 (41.5%)	23 (45.1%)	20 (60.6%)	26 (60.5%)	
Missing	17 (32.1%)	15 (29.4%)	5 (15.2%)	7 (16.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
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Table 2.6804: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Region
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N = 53)	RUX (N = 51)	MMB (N = 33)	RUX (N = 43)	p-value
EQ-5D-5L VAS Response Rate at Week 12					
Responder, n(%)	11 (20.8%)	13 (25.5%)	9 (27.3%)	9 (20.9%)	
Non-Responder, n(%)	42 (79.2%)	38 (74.5%)	24 (72.7%)	34 (79.1%)	
Non-missing	24 (45.3%)	23 (45.1%)	20 (60.6%)	29 (67.4%)	
Missing	18 (34.0%)	15 (29.4%)	4 (12.1%)	5 (11.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
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Table 2.6804: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Region
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N = 53)	RUX (N = 51)	MMB (N = 33)	RUX (N = 43)	p-value
EQ-5D-5L VAS Response Rate at Week 16					
Responder, n(%)	8 (15.1%)	12 (23.5%)	7 (21.2%)	8 (18.6%)	
Non-Responder, n(%)	45 (84.9%)	39 (76.5%)	26 (78.8%)	35 (81.4%)	
Non-missing	25 (47.2%)	22 (43.1%)	20 (60.6%)	29 (67.4%)	
Missing	20 (37.7%)	17 (33.3%)	6 (18.2%)	6 (14.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
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Table 2.6804: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Region
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N = 53)	RUX (N = 51)	MMB (N = 33)	RUX (N = 43)	p-value
EQ-5D-5L VAS Response Rate at Week 20					
Responder, n(%)	9 (17.0%)	11 (21.6%)	7 (21.2%)	9 (20.9%)	
Non-Responder, n(%)	44 (83.0%)	40 (78.4%)	26 (78.8%)	34 (79.1%)	
Non-missing	21 (39.6%)	21 (41.2%)	21 (63.6%)	28 (65.1%)	
Missing	23 (43.4%)	19 (37.3%)	5 (15.2%)	6 (14.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

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Table 2.6804: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Region
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N = 53)	RUX (N = 51)	MMB (N = 33)	RUX (N = 43)	p-value
EQ-5D-5L VAS Response Rate at Week 24					
Responder, n(%)	10 (18.9%)	11 (21.6%)	10 (30.3%)	10 (23.3%)	
Unadjusted Inverse Relative Risk (95% CI)	1.14 (0.53, 2.46)		0.77 (0.36, 1.62)		
p-value [1]	0.73		0.49		
Unadjusted interaction test for Treatment*Region [3]					0.47
Unadjusted Inverse Odds Ratio (95% CI)	1.18 (0.45, 3.08)		0.70 (0.25, 1.94)		
p-value [1]	0.73		0.49		
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.18, 0.13)		0.07 (-0.13, 0.27)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Region [3]					NE
Non-Responder, n(%)	43 (81.1%)	40 (78.4%)	23 (69.7%)	33 (76.7%)	
Non-missing	21 (39.6%)	22 (43.1%)	17 (51.5%)	25 (58.1%)	
Missing	22 (41.5%)	18 (35.3%)	6 (18.2%)	8 (18.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
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Table 2.6807: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 28)	RUX (N = 21)	MMB (N = 58)	RUX (N = 73)	p-value
EQ-5D-5L VAS Response Rate at Week 4					
Responder, n(%)	3 (10.7%)	5 (23.8%)	14 (24.1%)	20 (27.4%)	
Non-Responder, n(%)	25 (89.3%)	16 (76.2%)	44 (75.9%)	53 (72.6%)	
Non-missing	19 (67.9%)	14 (66.7%)	33 (56.9%)	36 (49.3%)	
Missing	6 (21.4%)	2 (9.5%)	11 (19.0%)	17 (23.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
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Table 2.6807: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 28)	RUX (N = 21)	MMB (N = 58)	RUX (N = 73)	p-value
EQ-5D-5L VAS Response Rate at Week 8					
Responder, n(%)	7 (25.0%)	6 (28.6%)	15 (25.9%)	17 (23.3%)	
Non-Responder, n(%)	21 (75.0%)	15 (71.4%)	43 (74.1%)	56 (76.7%)	
Non-missing	12 (42.9%)	13 (61.9%)	30 (51.7%)	36 (49.3%)	
Missing	9 (32.1%)	2 (9.5%)	13 (22.4%)	20 (27.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

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Table 2.6807: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 28)	RUX (N = 21)	MMB (N = 58)	RUX (N = 73)	p-value
EQ-5D-5L VAS Response Rate at Week 12					
Responder, n(%)	6 (21.4%)	5 (23.8%)	14 (24.1%)	17 (23.3%)	
Non-Responder, n(%)	22 (78.6%)	16 (76.2%)	44 (75.9%)	56 (76.7%)	
Non-missing	12 (42.9%)	12 (57.1%)	32 (55.2%)	40 (54.8%)	
Missing	10 (35.7%)	4 (19.0%)	12 (20.7%)	16 (21.9%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

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Table 2.6807: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 28)	RUX (N = 21)	MMB (N = 58)	RUX (N = 73)	p-value
EQ-5D-5L VAS Response Rate at Week 16					
Responder, n(%)	2 (7.1%)	5 (23.8%)	13 (22.4%)	15 (20.5%)	
Non-Responder, n(%)	26 (92.9%)	16 (76.2%)	45 (77.6%)	58 (79.5%)	
Non-missing	14 (50.0%)	12 (57.1%)	31 (53.4%)	39 (53.4%)	
Missing	12 (42.9%)	4 (19.0%)	14 (24.1%)	19 (26.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

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Table 2.6807: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 28)	RUX (N = 21)	MMB (N = 58)	RUX (N = 73)	p-value
EQ-5D-5L VAS Response Rate at Week 20					
Responder, n(%)	5 (17.9%)	3 (14.3%)	11 (19.0%)	17 (23.3%)	
Non-Responder, n(%)	23 (82.1%)	18 (85.7%)	47 (81.0%)	56 (76.7%)	
Non-missing	13 (46.4%)	14 (66.7%)	29 (50.0%)	35 (47.9%)	
Missing	10 (35.7%)	4 (19.0%)	18 (31.0%)	21 (28.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

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Table 2.6807: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 28)	RUX (N = 21)	MMB (N = 58)	RUX (N = 73)	p-value
EQ-5D-5L VAS Response Rate at Week 24					
Responder, n(%)	5 (17.9%)	4 (19.0%)	15 (25.9%)	17 (23.3%)	
Unadjusted Inverse Relative Risk (95% CI)	1.07 (0.33, 3.50)		0.90 (0.49, 1.65)		
p-value [1]	0.92		0.73		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.80
Unadjusted Inverse Odds Ratio (95% CI)	1.08 (0.25, 4.64)		0.87 (0.39, 1.94)		
p-value [1]	0.92		0.73		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.23, 0.21)		0.03 (-0.12, 0.17)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.06 (0.33, 3.36)		NE		
p-value [2]	0.92		NE		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE
Non-Responder, n(%)	23 (82.1%)	17 (81.0%)	43 (74.1%)	56 (76.7%)	
Non-missing	13 (46.4%)	12 (57.1%)	25 (43.1%)	35 (47.9%)	
Missing	10 (35.7%)	5 (23.8%)	18 (31.0%)	21 (28.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
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Table 2.6806: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline
IPSS Two-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 28)	RUX (N = 24)	MMB (N = 58)	RUX (N = 70)	p-value
EQ-5D-5L VAS Response Rate at Week 4					
Responder, n(%)	5 (17.9%)	8 (33.3%)	12 (20.7%)	17 (24.3%)	
Non-Responder, n(%)	23 (82.1%)	16 (66.7%)	46 (79.3%)	53 (75.7%)	
Non-missing	15 (53.6%)	11 (45.8%)	37 (63.8%)	39 (55.7%)	
Missing	8 (28.6%)	5 (20.8%)	9 (15.5%)	14 (20.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-vas-gba-improv.sas V.03.05 Output file: t-subgrp-vas-imp-gba-ip2.pdf 29AUG2023: 9:46

Table 2.6806: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline IPSS Two-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 28)	RUX (N = 24)	MMB (N = 58)	RUX (N = 70)	p-value
EQ-5D-5L VAS Response Rate at Week 8					
Responder, n(%)	7 (25.0%)	7 (29.2%)	15 (25.9%)	16 (22.9%)	
Non-Responder, n(%)	21 (75.0%)	17 (70.8%)	43 (74.1%)	54 (77.1%)	
Non-missing	12 (42.9%)	11 (45.8%)	30 (51.7%)	38 (54.3%)	
Missing	9 (32.1%)	6 (25.0%)	13 (22.4%)	16 (22.9%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-vas-gba-improv.sas V.03.05 Output file: t-subgrp-vas-imp-gba-ip2.pdf 29AUG2023: 9:46

Table 2.6806: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline
IPSS Two-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 28)	RUX (N = 24)	MMB (N = 58)	RUX (N = 70)	p-value
EQ-5D-5L VAS Response Rate at Week 12					
Responder, n(%)	4 (14.3%)	5 (20.8%)	16 (27.6%)	17 (24.3%)	
Non-Responder, n(%)	24 (85.7%)	19 (79.2%)	42 (72.4%)	53 (75.7%)	
Non-missing	15 (53.6%)	14 (58.3%)	29 (50.0%)	38 (54.3%)	
Missing	9 (32.1%)	5 (20.8%)	13 (22.4%)	15 (21.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
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Table 2.6806: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline
IPSS Two-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 28)	RUX (N = 24)	MMB (N = 58)	RUX (N = 70)	p-value
EQ-5D-5L VAS Response Rate at Week 16					
Responder, n(%)	3 (10.7%)	4 (16.7%)	12 (20.7%)	16 (22.9%)	
Non-Responder, n(%)	25 (89.3%)	20 (83.3%)	46 (79.3%)	54 (77.1%)	
Non-missing	15 (53.6%)	13 (54.2%)	30 (51.7%)	38 (54.3%)	
Missing	10 (35.7%)	7 (29.2%)	16 (27.6%)	16 (22.9%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-vas-gba-improv.sas V.03.05 Output file: t-subgrp-vas-imp-gba-ip2.pdf 29AUG2023: 9:46

Table 2.6806: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline
IPSS Two-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 28)	RUX (N = 24)	MMB (N = 58)	RUX (N = 70)	p-value
EQ-5D-5L VAS Response Rate at Week 20					
Responder, n(%)	4 (14.3%)	4 (16.7%)	12 (20.7%)	16 (22.9%)	
Non-Responder, n(%)	24 (85.7%)	20 (83.3%)	46 (79.3%)	54 (77.1%)	
Non-missing	14 (50.0%)	12 (50.0%)	28 (48.3%)	37 (52.9%)	
Missing	10 (35.7%)	8 (33.3%)	18 (31.0%)	17 (24.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-vas-gba-improv.sas V.03.05 Output file: t-subgrp-vas-imp-gba-ip2.pdf 29AUG2023: 9:46

Table 2.6806: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline
IPSS Two-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 28)	RUX (N = 24)	MMB (N = 58)	RUX (N = 70)	p-value
EQ-5D-5L VAS Response Rate at Week 24					
Responder, n(%)	4 (14.3%)	4 (16.7%)	16 (27.6%)	17 (24.3%)	
Unadjusted Inverse Relative Risk (95% CI)	1.17 (0.33, 4.17)		0.88 (0.49, 1.58)		
p-value [1]	0.81		0.67		
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.70
Unadjusted Inverse Odds Ratio (95% CI)	1.20 (0.27, 5.42)		0.84 (0.38, 1.86)		
p-value [1]	0.81		0.67		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.22, 0.17)		0.03 (-0.12, 0.19)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*IPSS 2-Level Risk [3]					NE
Non-Responder, n(%)	24 (85.7%)	20 (83.3%)	42 (72.4%)	53 (75.7%)	
Non-missing	13 (46.4%)	13 (54.2%)	25 (43.1%)	34 (48.6%)	
Missing	11 (39.3%)	7 (29.2%)	17 (29.3%)	19 (27.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-vas-gba-improv.sas V.03.05 Output file: t-subgrp-vas-imp-gba-ip2.pdf 29AUG2023: 9:46

Table 2.6805: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 2)	RUX (N = 4)	MMB (N = 26)	RUX (N = 20)
EQ-5D-5L VAS Response Rate at Week 4				
Responder, n(%)	0	0	5 (19.2%)	8 (40.0%)
Non-Responder, n(%)	2 (100.0%)	4 (100.0%)	21 (80.8%)	12 (60.0%)
Non-missing	1 (50.0%)	3 (75.0%)	14 (53.8%)	8 (40.0%)
Missing	1 (50.0%)	1 (25.0%)	7 (26.9%)	4 (20.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-vas-gba-improv.sas V.03.05 Output file: t-subgrp-vas-imp-gba-ip3.pdf 29AUG2023: 9:46

Table 2.6805: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline
IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 58)	RUX (N = 70)	p-value
EQ-5D-5L VAS Response Rate at Week 4			
Responder, n(%)	12 (20.7%)	17 (24.3%)	
Non-Responder, n(%)	46 (79.3%)	53 (75.7%)	
Non-missing	37 (63.8%)	39 (55.7%)	
Missing	9 (15.5%)	14 (20.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.6805: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 2)	RUX (N = 4)	MMB (N = 26)	RUX (N = 20)
EQ-5D-5L VAS Response Rate at Week 8				
Responder, n(%)	0	0	7 (26.9%)	7 (35.0%)
Non-Responder, n(%)	2 (100.0%)	4 (100.0%)	19 (73.1%)	13 (65.0%)
Non-missing	1 (50.0%)	3 (75.0%)	11 (42.3%)	8 (40.0%)
Missing	1 (50.0%)	1 (25.0%)	8 (30.8%)	5 (25.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.6805: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline
IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 58)	RUX (N = 70)	p-value
EQ-5D-5L VAS Response Rate at Week 8			
Responder, n(%)	15 (25.9%)	16 (22.9%)	
Non-Responder, n(%)	43 (74.1%)	54 (77.1%)	
Non-missing	30 (51.7%)	38 (54.3%)	
Missing	13 (22.4%)	16 (22.9%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.6805: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline
IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 2)	RUX (N = 4)	MMB (N = 26)	RUX (N = 20)
EQ-5D-5L VAS Response Rate at Week 12				
Responder, n(%)	0	0	4 (15.4%)	5 (25.0%)
Non-Responder, n(%)	2 (100.0%)	4 (100.0%)	22 (84.6%)	15 (75.0%)
Non-missing	1 (50.0%)	3 (75.0%)	14 (53.8%)	11 (55.0%)
Missing	1 (50.0%)	1 (25.0%)	8 (30.8%)	4 (20.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.6805: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline
IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 58)	RUX (N = 70)	p-value
EQ-5D-5L VAS Response Rate at Week 12			
Responder, n(%)	16 (27.6%)	17 (24.3%)	
Non-Responder, n(%)	42 (72.4%)	53 (75.7%)	
Non-missing	29 (50.0%)	38 (54.3%)	
Missing	13 (22.4%)	15 (21.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.6805: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline
IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 2)	RUX (N = 4)	MMB (N = 26)	RUX (N = 20)
EQ-5D-5L VAS Response Rate at Week 16				
Responder, n(%)	0	0	3 (11.5%)	4 (20.0%)
Non-Responder, n(%)	2 (100.0%)	4 (100.0%)	23 (88.5%)	16 (80.0%)
Non-missing	1 (50.0%)	3 (75.0%)	14 (53.8%)	10 (50.0%)
Missing	1 (50.0%)	1 (25.0%)	9 (34.6%)	6 (30.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.6805: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline
IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 58)	RUX (N = 70)	p-value
EQ-5D-5L VAS Response Rate at Week 16			
Responder, n(%)	12 (20.7%)	16 (22.9%)	
Non-Responder, n(%)	46 (79.3%)	54 (77.1%)	
Non-missing	30 (51.7%)	38 (54.3%)	
Missing	16 (27.6%)	16 (22.9%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.6805: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline
IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 2)	RUX (N = 4)	MMB (N = 26)	RUX (N = 20)
EQ-5D-5L VAS Response Rate at Week 20				
Responder, n(%)	0	0	4 (15.4%)	4 (20.0%)
Non-Responder, n(%)	2 (100.0%)	4 (100.0%)	22 (84.6%)	16 (80.0%)
Non-missing	1 (50.0%)	2 (50.0%)	13 (50.0%)	10 (50.0%)
Missing	1 (50.0%)	2 (50.0%)	9 (34.6%)	6 (30.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

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Table 2.6805: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline
IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 58)	RUX (N = 70)	p-value
EQ-5D-5L VAS Response Rate at Week 20			
Responder, n(%)	12 (20.7%)	16 (22.9%)	
Non-Responder, n(%)	46 (79.3%)	54 (77.1%)	
Non-missing	28 (48.3%)	37 (52.9%)	
Missing	18 (31.0%)	17 (24.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.6805: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline
IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 2)	RUX (N = 4)	MMB (N = 26)	RUX (N = 20)
EQ-5D-5L VAS Response Rate at Week 24				
Responder, n(%)	0	0	4 (15.4%)	4 (20.0%)
Unadjusted Inverse Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Non-Responder, n(%)	2 (100.0%)	4 (100.0%)	22 (84.6%)	16 (80.0%)
Non-missing	1 (50.0%)	3 (75.0%)	12 (46.2%)	10 (50.0%)
Missing	1 (50.0%)	1 (25.0%)	10 (38.5%)	6 (30.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.6805: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 58)	RUX (N = 70)	p-value
EQ-5D-5L VAS Response Rate at Week 24			
Responder, n(%)	16 (27.6%)	17 (24.3%)	
Unadjusted Inverse Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	42 (72.4%)	53 (75.7%)	
Non-missing	25 (43.1%)	34 (48.6%)	
Missing	17 (29.3%)	19 (27.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.6808: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline
MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 59)	RUX (N = 54)	MMB (N = 16)	RUX (N = 28)
EQ-5D-5L VAS Response Rate at Week 4				
Responder, n(%)	10 (16.9%)	16 (29.6%)	5 (31.3%)	9 (32.1%)
Non-Responder, n(%)	49 (83.1%)	38 (70.4%)	11 (68.8%)	19 (67.9%)
Non-missing	40 (67.8%)	33 (61.1%)	6 (37.5%)	10 (35.7%)
Missing	9 (15.3%)	5 (9.3%)	5 (31.3%)	9 (32.1%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
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Table 2.6808: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline
MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 11)	RUX (N = 12)	p-value
EQ-5D-5L VAS Response Rate at Week 4			
Responder, n(%)	2 (18.2%)	0	
Non-Responder, n(%)	9 (81.8%)	12 (100.0%)	
Non-missing	6 (54.5%)	7 (58.3%)	
Missing	3 (27.3%)	5 (41.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
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Table 2.6808: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline
MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 59)	RUX (N = 54)	MMB (N = 16)	RUX (N = 28)
EQ-5D-5L VAS Response Rate at Week 8				
Responder, n(%)	14 (23.7%)	15 (27.8%)	3 (18.8%)	7 (25.0%)
Non-Responder, n(%)	45 (76.3%)	39 (72.2%)	13 (81.3%)	21 (75.0%)
Non-missing	32 (54.2%)	31 (57.4%)	8 (50.0%)	12 (42.9%)
Missing	13 (22.0%)	8 (14.8%)	5 (31.3%)	9 (32.1%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
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Table 2.6808: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 11)	RUX (N = 12)	p-value
EQ-5D-5L VAS Response Rate at Week 8			
Responder, n(%)	5 (45.5%)	1 (8.3%)	
Non-Responder, n(%)	6 (54.5%)	11 (91.7%)	
Non-missing	2 (18.2%)	6 (50.0%)	
Missing	4 (36.4%)	5 (41.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
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Table 2.6808: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline
MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 59)	RUX (N = 54)	MMB (N = 16)	RUX (N = 28)
EQ-5D-5L VAS Response Rate at Week 12				
Responder, n(%)	13 (22.0%)	15 (27.8%)	4 (25.0%)	6 (21.4%)
Non-Responder, n(%)	46 (78.0%)	39 (72.2%)	12 (75.0%)	22 (78.6%)
Non-missing	34 (57.6%)	34 (63.0%)	6 (37.5%)	12 (42.9%)
Missing	12 (20.3%)	5 (9.3%)	6 (37.5%)	10 (35.7%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
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Table 2.6808: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline
MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 11)	RUX (N = 12)	p-value
EQ-5D-5L VAS Response Rate at Week 12			
Responder, n(%)	3 (27.3%)	1 (8.3%)	
Non-Responder, n(%)	8 (72.7%)	11 (91.7%)	
Non-missing	4 (36.4%)	6 (50.0%)	
Missing	4 (36.4%)	5 (41.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
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Table 2.6808: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline
MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 59)	RUX (N = 54)	MMB (N = 16)	RUX (N = 28)
EQ-5D-5L VAS Response Rate at Week 16				
Responder, n(%)	12 (20.3%)	13 (24.1%)	2 (12.5%)	4 (14.3%)
Non-Responder, n(%)	47 (79.7%)	41 (75.9%)	14 (87.5%)	24 (85.7%)
Non-missing	32 (54.2%)	33 (61.1%)	8 (50.0%)	13 (46.4%)
Missing	15 (25.4%)	8 (14.8%)	6 (37.5%)	11 (39.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-vas-gba-improv.sas V.03.05 Output file: t-subgrp-vas-imp-gba-mf.pdf 29AUG2023: 9:47

Table 2.6808: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 11)	RUX (N = 12)	p-value
EQ-5D-5L VAS Response Rate at Week 16			
Responder, n(%)	1 (9.1%)	3 (25.0%)	
Non-Responder, n(%)	10 (90.9%)	9 (75.0%)	
Non-missing	5 (45.5%)	5 (41.7%)	
Missing	5 (45.5%)	4 (33.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
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Table 2.6808: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline
MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 59)	RUX (N = 54)	MMB (N = 16)	RUX (N = 28)
EQ-5D-5L VAS Response Rate at Week 20				
Responder, n(%)	8 (13.6%)	14 (25.9%)	4 (25.0%)	6 (21.4%)
Non-Responder, n(%)	51 (86.4%)	40 (74.1%)	12 (75.0%)	22 (78.6%)
Non-missing	33 (55.9%)	31 (57.4%)	5 (31.3%)	11 (39.3%)
Missing	18 (30.5%)	9 (16.7%)	7 (43.8%)	11 (39.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-vas-gba-improv.sas V.03.05 Output file: t-subgrp-vas-imp-gba-mf.pdf 29AUG2023: 9:47

Table 2.6808: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 11)	RUX (N = 12)	p-value
EQ-5D-5L VAS Response Rate at Week 20			
Responder, n(%)	4 (36.4%)	0	
Non-Responder, n(%)	7 (63.6%)	12 (100.0%)	
Non-missing	4 (36.4%)	7 (58.3%)	
Missing	3 (27.3%)	5 (41.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-vas-gba-improv.sas V.03.05 Output file: t-subgrp-vas-imp-gba-mf.pdf 29AUG2023: 9:47

Table 2.6808: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 59)	RUX (N = 54)	MMB (N = 16)	RUX (N = 28)
EQ-5D-5L VAS Response Rate at Week 24				
Responder, n(%)	13 (22.0%)	15 (27.8%)	4 (25.0%)	5 (17.9%)
Unadjusted Inverse Relative Risk (95% CI)	1.26 (0.66, 2.40)		0.71 (0.22, 2.28)	
p-value [1]	0.48		0.57	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	1.36 (0.58, 3.20)		0.65 (0.15, 2.89)	
p-value [1]	0.48		0.57	
Unadjusted Absolute Risk Difference (95% CI)	-0.06 (-0.22, 0.10)		0.07 (-0.18, 0.33)	
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE	
p-value [2]	NE		NE	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	46 (78.0%)	39 (72.2%)	12 (75.0%)	23 (82.1%)
Non-missing	29 (49.2%)	29 (53.7%)	5 (31.3%)	12 (42.9%)
Missing	17 (28.8%)	10 (18.5%)	7 (43.8%)	11 (39.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.6808: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 11)	RUX (N = 12)	p-value
EQ-5D-5L VAS Response Rate at Week 24			
Responder, n(%)	3 (27.3%)	1 (8.3%)	
Unadjusted Inverse Relative Risk (95% CI)	0.31 (0.04, 2.52)		
p-value [1]	0.27		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.33
Unadjusted Inverse Odds Ratio (95% CI)	0.24 (0.02, 2.78)		
p-value [1]	0.25		
Unadjusted Absolute Risk Difference (95% CI)	0.19 (-0.12, 0.50)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NE
Non-Responder, n(%)	8 (72.7%)	11 (91.7%)	
Non-missing	4 (36.4%)	6 (50.0%)	
Missing	4 (36.4%)	5 (41.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-vas-gba-improv.sas V.03.05 Output file: t-subgrp-vas-imp-gba-mf.pdf 29AUG2023: 9:47

Table 2.6803: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 50)	RUX (N = 56)	MMB (N = 36)	RUX (N = 38)	p-value
EQ-5D-5L VAS Response Rate at Week 4					
Responder, n(%)	11 (22.0%)	17 (30.4%)	6 (16.7%)	8 (21.1%)	
Non-Responder, n(%)	39 (78.0%)	39 (69.6%)	30 (83.3%)	30 (78.9%)	
Non-missing	30 (60.0%)	31 (55.4%)	22 (61.1%)	19 (50.0%)	
Missing	9 (18.0%)	8 (14.3%)	8 (22.2%)	11 (28.9%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-vas-gba-improv.sas V.03.05 Output file: t-subgrp-vas-imp-gba-sex.pdf 29AUG2023: 9:46

Table 2.6803: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 50)	RUX (N = 56)	MMB (N = 36)	RUX (N = 38)	p-value
EQ-5D-5L VAS Response Rate at Week 8					
Responder, n(%)	14 (28.0%)	18 (32.1%)	8 (22.2%)	5 (13.2%)	
Non-Responder, n(%)	36 (72.0%)	38 (67.9%)	28 (77.8%)	33 (86.8%)	
Non-missing	24 (48.0%)	28 (50.0%)	18 (50.0%)	21 (55.3%)	
Missing	12 (24.0%)	10 (17.9%)	10 (27.8%)	12 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-vas-gba-improv.sas V.03.05 Output file: t-subgrp-vas-imp-gba-sex.pdf 29AUG2023: 9:46

Table 2.6803: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 50)	RUX (N = 56)	MMB (N = 36)	RUX (N = 38)	p-value
EQ-5D-5L VAS Response Rate at Week 12					
Responder, n(%)	14 (28.0%)	15 (26.8%)	6 (16.7%)	7 (18.4%)	
Non-Responder, n(%)	36 (72.0%)	41 (73.2%)	30 (83.3%)	31 (81.6%)	
Non-missing	25 (50.0%)	31 (55.4%)	19 (52.8%)	21 (55.3%)	
Missing	11 (22.0%)	10 (17.9%)	11 (30.6%)	10 (26.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-vas-gba-improv.sas V.03.05 Output file: t-subgrp-vas-imp-gba-sex.pdf 29AUG2023: 9:46

Table 2.6803: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 50)	RUX (N = 56)	MMB (N = 36)	RUX (N = 38)	p-value
EQ-5D-5L VAS Response Rate at Week 16					
Responder, n(%)	10 (20.0%)	16 (28.6%)	5 (13.9%)	4 (10.5%)	
Non-Responder, n(%)	40 (80.0%)	40 (71.4%)	31 (86.1%)	34 (89.5%)	
Non-missing	25 (50.0%)	29 (51.8%)	20 (55.6%)	22 (57.9%)	
Missing	15 (30.0%)	11 (19.6%)	11 (30.6%)	12 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-vas-gba-improv.sas V.03.05 Output file: t-subgrp-vas-imp-gba-sex.pdf 29AUG2023: 9:46

Table 2.6803: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 50)	RUX (N = 56)	MMB (N = 36)	RUX (N = 38)	p-value
EQ-5D-5L VAS Response Rate at Week 20					
Responder, n(%)	11 (22.0%)	16 (28.6%)	5 (13.9%)	4 (10.5%)	
Non-Responder, n(%)	39 (78.0%)	40 (71.4%)	31 (86.1%)	34 (89.5%)	
Non-missing	23 (46.0%)	28 (50.0%)	19 (52.8%)	21 (55.3%)	
Missing	16 (32.0%)	12 (21.4%)	12 (33.3%)	13 (34.2%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-vas-gba-improv.sas V.03.05 Output file: t-subgrp-vas-imp-gba-sex.pdf 29AUG2023: 9:46

Table 2.6803: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 50)	RUX (N = 56)	MMB (N = 36)	RUX (N = 38)	p-value
EQ-5D-5L VAS Response Rate at Week 24					
Responder, n(%)	13 (26.0%)	13 (23.2%)	7 (19.4%)	8 (21.1%)	
Unadjusted Inverse Relative Risk (95% CI)	0.89 (0.46, 1.74)		1.08 (0.44, 2.68)		
p-value [1]	0.74		0.86		
Unadjusted interaction test for Treatment*Gender [3]					0.74
Unadjusted Inverse Odds Ratio (95% CI)	0.86 (0.35, 2.09)		1.10 (0.35, 3.44)		
p-value [1]	0.74		0.86		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.14, 0.19)		-0.02 (-0.20, 0.17)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Gender [3]					NE
Non-Responder, n(%)	37 (74.0%)	43 (76.8%)	29 (80.6%)	30 (78.9%)	
Non-missing	22 (44.0%)	29 (51.8%)	16 (44.4%)	18 (47.4%)	
Missing	15 (30.0%)	14 (25.0%)	13 (36.1%)	12 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.6810: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N = 47)	RUX (N = 43)	MMB (N = 39)	RUX (N = 51)	p-value
EQ-5D-5L VAS Response Rate at Week 4					
Responder, n(%)	11 (23.4%)	13 (30.2%)	6 (15.4%)	12 (23.5%)	
Non-Responder, n(%)	36 (76.6%)	30 (69.8%)	33 (84.6%)	39 (76.5%)	
Non-missing	29 (61.7%)	21 (48.8%)	23 (59.0%)	29 (56.9%)	
Missing	7 (14.9%)	9 (20.9%)	10 (25.6%)	10 (19.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-vas-gba-improv.sas V.03.05 Output file: t-subgrp-vas-imp-gba-svb.pdf 29AUG2023: 9:47

Table 2.6810: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N = 47)	RUX (N = 43)	MMB (N = 39)	RUX (N = 51)	p-value
EQ-5D-5L VAS Response Rate at Week 8					
Responder, n(%)	13 (27.7%)	10 (23.3%)	9 (23.1%)	13 (25.5%)	
Non-Responder, n(%)	34 (72.3%)	33 (76.7%)	30 (76.9%)	38 (74.5%)	
Non-missing	23 (48.9%)	22 (51.2%)	19 (48.7%)	27 (52.9%)	
Missing	11 (23.4%)	11 (25.6%)	11 (28.2%)	11 (21.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-vas-gba-improv.sas V.03.05 Output file: t-subgrp-vas-imp-gba-svb.pdf 29AUG2023: 9:47

Table 2.6810: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N = 47)	RUX (N = 43)	MMB (N = 39)	RUX (N = 51)	p-value
EQ-5D-5L VAS Response Rate at Week 12					
Responder, n(%)	9 (19.1%)	9 (20.9%)	11 (28.2%)	13 (25.5%)	
Non-Responder, n(%)	38 (80.9%)	34 (79.1%)	28 (71.8%)	38 (74.5%)	
Non-missing	27 (57.4%)	24 (55.8%)	17 (43.6%)	28 (54.9%)	
Missing	11 (23.4%)	10 (23.3%)	11 (28.2%)	10 (19.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-vas-gba-improv.sas V.03.05 Output file: t-subgrp-vas-imp-gba-svb.pdf 29AUG2023: 9:47

Table 2.6810: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N = 47)	RUX (N = 43)	MMB (N = 39)	RUX (N = 51)	p-value
EQ-5D-5L VAS Response Rate at Week 16					
Responder, n(%)	8 (17.0%)	7 (16.3%)	7 (17.9%)	13 (25.5%)	
Non-Responder, n(%)	39 (83.0%)	36 (83.7%)	32 (82.1%)	38 (74.5%)	
Non-missing	26 (55.3%)	24 (55.8%)	19 (48.7%)	27 (52.9%)	
Missing	13 (27.7%)	12 (27.9%)	13 (33.3%)	11 (21.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-vas-gba-improv.sas V.03.05 Output file: t-subgrp-vas-imp-gba-svb.pdf 29AUG2023: 9:47

Table 2.6810: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N = 47)	RUX (N = 43)	MMB (N = 39)	RUX (N = 51)	p-value
EQ-5D-5L VAS Response Rate at Week 20					
Responder, n(%)	11 (23.4%)	9 (20.9%)	5 (12.8%)	11 (21.6%)	
Non-Responder, n(%)	36 (76.6%)	34 (79.1%)	34 (87.2%)	40 (78.4%)	
Non-missing	21 (44.7%)	23 (53.5%)	21 (53.8%)	26 (51.0%)	
Missing	15 (31.9%)	11 (25.6%)	13 (33.3%)	14 (27.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-vas-gba-improv.sas V.03.05 Output file: t-subgrp-vas-imp-gba-svb.pdf 29AUG2023: 9:47

Table 2.6810: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N = 47)	RUX (N = 43)	MMB (N = 39)	RUX (N = 51)	p-value
EQ-5D-5L VAS Response Rate at Week 24					
Responder, n(%)	13 (27.7%)	12 (27.9%)	7 (17.9%)	9 (17.6%)	
Unadjusted Inverse Relative Risk (95% CI)	1.01 (0.52, 1.97)		0.98 (0.40, 2.41)		
p-value [1]	0.98		0.97		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.96
Unadjusted Inverse Odds Ratio (95% CI)	1.01 (0.40, 2.55)		0.98 (0.33, 2.91)		
p-value [1]	0.98		0.97		
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.19, 0.18)		0.00 (-0.16, 0.16)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NE
Non-Responder, n(%)	34 (72.3%)	31 (72.1%)	32 (82.1%)	42 (82.4%)	
Non-missing	22 (46.8%)	19 (44.2%)	16 (41.0%)	28 (54.9%)	
Missing	12 (25.5%)	12 (27.9%)	16 (41.0%)	14 (27.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.6809: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline TSS
Double-Blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 44)	RUX (N = 55)	MMB (N = 41)	RUX (N = 38)	p-value
EQ-5D-5L VAS Response Rate at Week 4					
Responder, n(%)	6 (13.6%)	16 (29.1%)	11 (26.8%)	8 (21.1%)	
Non-Responder, n(%)	38 (86.4%)	39 (70.9%)	30 (73.2%)	30 (78.9%)	
Non-missing	32 (72.7%)	30 (54.5%)	19 (46.3%)	20 (52.6%)	
Missing	6 (13.6%)	9 (16.4%)	11 (26.8%)	10 (26.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.6809: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline TSS
Double-Blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 44)	RUX (N = 55)	MMB (N = 41)	RUX (N = 38)	p-value
EQ-5D-5L VAS Response Rate at Week 8					
Responder, n(%)	9 (20.5%)	14 (25.5%)	13 (31.7%)	8 (21.1%)	
Non-Responder, n(%)	35 (79.5%)	41 (74.5%)	28 (68.3%)	30 (78.9%)	
Non-missing	26 (59.1%)	31 (56.4%)	15 (36.6%)	18 (47.4%)	
Missing	9 (20.5%)	10 (18.2%)	13 (31.7%)	12 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.6809: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline TSS
Double-Blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 44)	RUX (N = 55)	MMB (N = 41)	RUX (N = 38)	p-value
EQ-5D-5L VAS Response Rate at Week 12					
Responder, n(%)	8 (18.2%)	10 (18.2%)	11 (26.8%)	11 (28.9%)	
Non-Responder, n(%)	36 (81.8%)	45 (81.8%)	30 (73.2%)	27 (71.1%)	
Non-missing	28 (63.6%)	36 (65.5%)	16 (39.0%)	16 (42.1%)	
Missing	8 (18.2%)	9 (16.4%)	14 (34.1%)	11 (28.9%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.6809: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline TSS
Double-Blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 44)	RUX (N = 55)	MMB (N = 41)	RUX (N = 38)	p-value
EQ-5D-5L VAS Response Rate at Week 16					
Responder, n(%)	6 (13.6%)	11 (20.0%)	9 (22.0%)	8 (21.1%)	
Non-Responder, n(%)	38 (86.4%)	44 (80.0%)	32 (78.0%)	30 (78.9%)	
Non-missing	27 (61.4%)	31 (56.4%)	17 (41.5%)	20 (52.6%)	
Missing	11 (25.0%)	13 (23.6%)	15 (36.6%)	10 (26.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-vas-gba-improv.sas V.03.05 Output file: t-subgrp-vas-imp-gba-tss.pdf 29AUG2023: 9:47

Table 2.6809: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline TSS
Double-Blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 44)	RUX (N = 55)	MMB (N = 41)	RUX (N = 38)	p-value
EQ-5D-5L VAS Response Rate at Week 20					
Responder, n(%)	8 (18.2%)	12 (21.8%)	8 (19.5%)	7 (18.4%)	
Non-Responder, n(%)	36 (81.8%)	43 (78.2%)	33 (80.5%)	31 (81.6%)	
Non-missing	25 (56.8%)	30 (54.5%)	16 (39.0%)	19 (50.0%)	
Missing	11 (25.0%)	13 (23.6%)	17 (41.5%)	12 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-vas-gba-improv.sas V.03.05 Output file: t-subgrp-vas-imp-gba-tss.pdf 29AUG2023: 9:47

Table 2.6809: Analysis of Response Rate (improvement, 15% criterion) in EQ-5D-5L VAS by Visit and Baseline TSS
Double-Blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 44)	RUX (N = 55)	MMB (N = 41)	RUX (N = 38)	p-value
EQ-5D-5L VAS Response Rate at Week 24					
Responder, n(%)	9 (20.5%)	12 (21.8%)	10 (24.4%)	8 (21.1%)	
Unadjusted Inverse Relative Risk (95% CI)	1.07 (0.49, 2.30)		0.86 (0.38, 1.96)		
p-value [1]	0.87		0.72		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.71
Unadjusted Inverse Odds Ratio (95% CI)	1.09 (0.41, 2.87)		0.83 (0.29, 2.38)		
p-value [1]	0.87		0.72		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.18, 0.15)		0.03 (-0.15, 0.22)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NE
Non-Responder, n(%)	35 (79.5%)	43 (78.2%)	31 (75.6%)	30 (78.9%)	
Non-missing	26 (59.1%)	30 (54.5%)	12 (29.3%)	17 (44.7%)	
Missing	9 (20.5%)	13 (23.6%)	19 (46.3%)	13 (34.2%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-vas-gba-improv.sas V.03.05 Output file: t-subgrp-vas-imp-gba-tss.pdf 29AUG2023: 9:47

Table 2.7202: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	RUX (N = 36)	MMB (N = 62)	RUX (N = 58)	p-value
SF3602-Physical Functioning: NBS at Week 24					
Responder, n(%)	1 (4.2%)	5 (13.9%)	7 (11.3%)	4 (6.9%)	
Unadjusted Relative Risk (95% CI)	0.30 (0.04, 2.41)		1.64 (0.51, 5.30)		
p-value [1]	0.26		0.41		
Unadjusted interaction test for Treatment*Age Group [3]					0.11
Unadjusted Odds Ratio (95% CI)	0.27 (0.03, 2.47)		1.72 (0.48, 6.21)		
p-value [1]	0.25		0.41		
Unadjusted Absolute Risk Difference (95% CI)	-0.10 (-0.24, 0.04)		0.04 (-0.06, 0.15)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Age Group [3]					0.057
Non-Responder, n(%)	23 (95.8%)	31 (86.1%)	55 (88.7%)	54 (93.1%)	
Non-missing	14 (58.3%)	20 (55.6%)	36 (58.1%)	38 (65.5%)	
Missing	9 (37.5%)	11 (30.6%)	19 (30.6%)	16 (27.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-deter-age.pdf 29AUG2023: 9:43

Table 2.7202: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	RUX (N = 36)	MMB (N = 62)	RUX (N = 58)	p-value
SF3602-Role Physical: NBS at Week 24					
Responder, n(%)	4 (16.7%)	4 (11.1%)	6 (9.7%)	11 (19.0%)	
Unadjusted Relative Risk (95% CI)	1.50 (0.41, 5.43)		0.51 (0.20, 1.29)		
p-value [1]	0.54		0.16		
Unadjusted interaction test for Treatment*Age Group [3]					0.21
Unadjusted Odds Ratio (95% CI)	1.60 (0.36, 7.13)		0.46 (0.16, 1.33)		
p-value [1]	0.54		0.15		
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.13, 0.24)		-0.09 (-0.22, 0.03)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Age Group [3]					0.19
Non-Responder, n(%)	20 (83.3%)	32 (88.9%)	56 (90.3%)	47 (81.0%)	
Non-missing	11 (45.8%)	21 (58.3%)	37 (59.7%)	31 (53.4%)	
Missing	9 (37.5%)	11 (30.6%)	19 (30.6%)	16 (27.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7202: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	RUX (N = 36)	MMB (N = 62)	RUX (N = 58)	p-value
SF3602-Bodily Pain: NBS at Week 24					
Responder, n(%)	3 (12.5%)	2 (5.6%)	7 (11.3%)	7 (12.1%)	
Unadjusted Relative Risk (95% CI)	2.25 (0.41, 12.48)		0.94 (0.35, 2.50)		
p-value [1]	0.35		0.89		
Unadjusted interaction test for Treatment*Age Group [3]					0.39
Unadjusted Odds Ratio (95% CI)	2.43 (0.37, 15.76)		0.93 (0.30, 2.83)		
p-value [1]	0.35		0.89		
Unadjusted Absolute Risk Difference (95% CI)	0.07 (-0.08, 0.22)		-0.01 (-0.12, 0.11)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Age Group [3]					NE
Non-Responder, n(%)	21 (87.5%)	34 (94.4%)	55 (88.7%)	51 (87.9%)	
Non-missing	12 (50.0%)	23 (63.9%)	36 (58.1%)	35 (60.3%)	
Missing	9 (37.5%)	11 (30.6%)	19 (30.6%)	16 (27.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7202: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	RUX (N = 36)	MMB (N = 62)	RUX (N = 58)	p-value
SF3602-General Health: NBS at Week 24					
Responder, n(%)	0	4 (11.1%)	3 (4.8%)	9 (15.5%)	
Unadjusted Relative Risk (95% CI)	0.16 (0.01, 2.92)		0.31 (0.09, 1.10)		
p-value [1]	0.22		0.069		
Unadjusted interaction test for Treatment*Age Group [3]					NE
Unadjusted Odds Ratio (95% CI)	0.15 (0.01, 2.87)		0.28 (0.07, 1.08)		
p-value [1]	0.21		0.064		
Unadjusted Absolute Risk Difference (95% CI)	-0.10 (-0.22, 0.02)		-0.11 (-0.21, 0.00)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Age Group [3]					NE
Non-Responder, n(%)	24 (100.0%)	32 (88.9%)	59 (95.2%)	49 (84.5%)	
Non-missing	15 (62.5%)	21 (58.3%)	40 (64.5%)	33 (56.9%)	
Missing	9 (37.5%)	11 (30.6%)	19 (30.6%)	16 (27.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7202: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	RUX (N = 36)	MMB (N = 62)	RUX (N = 58)	p-value
SF3602-Vitality: NBS at Week 24					
Responder, n(%)	1 (4.2%)	3 (8.3%)	5 (8.1%)	5 (8.6%)	
Unadjusted Relative Risk (95% CI)	0.50 (0.06, 4.53)		0.94 (0.29, 3.07)		
p-value [1]	0.54		0.91		
Unadjusted interaction test for Treatment*Age Group [3]					0.60
Unadjusted Odds Ratio (95% CI)	0.48 (0.05, 4.89)		0.93 (0.25, 3.39)		
p-value [1]	0.53		0.91		
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.16, 0.08)		-0.01 (-0.10, 0.09)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Age Group [3]					NE
Non-Responder, n(%)	23 (95.8%)	33 (91.7%)	57 (91.9%)	53 (91.4%)	
Non-missing	14 (58.3%)	22 (61.1%)	38 (61.3%)	37 (63.8%)	
Missing	9 (37.5%)	11 (30.6%)	19 (30.6%)	16 (27.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7202: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	RUX (N = 36)	MMB (N = 62)	RUX (N = 58)	p-value
SF3602-Social Functioning: NBS at Week 24					
Responder, n(%)	2 (8.3%)	2 (5.6%)	5 (8.1%)	5 (8.6%)	
Unadjusted Relative Risk (95% CI)	1.50 (0.23, 9.94)		0.94 (0.29, 3.07)		
p-value [1]	0.67		0.91		
Unadjusted interaction test for Treatment*Age Group [3]					0.68
Unadjusted Odds Ratio (95% CI)	1.55 (0.20, 11.79)		0.93 (0.25, 3.39)		
p-value [1]	0.67		0.91		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.11, 0.16)		-0.01 (-0.10, 0.09)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Age Group [3]					NE
Non-Responder, n(%)	22 (91.7%)	34 (94.4%)	57 (91.9%)	53 (91.4%)	
Non-missing	13 (54.2%)	23 (63.9%)	38 (61.3%)	37 (63.8%)	
Missing	9 (37.5%)	11 (30.6%)	19 (30.6%)	16 (27.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7202: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	RUX (N = 36)	MMB (N = 62)	RUX (N = 58)	p-value
SF3602-Role Emotional: NBS at Week 24					
Responder, n(%)	2 (8.3%)	5 (13.9%)	9 (14.5%)	8 (13.8%)	
Unadjusted Relative Risk (95% CI)	0.60 (0.13, 2.84)		1.05 (0.44, 2.54)		
p-value [1]	0.52		0.91		
Unadjusted interaction test for Treatment*Age Group [3]					0.52
Unadjusted Odds Ratio (95% CI)	0.56 (0.10, 3.17)		1.06 (0.38, 2.97)		
p-value [1]	0.52		0.91		
Unadjusted Absolute Risk Difference (95% CI)	-0.06 (-0.21, 0.10)		0.01 (-0.12, 0.13)		
Adjusted Relative Risk (95% CI) [2]	NE		1.23 (0.46, 3.29)		
p-value [2]	NE		0.68		
Adjusted interaction test for Treatment*Age Group [3]					0.54
Non-Responder, n(%)	22 (91.7%)	31 (86.1%)	53 (85.5%)	50 (86.2%)	
Non-missing	13 (54.2%)	20 (55.6%)	34 (54.8%)	34 (58.6%)	
Missing	9 (37.5%)	11 (30.6%)	19 (30.6%)	16 (27.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7202: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	RUX (N = 36)	MMB (N = 62)	RUX (N = 58)	p-value
SF3602-Mental Health: NBS at Week 24					
Responder, n(%)	1 (4.2%)	2 (5.6%)	6 (9.7%)	7 (12.1%)	
Unadjusted Relative Risk (95% CI)	0.75 (0.07, 7.82)		0.80 (0.29, 2.25)		
p-value [1]	0.81		0.67		
Unadjusted interaction test for Treatment*Age Group [3]					0.96
Unadjusted Odds Ratio (95% CI)	0.74 (0.06, 8.64)		0.78 (0.25, 2.48)		
p-value [1]	0.81		0.67		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.12, 0.10)		-0.02 (-0.14, 0.09)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Age Group [3]					NE
Non-Responder, n(%)	23 (95.8%)	34 (94.4%)	56 (90.3%)	51 (87.9%)	
Non-missing	14 (58.3%)	23 (63.9%)	37 (59.7%)	35 (60.3%)	
Missing	9 (37.5%)	11 (30.6%)	19 (30.6%)	16 (27.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7202: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	RUX (N = 36)	MMB (N = 62)	RUX (N = 58)	p-value
SF3602-Physical Component Summary at Week 24					
Responder, n(%)	0	1 (2.8%)	2 (3.2%)	4 (6.9%)	
Unadjusted Relative Risk (95% CI)	0.49 (0.02, 11.63)		0.47 (0.09, 2.46)		
p-value [1]	0.66		0.37		
Unadjusted interaction test for Treatment*Age Group [3]					NA
Unadjusted Odds Ratio (95% CI)	0.48 (0.02, 12.35)		0.45 (0.08, 2.56)		
p-value [1]	0.66		0.37		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.10, 0.06)		-0.04 (-0.12, 0.04)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Age Group [3]					NA
Non-Responder, n(%)	24 (100.0%)	35 (97.2%)	60 (96.8%)	54 (93.1%)	
Non-missing	15 (62.5%)	24 (66.7%)	41 (66.1%)	38 (65.5%)	
Missing	9 (37.5%)	11 (30.6%)	19 (30.6%)	16 (27.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-deter-age.pdf 29AUG2023: 9:43

Table 2.7202: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	RUX (N = 36)	MMB (N = 62)	RUX (N = 58)	p-value
SF3602-Mental Component Summary at Week 24					
Responder, n(%)	1 (4.2%)	1 (2.8%)	3 (4.8%)	4 (6.9%)	
Unadjusted Relative Risk (95% CI)	1.50 (0.10, 22.85)		0.70 (0.16, 3.00)		
p-value [1]	0.77		0.63		
Unadjusted interaction test for Treatment*Age Group [3]					NA
Unadjusted Odds Ratio (95% CI)	1.52 (0.09, 25.56)		0.69 (0.15, 3.21)		
p-value [1]	0.77		0.63		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.08, 0.11)		-0.02 (-0.10, 0.06)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Age Group [3]					NA
Non-Responder, n(%)	23 (95.8%)	35 (97.2%)	59 (95.2%)	54 (93.1%)	
Non-missing	14 (58.3%)	24 (66.7%)	40 (64.5%)	38 (65.5%)	
Missing	9 (37.5%)	11 (30.6%)	19 (30.6%)	16 (27.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7204: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Region
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N = 53)	RUX (N = 51)	MMB (N = 33)	RUX (N = 43)	p-value
SF3602-Physical Functioning: NBS at Week 24					
Responder, n(%)	4 (7.5%)	5 (9.8%)	4 (12.1%)	4 (9.3%)	
Unadjusted Relative Risk (95% CI)	0.77 (0.22, 2.71)		1.30 (0.35, 4.83)		
p-value [1]	0.68		0.69		
Unadjusted interaction test for Treatment*Region [3]					NA
Unadjusted Odds Ratio (95% CI)	0.75 (0.19, 2.97)		1.34 (0.31, 5.83)		
p-value [1]	0.68		0.69		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.13, 0.09)		0.03 (-0.11, 0.17)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Region [3]					NA
Non-Responder, n(%)	49 (92.5%)	46 (90.2%)	29 (87.9%)	39 (90.7%)	
Non-missing	27 (50.9%)	27 (52.9%)	23 (69.7%)	31 (72.1%)	
Missing	22 (41.5%)	19 (37.3%)	6 (18.2%)	8 (18.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-deter-geo.pdf 29AUG2023: 9:44

Table 2.7204: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Region
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N = 53)	RUX (N = 51)	MMB (N = 33)	RUX (N = 43)	p-value
SF3602-Role Physical: NBS at Week 24					
Responder, n(%)	5 (9.4%)	9 (17.6%)	5 (15.2%)	6 (14.0%)	
Unadjusted Relative Risk (95% CI)	0.53 (0.19, 1.49)		1.09 (0.36, 3.25)		
p-value [1]	0.23		0.88		
Unadjusted interaction test for Treatment*Region [3]					0.36
Unadjusted Odds Ratio (95% CI)	0.49 (0.15, 1.56)		1.10 (0.30, 3.98)		
p-value [1]	0.23		0.88		
Unadjusted Absolute Risk Difference (95% CI)	-0.08 (-0.21, 0.05)		0.01 (-0.15, 0.17)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Region [3]					0.37
Non-Responder, n(%)	48 (90.6%)	42 (82.4%)	28 (84.8%)	37 (86.0%)	
Non-missing	26 (49.1%)	23 (45.1%)	22 (66.7%)	29 (67.4%)	
Missing	22 (41.5%)	19 (37.3%)	6 (18.2%)	8 (18.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7204: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Region
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N = 53)	RUX (N = 51)	MMB (N = 33)	RUX (N = 43)	p-value
SF3602-Bodily Pain: NBS at Week 24					
Responder, n(%)	5 (9.4%)	4 (7.8%)	5 (15.2%)	5 (11.6%)	
Unadjusted Relative Risk (95% CI)	1.20 (0.34, 4.23)		1.30 (0.41, 4.13)		
p-value [1]	0.77		0.65		
Unadjusted interaction test for Treatment*Region [3]					0.93
Unadjusted Odds Ratio (95% CI)	1.22 (0.31, 4.84)		1.36 (0.36, 5.14)		
p-value [1]	0.77		0.65		
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.09, 0.12)		0.04 (-0.12, 0.19)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Region [3]					NE
Non-Responder, n(%)	48 (90.6%)	47 (92.2%)	28 (84.8%)	38 (88.4%)	
Non-missing	26 (49.1%)	28 (54.9%)	22 (66.7%)	30 (69.8%)	
Missing	22 (41.5%)	19 (37.3%)	6 (18.2%)	8 (18.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7204: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Region
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N = 53)	RUX (N = 51)	MMB (N = 33)	RUX (N = 43)	p-value
SF3602-General Health: NBS at Week 24					
Responder, n(%)	2 (3.8%)	9 (17.6%)	1 (3.0%)	4 (9.3%)	
Unadjusted Relative Risk (95% CI)	0.21 (0.05, 0.94)		0.33 (0.04, 2.78)		
p-value [1]	0.042		0.31		
Unadjusted interaction test for Treatment*Region [3]					0.77
Unadjusted Odds Ratio (95% CI)	0.18 (0.04, 0.89)		0.30 (0.03, 2.86)		
p-value [1]	0.036		0.30		
Unadjusted Absolute Risk Difference (95% CI)	-0.14 (-0.26, -0.02)		-0.06 (-0.17, 0.04)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Region [3]					NE
Non-Responder, n(%)	51 (96.2%)	42 (82.4%)	32 (97.0%)	39 (90.7%)	
Non-missing	29 (54.7%)	23 (45.1%)	26 (78.8%)	31 (72.1%)	
Missing	22 (41.5%)	19 (37.3%)	6 (18.2%)	8 (18.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7204: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Region
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N = 53)	RUX (N = 51)	MMB (N = 33)	RUX (N = 43)	p-value
SF3602-Vitality: NBS at Week 24					
Responder, n(%)	3 (5.7%)	3 (5.9%)	3 (9.1%)	5 (11.6%)	
Unadjusted Relative Risk (95% CI)	0.96 (0.20, 4.55)		0.78 (0.20, 3.04)		
p-value [1]	0.96		0.72		
Unadjusted interaction test for Treatment*Region [3]					NA
Unadjusted Odds Ratio (95% CI)	0.96 (0.18, 4.99)		0.76 (0.17, 3.44)		
p-value [1]	0.96		0.72		
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.09, 0.09)		-0.03 (-0.16, 0.11)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Region [3]					NA
Non-Responder, n(%)	50 (94.3%)	48 (94.1%)	30 (90.9%)	38 (88.4%)	
Non-missing	28 (52.8%)	29 (56.9%)	24 (72.7%)	30 (69.8%)	
Missing	22 (41.5%)	19 (37.3%)	6 (18.2%)	8 (18.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-deter-geo.pdf 29AUG2023: 9:44

Table 2.7204: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Region
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N = 53)	RUX (N = 51)	MMB (N = 33)	RUX (N = 43)	p-value
SF3602-Social Functioning: NBS at Week 24					
Responder, n(%)	5 (9.4%)	2 (3.9%)	2 (6.1%)	5 (11.6%)	
Unadjusted Relative Risk (95% CI)	2.41 (0.49, 11.85)		0.52 (0.11, 2.52)		
p-value [1]	0.28		0.42		
Unadjusted interaction test for Treatment*Region [3]					NA
Unadjusted Odds Ratio (95% CI)	2.55 (0.47, 13.80)		0.49 (0.09, 2.70)		
p-value [1]	0.28		0.41		
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.04, 0.15)		-0.06 (-0.18, 0.07)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Region [3]					NA
Non-Responder, n(%)	48 (90.6%)	49 (96.1%)	31 (93.9%)	38 (88.4%)	
Non-missing	26 (49.1%)	30 (58.8%)	25 (75.8%)	30 (69.8%)	
Missing	22 (41.5%)	19 (37.3%)	6 (18.2%)	8 (18.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7204: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Region
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N = 53)	RUX (N = 51)	MMB (N = 33)	RUX (N = 43)	p-value
SF3602-Role Emotional: NBS at Week 24					
Responder, n(%)	4 (7.5%)	8 (15.7%)	7 (21.2%)	5 (11.6%)	
Unadjusted Relative Risk (95% CI)	0.48 (0.15, 1.50)		1.82 (0.64, 5.24)		
p-value [1]	0.21		0.26		
Unadjusted interaction test for Treatment*Region [3]					0.091
Unadjusted Odds Ratio (95% CI)	0.44 (0.12, 1.56)		2.05 (0.59, 7.15)		
p-value [1]	0.20		0.26		
Unadjusted Absolute Risk Difference (95% CI)	-0.08 (-0.20, 0.04)		0.10 (-0.07, 0.27)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Region [3]					0.13
Non-Responder, n(%)	49 (92.5%)	43 (84.3%)	26 (78.8%)	38 (88.4%)	
Non-missing	27 (50.9%)	24 (47.1%)	20 (60.6%)	30 (69.8%)	
Missing	22 (41.5%)	19 (37.3%)	6 (18.2%)	8 (18.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-deter-geo.pdf 29AUG2023: 9:44

Table 2.7204: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Region
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N = 53)	RUX (N = 51)	MMB (N = 33)	RUX (N = 43)	p-value
SF3602-Mental Health: NBS at Week 24					
Responder, n(%)	3 (5.7%)	4 (7.8%)	4 (12.1%)	5 (11.6%)	
Unadjusted Relative Risk (95% CI)	0.72 (0.17, 3.07)		1.04 (0.30, 3.58)		
p-value [1]	0.66		0.95		
Unadjusted interaction test for Treatment*Region [3]					NA
Unadjusted Odds Ratio (95% CI)	0.71 (0.15, 3.32)		1.05 (0.26, 4.25)		
p-value [1]	0.66		0.95		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.12, 0.07)		0.00 (-0.14, 0.15)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Region [3]					NA
Non-Responder, n(%)	50 (94.3%)	47 (92.2%)	29 (87.9%)	38 (88.4%)	
Non-missing	28 (52.8%)	28 (54.9%)	23 (69.7%)	30 (69.8%)	
Missing	22 (41.5%)	19 (37.3%)	6 (18.2%)	8 (18.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-deter-geo.pdf 29AUG2023: 9:44

Table 2.7204: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Region
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N = 53)	RUX (N = 51)	MMB (N = 33)	RUX (N = 43)	p-value
SF3602-Physical Component Summary at Week 24					
Responder, n(%)	1 (1.9%)	4 (7.8%)	1 (3.0%)	1 (2.3%)	
Unadjusted Relative Risk (95% CI)	0.24 (0.03, 2.08)		1.30 (0.08, 20.07)		
p-value [1]	0.20		0.85		
Unadjusted interaction test for Treatment*Region [3]					NA
Unadjusted Odds Ratio (95% CI)	0.23 (0.02, 2.09)		1.31 (0.08, 21.80)		
p-value [1]	0.19		0.85		
Unadjusted Absolute Risk Difference (95% CI)	-0.06 (-0.14, 0.02)		0.01 (-0.07, 0.08)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Region [3]					NA
Non-Responder, n(%)	52 (98.1%)	47 (92.2%)	32 (97.0%)	42 (97.7%)	
Non-missing	30 (56.6%)	28 (54.9%)	26 (78.8%)	34 (79.1%)	
Missing	22 (41.5%)	19 (37.3%)	6 (18.2%)	8 (18.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-deter-geo.pdf 29AUG2023: 9:44

Table 2.7204: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Region
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N = 53)	RUX (N = 51)	MMB (N = 33)	RUX (N = 43)	p-value
SF3602-Mental Component Summary at Week 24					
Responder, n(%)	1 (1.9%)	2 (3.9%)	3 (9.1%)	3 (7.0%)	
Unadjusted Relative Risk (95% CI)	0.48 (0.04, 5.14)		1.30 (0.28, 6.05)		
p-value [1]	0.55		0.74		
Unadjusted interaction test for Treatment*Region [3]					NA
Unadjusted Odds Ratio (95% CI)	0.47 (0.04, 5.36)		1.33 (0.25, 7.07)		
p-value [1]	0.54		0.74		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.08, 0.04)		0.02 (-0.10, 0.15)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Region [3]					NA
Non-Responder, n(%)	52 (98.1%)	49 (96.1%)	30 (90.9%)	40 (93.0%)	
Non-missing	30 (56.6%)	30 (58.8%)	24 (72.7%)	32 (74.4%)	
Missing	22 (41.5%)	19 (37.3%)	6 (18.2%)	8 (18.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7207: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 28)	RUX (N = 21)	MMB (N = 58)	RUX (N = 73)	p-value
SF3602-Physical Functioning: NBS at Week 24					
Responder, n(%)	1 (3.6%)	3 (14.3%)	7 (12.1%)	6 (8.2%)	
Unadjusted Relative Risk (95% CI)	0.25 (0.03, 2.24)		1.47 (0.52, 4.13)		
p-value [1]	0.21		0.47		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.15
Unadjusted Odds Ratio (95% CI)	0.22 (0.02, 2.31)		1.53 (0.49, 4.84)		
p-value [1]	0.21		0.47		
Unadjusted Absolute Risk Difference (95% CI)	-0.11 (-0.27, 0.06)		0.04 (-0.07, 0.14)		
Adjusted Relative Risk (95% CI) [2]	0.25 (0.03, 2.07)		NE		
p-value [2]	0.20		NE		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.15
Non-Responder, n(%)	27 (96.4%)	18 (85.7%)	51 (87.9%)	67 (91.8%)	
Non-missing	17 (60.7%)	13 (61.9%)	33 (56.9%)	45 (61.6%)	
Missing	10 (35.7%)	5 (23.8%)	18 (31.0%)	22 (30.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7207: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 28)	RUX (N = 21)	MMB (N = 58)	RUX (N = 73)	p-value
SF3602-Role Physical: NBS at Week 24					
Responder, n(%)	5 (17.9%)	4 (19.0%)	5 (8.6%)	11 (15.1%)	
Unadjusted Relative Risk (95% CI)	0.94 (0.29, 3.07)		0.57 (0.21, 1.55)		
p-value [1]	0.92		0.27		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.53
Unadjusted Odds Ratio (95% CI)	0.92 (0.22, 3.96)		0.53 (0.17, 1.63)		
p-value [1]	0.92		0.27		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.23, 0.21)		-0.06 (-0.17, 0.04)		
Adjusted Relative Risk (95% CI) [2]	0.94 (0.29, 2.97)		NE		
p-value [2]	0.91		NE		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.55
Non-Responder, n(%)	23 (82.1%)	17 (81.0%)	53 (91.4%)	62 (84.9%)	
Non-missing	13 (46.4%)	12 (57.1%)	35 (60.3%)	40 (54.8%)	
Missing	10 (35.7%)	5 (23.8%)	18 (31.0%)	22 (30.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7207: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 28)	RUX (N = 21)	MMB (N = 58)	RUX (N = 73)	p-value
SF3602-Bodily Pain: NBS at Week 24					
Responder, n(%)	2 (7.1%)	2 (9.5%)	8 (13.8%)	7 (9.6%)	
Unadjusted Relative Risk (95% CI)	0.75 (0.11, 4.90)		1.44 (0.55, 3.73)		
p-value [1]	0.76		0.46		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.56
Unadjusted Odds Ratio (95% CI)	0.73 (0.09, 5.66)		1.51 (0.51, 4.44)		
p-value [1]	0.76		0.46		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.18, 0.13)		0.04 (-0.07, 0.15)		
Adjusted Relative Risk (95% CI) [2]	0.77 (0.11, 5.29)		NE		
p-value [2]	0.79		NE		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE
Non-Responder, n(%)	26 (92.9%)	19 (90.5%)	50 (86.2%)	66 (90.4%)	
Non-missing	16 (57.1%)	14 (66.7%)	32 (55.2%)	44 (60.3%)	
Missing	10 (35.7%)	5 (23.8%)	18 (31.0%)	22 (30.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7207: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 28)	RUX (N = 21)	MMB (N = 58)	RUX (N = 73)	p-value
SF3602-General Health: NBS at Week 24					
Responder, n(%)	1 (3.6%)	2 (9.5%)	2 (3.4%)	11 (15.1%)	
Unadjusted Relative Risk (95% CI)	0.38 (0.04, 3.87)		0.23 (0.05, 0.99)		
p-value [1]	0.41		0.049		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.74
Unadjusted Odds Ratio (95% CI)	0.35 (0.03, 4.16)		0.20 (0.04, 0.95)		
p-value [1]	0.41		0.043		
Unadjusted Absolute Risk Difference (95% CI)	-0.06 (-0.20, 0.08)		-0.12 (-0.21, -0.02)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE
Non-Responder, n(%)	27 (96.4%)	19 (90.5%)	56 (96.6%)	62 (84.9%)	
Non-missing	17 (60.7%)	14 (66.7%)	38 (65.5%)	40 (54.8%)	
Missing	10 (35.7%)	5 (23.8%)	18 (31.0%)	22 (30.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7207: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 28)	RUX (N = 21)	MMB (N = 58)	RUX (N = 73)	p-value
SF3602-Vitality: NBS at Week 24					
Responder, n(%)	2 (7.1%)	2 (9.5%)	4 (6.9%)	6 (8.2%)	
Unadjusted Relative Risk (95% CI)	0.75 (0.11, 4.90)		0.84 (0.25, 2.83)		
p-value [1]	0.76		0.78		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.92
Unadjusted Odds Ratio (95% CI)	0.73 (0.09, 5.66)		0.83 (0.22, 3.08)		
p-value [1]	0.76		0.78		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.18, 0.13)		-0.01 (-0.10, 0.08)		
Adjusted Relative Risk (95% CI) [2]	0.78 (0.13, 4.73)		NE		
p-value [2]	0.79		NE		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE
Non-Responder, n(%)	26 (92.9%)	19 (90.5%)	54 (93.1%)	67 (91.8%)	
Non-missing	16 (57.1%)	14 (66.7%)	36 (62.1%)	45 (61.6%)	
Missing	10 (35.7%)	5 (23.8%)	18 (31.0%)	22 (30.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-deter-hgb.pdf 29AUG2023: 9:44

Table 2.7207: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 28)	RUX (N = 21)	MMB (N = 58)	RUX (N = 73)	p-value
SF3602-Social Functioning: NBS at Week 24					
Responder, n(%)	3 (10.7%)	2 (9.5%)	4 (6.9%)	5 (6.8%)	
Unadjusted Relative Risk (95% CI)	1.13 (0.21, 6.14)		1.01 (0.28, 3.58)		
p-value [1]	0.89		0.99		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Unadjusted Odds Ratio (95% CI)	1.14 (0.17, 7.52)		1.01 (0.26, 3.93)		
p-value [1]	0.89		0.99		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.16, 0.18)		0.00 (-0.09, 0.09)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Non-Responder, n(%)	25 (89.3%)	19 (90.5%)	54 (93.1%)	68 (93.2%)	
Non-missing	15 (53.6%)	14 (66.7%)	36 (62.1%)	46 (63.0%)	
Missing	10 (35.7%)	5 (23.8%)	18 (31.0%)	22 (30.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7207: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 28)	RUX (N = 21)	MMB (N = 58)	RUX (N = 73)	p-value
SF3602-Role Emotional: NBS at Week 24					
Responder, n(%)	2 (7.1%)	3 (14.3%)	9 (15.5%)	10 (13.7%)	
Unadjusted Relative Risk (95% CI)	0.50 (0.09, 2.73)		1.13 (0.49, 2.60)		
p-value [1]	0.42		0.77		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.40
Unadjusted Odds Ratio (95% CI)	0.46 (0.07, 3.05)		1.16 (0.44, 3.07)		
p-value [1]	0.42		0.77		
Unadjusted Absolute Risk Difference (95% CI)	-0.07 (-0.25, 0.11)		0.02 (-0.10, 0.14)		
Adjusted Relative Risk (95% CI) [2]	0.48 (0.09, 2.46)		1.19 (0.53, 2.67)		
p-value [2]	0.38		0.68		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.37
Non-Responder, n(%)	26 (92.9%)	18 (85.7%)	49 (84.5%)	63 (86.3%)	
Non-missing	16 (57.1%)	13 (61.9%)	31 (53.4%)	41 (56.2%)	
Missing	10 (35.7%)	5 (23.8%)	18 (31.0%)	22 (30.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7207: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 28)	RUX (N = 21)	MMB (N = 58)	RUX (N = 73)	p-value
SF3602-Mental Health: NBS at Week 24					
Responder, n(%)	1 (3.6%)	0	6 (10.3%)	9 (12.3%)	
Unadjusted Relative Risk (95% CI)	2.28 (0.10, 53.23)		0.84 (0.32, 2.22)		
p-value [1]	0.61		0.72		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE
Unadjusted Odds Ratio (95% CI)	2.35 (0.09, 60.49)		0.82 (0.27, 2.45)		
p-value [1]	0.61		0.72		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.07, 0.13)		-0.02 (-0.13, 0.09)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE
Non-Responder, n(%)	27 (96.4%)	21 (100.0%)	52 (89.7%)	64 (87.7%)	
Non-missing	17 (60.7%)	16 (76.2%)	34 (58.6%)	42 (57.5%)	
Missing	10 (35.7%)	5 (23.8%)	18 (31.0%)	22 (30.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-deter-hgb.pdf 29AUG2023: 9:44

Table 2.7207: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 28)	RUX (N = 21)	MMB (N = 58)	RUX (N = 73)	p-value
SF3602-Physical Component Summary at Week 24					
Responder, n(%)	1 (3.6%)	1 (4.8%)	1 (1.7%)	4 (5.5%)	
Unadjusted Relative Risk (95% CI)	0.75 (0.05, 11.31)		0.31 (0.04, 2.74)		
p-value [1]	0.84		0.29		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Unadjusted Odds Ratio (95% CI)	0.74 (0.04, 12.57)		0.30 (0.03, 2.78)		
p-value [1]	0.84		0.29		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.13, 0.10)		-0.04 (-0.10, 0.02)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Non-Responder, n(%)	27 (96.4%)	20 (95.2%)	57 (98.3%)	69 (94.5%)	
Non-missing	17 (60.7%)	15 (71.4%)	39 (67.2%)	47 (64.4%)	
Missing	10 (35.7%)	5 (23.8%)	18 (31.0%)	22 (30.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7207: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 28)	RUX (N = 21)	MMB (N = 58)	RUX (N = 73)	p-value
SF3602-Mental Component Summary at Week 24					
Responder, n(%)	1 (3.6%)	1 (4.8%)	3 (5.2%)	4 (5.5%)	
Unadjusted Relative Risk (95% CI)	0.75 (0.05, 11.31)		0.94 (0.22, 4.05)		
p-value [1]	0.84		0.94		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Unadjusted Odds Ratio (95% CI)	0.74 (0.04, 12.57)		0.94 (0.20, 4.38)		
p-value [1]	0.84		0.94		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.13, 0.10)		0.00 (-0.08, 0.07)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Non-Responder, n(%)	27 (96.4%)	20 (95.2%)	55 (94.8%)	69 (94.5%)	
Non-missing	17 (60.7%)	15 (71.4%)	37 (63.8%)	47 (64.4%)	
Missing	10 (35.7%)	5 (23.8%)	18 (31.0%)	22 (30.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7206: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Two-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 28)	RUX (N = 24)	MMB (N = 58)	RUX (N = 70)	p-value
SF3602-Physical Functioning: NBS at Week 24					
Responder, n(%)	1 (3.6%)	3 (12.5%)	7 (12.1%)	6 (8.6%)	
Unadjusted Relative Risk (95% CI)	0.29 (0.03, 2.57)		1.41 (0.50, 3.96)		
p-value [1]	0.26		0.52		
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.18
Unadjusted Odds Ratio (95% CI)	0.26 (0.03, 2.68)		1.46 (0.46, 4.63)		
p-value [1]	0.26		0.52		
Unadjusted Absolute Risk Difference (95% CI)	-0.09 (-0.24, 0.06)		0.03 (-0.07, 0.14)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.23
Non-Responder, n(%)	27 (96.4%)	21 (87.5%)	51 (87.9%)	64 (91.4%)	
Non-missing	17 (60.7%)	14 (58.3%)	33 (56.9%)	44 (62.9%)	
Missing	10 (35.7%)	7 (29.2%)	18 (31.0%)	20 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7206: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Two-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 28)	RUX (N = 24)	MMB (N = 58)	RUX (N = 70)	p-value
SF3602-Role Physical: NBS at Week 24					
Responder, n(%)	4 (14.3%)	6 (25.0%)	6 (10.3%)	9 (12.9%)	
Unadjusted Relative Risk (95% CI)	0.57 (0.18, 1.79)		0.80 (0.30, 2.13)		
p-value [1]	0.34		0.66		
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.65
Unadjusted Odds Ratio (95% CI)	0.50 (0.12, 2.04)		0.78 (0.26, 2.34)		
p-value [1]	0.33		0.66		
Unadjusted Absolute Risk Difference (95% CI)	-0.11 (-0.32, 0.11)		-0.03 (-0.14, 0.09)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.72
Non-Responder, n(%)	24 (85.7%)	18 (75.0%)	52 (89.7%)	61 (87.1%)	
Non-missing	14 (50.0%)	11 (45.8%)	34 (58.6%)	41 (58.6%)	
Missing	10 (35.7%)	7 (29.2%)	18 (31.0%)	20 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7206: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Two-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 28)	RUX (N = 24)	MMB (N = 58)	RUX (N = 70)	p-value
SF3602-Bodily Pain: NBS at Week 24					
Responder, n(%)	4 (14.3%)	1 (4.2%)	6 (10.3%)	8 (11.4%)	
Unadjusted Relative Risk (95% CI)	3.43 (0.41, 28.63)		0.91 (0.33, 2.46)		
p-value [1]	0.26		0.85		
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.21
Unadjusted Odds Ratio (95% CI)	3.83 (0.40, 36.91)		0.89 (0.29, 2.74)		
p-value [1]	0.24		0.85		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.05, 0.25)		-0.01 (-0.12, 0.10)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*IPSS 2-Level Risk [3]					NE
Non-Responder, n(%)	24 (85.7%)	23 (95.8%)	52 (89.7%)	62 (88.6%)	
Non-missing	14 (50.0%)	16 (66.7%)	34 (58.6%)	42 (60.0%)	
Missing	10 (35.7%)	7 (29.2%)	18 (31.0%)	20 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7206: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Two-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 28)	RUX (N = 24)	MMB (N = 58)	RUX (N = 70)	p-value
SF3602-General Health: NBS at Week 24					
Responder, n(%)	0	5 (20.8%)	3 (5.2%)	8 (11.4%)	
Unadjusted Relative Risk (95% CI)	0.08 (0.00, 1.35)		0.45 (0.13, 1.63)		
p-value [1]	0.079		0.22		
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [3]					NE
Unadjusted Odds Ratio (95% CI)	0.06 (0.00, 1.19)		0.42 (0.11, 1.67)		
p-value [1]	0.065		0.22		
Unadjusted Absolute Risk Difference (95% CI)	-0.20 (-0.37, -0.03)		-0.06 (-0.16, 0.03)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*IPSS 2-Level Risk [3]					NE
Non-Responder, n(%)	28 (100.0%)	19 (79.2%)	55 (94.8%)	62 (88.6%)	
Non-missing	18 (64.3%)	12 (50.0%)	37 (63.8%)	42 (60.0%)	
Missing	10 (35.7%)	7 (29.2%)	18 (31.0%)	20 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7206: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Two-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 28)	RUX (N = 24)	MMB (N = 58)	RUX (N = 70)	p-value
SF3602-Vitality: NBS at Week 24					
Responder, n(%)	2 (7.1%)	2 (8.3%)	4 (6.9%)	6 (8.6%)	
Unadjusted Relative Risk (95% CI)	0.86 (0.13, 5.63)		0.80 (0.24, 2.72)		
p-value [1]	0.87		0.73		
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.96
Unadjusted Odds Ratio (95% CI)	0.85 (0.11, 6.51)		0.79 (0.21, 2.95)		
p-value [1]	0.87		0.73		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.16, 0.13)		-0.02 (-0.11, 0.08)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*IPSS 2-Level Risk [3]					NE
Non-Responder, n(%)	26 (92.9%)	22 (91.7%)	54 (93.1%)	64 (91.4%)	
Non-missing	16 (57.1%)	15 (62.5%)	36 (62.1%)	44 (62.9%)	
Missing	10 (35.7%)	7 (29.2%)	18 (31.0%)	20 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7206: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Two-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 28)	RUX (N = 24)	MMB (N = 58)	RUX (N = 70)	p-value
SF3602-Social Functioning: NBS at Week 24					
Responder, n(%)	3 (10.7%)	1 (4.2%)	4 (6.9%)	6 (8.6%)	
Unadjusted Relative Risk (95% CI)	2.57 (0.29, 23.13)		0.80 (0.24, 2.72)		
p-value [1]	0.40		0.73		
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.33
Unadjusted Odds Ratio (95% CI)	2.76 (0.27, 28.45)		0.79 (0.21, 2.95)		
p-value [1]	0.39		0.73		
Unadjusted Absolute Risk Difference (95% CI)	0.07 (-0.07, 0.21)		-0.02 (-0.11, 0.08)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*IPSS 2-Level Risk [3]					NE
Non-Responder, n(%)	25 (89.3%)	23 (95.8%)	54 (93.1%)	64 (91.4%)	
Non-missing	15 (53.6%)	16 (66.7%)	36 (62.1%)	44 (62.9%)	
Missing	10 (35.7%)	7 (29.2%)	18 (31.0%)	20 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7206: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Two-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 28)	RUX (N = 24)	MMB (N = 58)	RUX (N = 70)	p-value
SF3602-Role Emotional: NBS at Week 24					
Responder, n(%)	3 (10.7%)	6 (25.0%)	8 (13.8%)	7 (10.0%)	
Unadjusted Relative Risk (95% CI)	0.43 (0.12, 1.53)		1.38 (0.53, 3.58)		
p-value [1]	0.19		0.51		
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.15
Unadjusted Odds Ratio (95% CI)	0.36 (0.08, 1.63)		1.44 (0.49, 4.24)		
p-value [1]	0.19		0.51		
Unadjusted Absolute Risk Difference (95% CI)	-0.14 (-0.35, 0.06)		0.04 (-0.08, 0.15)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.18
Non-Responder, n(%)	25 (89.3%)	18 (75.0%)	50 (86.2%)	63 (90.0%)	
Non-missing	15 (53.6%)	11 (45.8%)	32 (55.2%)	43 (61.4%)	
Missing	10 (35.7%)	7 (29.2%)	18 (31.0%)	20 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7206: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Two-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 28)	RUX (N = 24)	MMB (N = 58)	RUX (N = 70)	p-value
SF3602-Mental Health: NBS at Week 24					
Responder, n(%)	2 (7.1%)	4 (16.7%)	5 (8.6%)	5 (7.1%)	
Unadjusted Relative Risk (95% CI)	0.43 (0.09, 2.14)		1.21 (0.37, 3.97)		
p-value [1]	0.30		0.76		
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.31
Unadjusted Odds Ratio (95% CI)	0.38 (0.06, 2.31)		1.23 (0.34, 4.46)		
p-value [1]	0.30		0.76		
Unadjusted Absolute Risk Difference (95% CI)	-0.10 (-0.27, 0.08)		0.01 (-0.08, 0.11)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*IPSS 2-Level Risk [3]					NE
Non-Responder, n(%)	26 (92.9%)	20 (83.3%)	53 (91.4%)	65 (92.9%)	
Non-missing	16 (57.1%)	13 (54.2%)	35 (60.3%)	45 (64.3%)	
Missing	10 (35.7%)	7 (29.2%)	18 (31.0%)	20 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7206: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Two-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 28)	RUX (N = 24)	MMB (N = 58)	RUX (N = 70)	p-value
SF3602-Physical Component Summary at Week 24					
Responder, n(%)	0	2 (8.3%)	2 (3.4%)	3 (4.3%)	
Unadjusted Relative Risk (95% CI)	0.17 (0.01, 3.42)		0.80 (0.14, 4.65)		
p-value [1]	0.25		0.81		
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [3]					NA
Unadjusted Odds Ratio (95% CI)	0.16 (0.01, 3.46)		0.80 (0.13, 4.94)		
p-value [1]	0.24		0.81		
Unadjusted Absolute Risk Difference (95% CI)	-0.08 (-0.21, 0.04)		-0.01 (-0.08, 0.06)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*IPSS 2-Level Risk [3]					NA
Non-Responder, n(%)	28 (100.0%)	22 (91.7%)	56 (96.6%)	67 (95.7%)	
Non-missing	18 (64.3%)	15 (62.5%)	38 (65.5%)	47 (67.1%)	
Missing	10 (35.7%)	7 (29.2%)	18 (31.0%)	20 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7206: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Two-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 28)	RUX (N = 24)	MMB (N = 58)	RUX (N = 70)	p-value
SF3602-Mental Component Summary at Week 24					
Responder, n(%)	2 (7.1%)	1 (4.2%)	2 (3.4%)	4 (5.7%)	
Unadjusted Relative Risk (95% CI)	1.71 (0.17, 17.76)		0.60 (0.11, 3.18)		
p-value [1]	0.65		0.55		
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [3]					NA
Unadjusted Odds Ratio (95% CI)	1.77 (0.15, 20.82)		0.59 (0.10, 3.34)		
p-value [1]	0.65		0.55		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.09, 0.15)		-0.02 (-0.09, 0.05)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*IPSS 2-Level Risk [3]					NA
Non-Responder, n(%)	26 (92.9%)	23 (95.8%)	56 (96.6%)	66 (94.3%)	
Non-missing	16 (57.1%)	16 (66.7%)	38 (65.5%)	46 (65.7%)	
Missing	10 (35.7%)	7 (29.2%)	18 (31.0%)	20 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7205: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 2)	RUX (N = 4)	MMB (N = 26)	RUX (N = 20)
SF3602-Physical Functioning: NBS at Week 24				
Responder, n(%)	0	1 (25.0%)	1 (3.8%)	2 (10.0%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Non-Responder, n(%)	2 (100.0%)	3 (75.0%)	25 (96.2%)	18 (90.0%)
Non-missing	1 (50.0%)	2 (50.0%)	16 (61.5%)	12 (60.0%)
Missing	1 (50.0%)	1 (25.0%)	9 (34.6%)	6 (30.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.7205: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 58)	RUX (N = 70)	p-value
SF3602-Physical Functioning: NBS at Week 24			
Responder, n(%)	7 (12.1%)	6 (8.6%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	51 (87.9%)	64 (91.4%)	
Non-missing	33 (56.9%)	44 (62.9%)	
Missing	18 (31.0%)	20 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-deter-ip3.pdf 29AUG2023: 9:44

Table 2.7205: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 2)	RUX (N = 4)	MMB (N = 26)	RUX (N = 20)
SF3602-Role Physical: NBS at Week 24				
Responder, n(%)	0	1 (25.0%)	4 (15.4%)	5 (25.0%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Non-Responder, n(%)	2 (100.0%)	3 (75.0%)	22 (84.6%)	15 (75.0%)
Non-missing	1 (50.0%)	2 (50.0%)	13 (50.0%)	9 (45.0%)
Missing	1 (50.0%)	1 (25.0%)	9 (34.6%)	6 (30.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.7205: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 58)	RUX (N = 70)	p-value
SF3602-Role Physical: NBS at Week 24			
Responder, n(%)	6 (10.3%)	9 (12.9%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	52 (89.7%)	61 (87.1%)	
Non-missing	34 (58.6%)	41 (58.6%)	
Missing	18 (31.0%)	20 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-deter-ip3.pdf 29AUG2023: 9:44

Table 2.7205: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 2)	RUX (N = 4)	MMB (N = 26)	RUX (N = 20)
SF3602-Bodily Pain: NBS at Week 24				
Responder, n(%)	0	0	4 (15.4%)	1 (5.0%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Non-Responder, n(%)	2 (100.0%)	4 (100.0%)	22 (84.6%)	19 (95.0%)
Non-missing	1 (50.0%)	3 (75.0%)	13 (50.0%)	13 (65.0%)
Missing	1 (50.0%)	1 (25.0%)	9 (34.6%)	6 (30.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.7205: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 58)	RUX (N = 70)	p-value
SF3602-Bodily Pain: NBS at Week 24			
Responder, n(%)	6 (10.3%)	8 (11.4%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	52 (89.7%)	62 (88.6%)	
Non-missing	34 (58.6%)	42 (60.0%)	
Missing	18 (31.0%)	20 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
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Table 2.7205: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 2)	RUX (N = 4)	MMB (N = 26)	RUX (N = 20)
SF3602-General Health: NBS at Week 24				
Responder, n(%)	0	1 (25.0%)	0	4 (20.0%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Non-Responder, n(%)	2 (100.0%)	3 (75.0%)	26 (100.0%)	16 (80.0%)
Non-missing	1 (50.0%)	2 (50.0%)	17 (65.4%)	10 (50.0%)
Missing	1 (50.0%)	1 (25.0%)	9 (34.6%)	6 (30.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.7205: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 58)	RUX (N = 70)	p-value
SF3602-General Health: NBS at Week 24			
Responder, n(%)	3 (5.2%)	8 (11.4%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	55 (94.8%)	62 (88.6%)	
Non-missing	37 (63.8%)	42 (60.0%)	
Missing	18 (31.0%)	20 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

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Table 2.7205: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 2)	RUX (N = 4)	MMB (N = 26)	RUX (N = 20)
SF3602-Vitality: NBS at Week 24				
Responder, n(%)	0	0	2 (7.7%)	2 (10.0%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Non-Responder, n(%)	2 (100.0%)	4 (100.0%)	24 (92.3%)	18 (90.0%)
Non-missing	1 (50.0%)	3 (75.0%)	15 (57.7%)	12 (60.0%)
Missing	1 (50.0%)	1 (25.0%)	9 (34.6%)	6 (30.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.7205: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 58)	RUX (N = 70)	p-value
SF3602-Vitality: NBS at Week 24			
Responder, n(%)	4 (6.9%)	6 (8.6%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	54 (93.1%)	64 (91.4%)	
Non-missing	36 (62.1%)	44 (62.9%)	
Missing	18 (31.0%)	20 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.7205: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 2)	RUX (N = 4)	MMB (N = 26)	RUX (N = 20)
SF3602-Social Functioning: NBS at Week 24				
Responder, n(%)	0	0	3 (11.5%)	1 (5.0%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Non-Responder, n(%)	2 (100.0%)	4 (100.0%)	23 (88.5%)	19 (95.0%)
Non-missing	1 (50.0%)	3 (75.0%)	14 (53.8%)	13 (65.0%)
Missing	1 (50.0%)	1 (25.0%)	9 (34.6%)	6 (30.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.7205: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 58)	RUX (N = 70)	p-value
SF3602-Social Functioning: NBS at Week 24			
Responder, n(%)	4 (6.9%)	6 (8.6%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	54 (93.1%)	64 (91.4%)	
Non-missing	36 (62.1%)	44 (62.9%)	
Missing	18 (31.0%)	20 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.7205: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 2)	RUX (N = 4)	MMB (N = 26)	RUX (N = 20)
SF3602-Role Emotional: NBS at Week 24				
Responder, n(%)	0	2 (50.0%)	3 (11.5%)	4 (20.0%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Non-Responder, n(%)	2 (100.0%)	2 (50.0%)	23 (88.5%)	16 (80.0%)
Non-missing	1 (50.0%)	1 (25.0%)	14 (53.8%)	10 (50.0%)
Missing	1 (50.0%)	1 (25.0%)	9 (34.6%)	6 (30.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.7205: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 58)	RUX (N = 70)	p-value
SF3602-Role Emotional: NBS at Week 24			
Responder, n(%)	8 (13.8%)	7 (10.0%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	50 (86.2%)	63 (90.0%)	
Non-missing	32 (55.2%)	43 (61.4%)	
Missing	18 (31.0%)	20 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.7205: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 2)	RUX (N = 4)	MMB (N = 26)	RUX (N = 20)
SF3602-Mental Health: NBS at Week 24				
Responder, n(%)	0	1 (25.0%)	2 (7.7%)	3 (15.0%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Non-Responder, n(%)	2 (100.0%)	3 (75.0%)	24 (92.3%)	17 (85.0%)
Non-missing	1 (50.0%)	2 (50.0%)	15 (57.7%)	11 (55.0%)
Missing	1 (50.0%)	1 (25.0%)	9 (34.6%)	6 (30.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.7205: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 58)	RUX (N = 70)	p-value
SF3602-Mental Health: NBS at Week 24			
Responder, n(%)	5 (8.6%)	5 (7.1%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	53 (91.4%)	65 (92.9%)	
Non-missing	35 (60.3%)	45 (64.3%)	
Missing	18 (31.0%)	20 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.7205: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 2)	RUX (N = 4)	MMB (N = 26)	RUX (N = 20)
SF3602-Physical Component Summary at Week 24				
Responder, n(%)	0	0	0	2 (10.0%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Non-Responder, n(%)	2 (100.0%)	4 (100.0%)	26 (100.0%)	18 (90.0%)
Non-missing	1 (50.0%)	3 (75.0%)	17 (65.4%)	12 (60.0%)
Missing	1 (50.0%)	1 (25.0%)	9 (34.6%)	6 (30.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.7205: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 58)	RUX (N = 70)	p-value
SF3602-Physical Component Summary at Week 24			
Responder, n(%)	2 (3.4%)	3 (4.3%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	56 (96.6%)	67 (95.7%)	
Non-missing	38 (65.5%)	47 (67.1%)	
Missing	18 (31.0%)	20 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.7205: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 2)	RUX (N = 4)	MMB (N = 26)	RUX (N = 20)
SF3602-Mental Component Summary at Week 24				
Responder, n(%)	0	0	2 (7.7%)	1 (5.0%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Non-Responder, n(%)	2 (100.0%)	4 (100.0%)	24 (92.3%)	19 (95.0%)
Non-missing	1 (50.0%)	3 (75.0%)	15 (57.7%)	13 (65.0%)
Missing	1 (50.0%)	1 (25.0%)	9 (34.6%)	6 (30.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.7205: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 58)	RUX (N = 70)	p-value
SF3602-Mental Component Summary at Week 24			
Responder, n(%)	2 (3.4%)	4 (5.7%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	56 (96.6%)	66 (94.3%)	
Non-missing	38 (65.5%)	46 (65.7%)	
Missing	18 (31.0%)	20 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.7208: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 59)	RUX (N = 54)	MMB (N = 16)	RUX (N = 28)
SF3602-Physical Functioning: NBS at Week 24				
Responder, n(%)	6 (10.2%)	5 (9.3%)	1 (6.3%)	2 (7.1%)
Unadjusted Relative Risk (95% CI)	1.10 (0.36, 3.39)		0.88 (0.09, 8.91)	
p-value [1]	0.87		0.91	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Odds Ratio (95% CI)	1.11 (0.32, 3.87)		0.87 (0.07, 10.38)	
p-value [1]	0.87		0.91	
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.10, 0.12)		-0.01 (-0.16, 0.14)	
Adjusted Relative Risk (95% CI) [2]	1.06 (0.37, 3.05)		NE	
p-value [2]	0.91		NE	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	53 (89.8%)	49 (90.7%)	15 (93.8%)	26 (92.9%)
Non-missing	36 (61.0%)	39 (72.2%)	8 (50.0%)	14 (50.0%)
Missing	17 (28.8%)	10 (18.5%)	7 (43.8%)	12 (42.9%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7208: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 11)	RUX (N = 12)	p-value
SF3602-Physical Functioning: NBS at Week 24			
Responder, n(%)	1 (9.1%)	2 (16.7%)	
Unadjusted Relative Risk (95% CI)	0.55 (0.06, 5.21)		
p-value [1]	0.60		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.85
Unadjusted Odds Ratio (95% CI)	0.50 (0.04, 6.44)		
p-value [1]	0.59		
Unadjusted Absolute Risk Difference (95% CI)	-0.08 (-0.35, 0.20)		
Adjusted Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.95
Non-Responder, n(%)	10 (90.9%)	10 (83.3%)	
Non-missing	6 (54.5%)	5 (41.7%)	
Missing	4 (36.4%)	5 (41.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
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Table 2.7208: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 59)	RUX (N = 54)	MMB (N = 16)	RUX (N = 28)
SF3602-Role Physical: NBS at Week 24				
Responder, n(%)	5 (8.5%)	11 (20.4%)	3 (18.8%)	3 (10.7%)
Unadjusted Relative Risk (95% CI)	0.42 (0.15, 1.12)		1.75 (0.40, 7.67)	
p-value [1]	0.083		0.46	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Odds Ratio (95% CI)	0.36 (0.12, 1.12)		1.92 (0.34, 10.90)	
p-value [1]	0.078		0.46	
Unadjusted Absolute Risk Difference (95% CI)	-0.12 (-0.25, 0.01)		0.08 (-0.14, 0.30)	
Adjusted Relative Risk (95% CI) [2]	0.39 (0.15, 1.00)		NE	
p-value [2]	0.049		NE	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	54 (91.5%)	43 (79.6%)	13 (81.3%)	25 (89.3%)
Non-missing	37 (62.7%)	33 (61.1%)	6 (37.5%)	13 (46.4%)
Missing	17 (28.8%)	10 (18.5%)	7 (43.8%)	12 (42.9%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7208: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 11)	RUX (N = 12)	p-value
SF3602-Role Physical: NBS at Week 24			
Responder, n(%)	2 (18.2%)	1 (8.3%)	
Unadjusted Relative Risk (95% CI)	2.18 (0.23, 20.84)		
p-value [1]	0.50		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.21
Unadjusted Odds Ratio (95% CI)	2.44 (0.19, 31.53)		
p-value [1]	0.49		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.18, 0.37)		
Adjusted Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.16
Non-Responder, n(%)	9 (81.8%)	11 (91.7%)	
Non-missing	5 (45.5%)	6 (50.0%)	
Missing	4 (36.4%)	5 (41.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

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Table 2.7208: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 59)	RUX (N = 54)	MMB (N = 16)	RUX (N = 28)
SF3602-Bodily Pain: NBS at Week 24				
Responder, n(%)	8 (13.6%)	5 (9.3%)	1 (6.3%)	3 (10.7%)
Unadjusted Relative Risk (95% CI)	1.46 (0.51, 4.20)		0.58 (0.07, 5.15)	
p-value [1]	0.48		0.63	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Odds Ratio (95% CI)	1.54 (0.47, 5.02)		0.56 (0.05, 5.84)	
p-value [1]	0.48		0.62	
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.07, 0.16)		-0.04 (-0.21, 0.12)	
Adjusted Relative Risk (95% CI) [2]	NE		NE	
p-value [2]	NE		NE	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	51 (86.4%)	49 (90.7%)	15 (93.8%)	25 (89.3%)
Non-missing	34 (57.6%)	39 (72.2%)	8 (50.0%)	13 (46.4%)
Missing	17 (28.8%)	10 (18.5%)	7 (43.8%)	12 (42.9%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7208: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 11)	RUX (N = 12)	p-value
SF3602-Bodily Pain: NBS at Week 24			
Responder, n(%)	1 (9.1%)	1 (8.3%)	
Unadjusted Relative Risk (95% CI)	1.09 (0.08, 15.42)		
p-value [1]	0.95		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.72
Unadjusted Odds Ratio (95% CI)	1.10 (0.06, 20.01)		
p-value [1]	0.95		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.22, 0.24)		
Adjusted Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NE
Non-Responder, n(%)	10 (90.9%)	11 (91.7%)	
Non-missing	6 (54.5%)	6 (50.0%)	
Missing	4 (36.4%)	5 (41.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

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Table 2.7208: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 59)	RUX (N = 54)	MMB (N = 16)	RUX (N = 28)
SF3602-General Health: NBS at Week 24				
Responder, n(%)	2 (3.4%)	8 (14.8%)	0	4 (14.3%)
Unadjusted Relative Risk (95% CI)	0.23 (0.05, 1.03)		0.19 (0.01, 3.31)	
p-value [1]	0.055		0.25	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Odds Ratio (95% CI)	0.20 (0.04, 1.00)		0.16 (0.01, 3.27)	
p-value [1]	0.050		0.24	
Unadjusted Absolute Risk Difference (95% CI)	-0.11 (-0.22, -0.01		-0.13 (-0.28, 0.03)	
Adjusted Relative Risk (95% CI) [2]	NE		NE	
p-value [2]	NE		NE	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	57 (96.6%)	46 (85.2%)	16 (100.0%)	24 (85.7%)
Non-missing	40 (67.8%)	36 (66.7%)	9 (56.3%)	12 (42.9%)
Missing	17 (28.8%)	10 (18.5%)	7 (43.8%)	12 (42.9%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7208: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 11)	RUX (N = 12)	p-value
SF3602-General Health: NBS at Week 24			
Responder, n(%)	1 (9.1%)	1 (8.3%)	
Unadjusted Relative Risk (95% CI)	1.09 (0.08, 15.42)		
p-value [1]	0.95		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NE
Unadjusted Odds Ratio (95% CI)	1.10 (0.06, 20.01)		
p-value [1]	0.95		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.22, 0.24)		
Adjusted Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NE
Non-Responder, n(%)	10 (90.9%)	11 (91.7%)	
Non-missing	6 (54.5%)	6 (50.0%)	
Missing	4 (36.4%)	5 (41.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7208: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 59)	RUX (N = 54)	MMB (N = 16)	RUX (N = 28)
SF3602-Vitality: NBS at Week 24				
Responder, n(%)	4 (6.8%)	3 (5.6%)	1 (6.3%)	2 (7.1%)
Unadjusted Relative Risk (95% CI)	1.22 (0.29, 5.21)		0.88 (0.09, 8.91)	
p-value [1]	0.79		0.91	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Odds Ratio (95% CI)	1.24 (0.26, 5.79)		0.87 (0.07, 10.38)	
p-value [1]	0.79		0.91	
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.08, 0.10)		-0.01 (-0.16, 0.14)	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	55 (93.2%)	51 (94.4%)	15 (93.8%)	26 (92.9%)
Non-missing	38 (64.4%)	41 (75.9%)	8 (50.0%)	14 (50.0%)
Missing	17 (28.8%)	10 (18.5%)	7 (43.8%)	12 (42.9%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7208: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 11)	RUX (N = 12)	p-value
SF3602-Vitality: NBS at Week 24			
Responder, n(%)	1 (9.1%)	3 (25.0%)	
Unadjusted Relative Risk (95% CI)	0.36 (0.04, 3.00)		
p-value [1]	0.35		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Unadjusted Odds Ratio (95% CI)	0.30 (0.03, 3.43)		
p-value [1]	0.33		
Unadjusted Absolute Risk Difference (95% CI)	-0.16 (-0.46, 0.14)		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Non-Responder, n(%)	10 (90.9%)	9 (75.0%)	
Non-missing	6 (54.5%)	4 (33.3%)	
Missing	4 (36.4%)	5 (41.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-deter-mf.pdf 29AUG2023: 9:44

Table 2.7208: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 59)	RUX (N = 54)	MMB (N = 16)	RUX (N = 28)
SF3602-Social Functioning: NBS at Week 24				
Responder, n(%)	4 (6.8%)	4 (7.4%)	2 (12.5%)	0
Unadjusted Relative Risk (95% CI)	0.92 (0.24, 3.48)		8.53 (0.43, 167.39)	
p-value [1]	0.90		0.16	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Odds Ratio (95% CI)	0.91 (0.22, 3.83)		9.83 (0.44, 218.49)	
p-value [1]	0.90		0.15	
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.10, 0.09)		0.13 (-0.05, 0.30)	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	55 (93.2%)	50 (92.6%)	14 (87.5%)	28 (100.0%)
Non-missing	38 (64.4%)	40 (74.1%)	7 (43.8%)	16 (57.1%)
Missing	17 (28.8%)	10 (18.5%)	7 (43.8%)	12 (42.9%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-deter-mf.pdf 29AUG2023: 9:44

Table 2.7208: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 11)	RUX (N = 12)	p-value
SF3602-Social Functioning: NBS at Week 24			
Responder, n(%)	1 (9.1%)	3 (25.0%)	
Unadjusted Relative Risk (95% CI)	0.36 (0.04, 3.00)		
p-value [1]	0.35		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Unadjusted Odds Ratio (95% CI)	0.30 (0.03, 3.43)		
p-value [1]	0.33		
Unadjusted Absolute Risk Difference (95% CI)	-0.16 (-0.46, 0.14)		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Non-Responder, n(%)	10 (90.9%)	9 (75.0%)	
Non-missing	6 (54.5%)	4 (33.3%)	
Missing	4 (36.4%)	5 (41.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-deter-mf.pdf 29AUG2023: 9:44

Table 2.7208: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 59)	RUX (N = 54)	MMB (N = 16)	RUX (N = 28)
SF3602-Role Emotional: NBS at Week 24				
Responder, n(%)	10 (16.9%)	8 (14.8%)	1 (6.3%)	2 (7.1%)
Unadjusted Relative Risk (95% CI)	1.14 (0.49, 2.69)		0.88 (0.09, 8.91)	
p-value [1]	0.76		0.91	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Odds Ratio (95% CI)	1.17 (0.43, 3.23)		0.87 (0.07, 10.38)	
p-value [1]	0.76		0.91	
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.11, 0.16)		-0.01 (-0.16, 0.14)	
Adjusted Relative Risk (95% CI) [2]	1.25 (0.54, 2.90)		NE	
p-value [2]	0.60		NE	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	49 (83.1%)	46 (85.2%)	15 (93.8%)	26 (92.9%)
Non-missing	32 (54.2%)	36 (66.7%)	8 (50.0%)	14 (50.0%)
Missing	17 (28.8%)	10 (18.5%)	7 (43.8%)	12 (42.9%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7208: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 11)	RUX (N = 12)	p-value
SF3602-Role Emotional: NBS at Week 24			
Responder, n(%)	0	3 (25.0%)	
Unadjusted Relative Risk (95% CI)	0.15 (0.01, 2.70)		
p-value [1]	0.20		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NE
Unadjusted Odds Ratio (95% CI)	0.12 (0.01, 2.58)		
p-value [1]	0.17		
Unadjusted Absolute Risk Difference (95% CI)	-0.23 (-0.49, 0.04)		
Adjusted Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NE
Non-Responder, n(%)	11 (100.0%)	9 (75.0%)	
Non-missing	7 (63.6%)	4 (33.3%)	
Missing	4 (36.4%)	5 (41.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-deter-mf.pdf 29AUG2023: 9:44

Table 2.7208: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 59)	RUX (N = 54)	MMB (N = 16)	RUX (N = 28)
SF3602-Mental Health: NBS at Week 24				
Responder, n(%)	7 (11.9%)	4 (7.4%)	0	3 (10.7%)
Unadjusted Relative Risk (95% CI)	1.60 (0.50, 5.17)		0.24 (0.01, 4.44)	
p-value [1]	0.43		0.34	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Odds Ratio (95% CI)	1.68 (0.46, 6.10)		0.22 (0.01, 4.56)	
p-value [1]	0.43		0.33	
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.06, 0.15)		-0.09 (-0.23, 0.05)	
Adjusted Relative Risk (95% CI) [2]	NE		NE	
p-value [2]	NE		NE	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	52 (88.1%)	50 (92.6%)	16 (100.0%)	25 (89.3%)
Non-missing	35 (59.3%)	40 (74.1%)	9 (56.3%)	13 (46.4%)
Missing	17 (28.8%)	10 (18.5%)	7 (43.8%)	12 (42.9%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7208: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 11)	RUX (N = 12)	p-value
SF3602-Mental Health: NBS at Week 24			
Responder, n(%)	0	2 (16.7%)	
Unadjusted Relative Risk (95% CI)	0.22 (0.01, 4.07)		
p-value [1]	0.31		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NE
Unadjusted Odds Ratio (95% CI)	0.18 (0.01, 4.26)		
p-value [1]	0.29		
Unadjusted Absolute Risk Difference (95% CI)	-0.15 (-0.39, 0.09)		
Adjusted Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NE
Non-Responder, n(%)	11 (100.0%)	10 (83.3%)	
Non-missing	7 (63.6%)	5 (41.7%)	
Missing	4 (36.4%)	5 (41.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-deter-mf.pdf 29AUG2023: 9:44

Table 2.7208: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 59)	RUX (N = 54)	MMB (N = 16)	RUX (N = 28)
SF3602-Physical Component Summary at Week 24				
Responder, n(%)	1 (1.7%)	5 (9.3%)	1 (6.3%)	0
Unadjusted Relative Risk (95% CI)	0.18 (0.02, 1.52)		5.12 (0.22, 118.73)	
p-value [1]	0.12		0.31	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Odds Ratio (95% CI)	0.17 (0.02, 1.50)		5.52 (0.21, 143.68)	
p-value [1]	0.11		0.30	
Unadjusted Absolute Risk Difference (95% CI)	-0.08 (-0.16, 0.01)		0.07 (-0.07, 0.21)	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	58 (98.3%)	49 (90.7%)	15 (93.8%)	28 (100.0%)
Non-missing	41 (69.5%)	39 (72.2%)	8 (50.0%)	16 (57.1%)
Missing	17 (28.8%)	10 (18.5%)	7 (43.8%)	12 (42.9%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7208: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 11)	RUX (N = 12)	p-value
SF3602-Physical Component Summary at Week 24			
Responder, n(%)	0	0	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Non-Responder, n(%)	11 (100.0%)	12 (100.0%)	
Non-missing	7 (63.6%)	7 (58.3%)	
Missing	4 (36.4%)	5 (41.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
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Table 2.7208: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 59)	RUX (N = 54)	MMB (N = 16)	RUX (N = 28)
SF3602-Mental Component Summary at Week 24				
Responder, n(%)	4 (6.8%)	0	0	2 (7.1%)
Unadjusted Relative Risk (95% CI)	8.25 (0.45, 149.76)		0.34 (0.02, 6.70)	
p-value [1]	0.15		0.48	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Odds Ratio (95% CI)	8.84 (0.46, 168.12)		0.32 (0.01, 7.12)	
p-value [1]	0.15		0.47	
Unadjusted Absolute Risk Difference (95% CI)	0.07 (-0.01, 0.14)		-0.06 (-0.19, 0.07)	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	55 (93.2%)	54 (100.0%)	16 (100.0%)	26 (92.9%)
Non-missing	38 (64.4%)	44 (81.5%)	9 (56.3%)	14 (50.0%)
Missing	17 (28.8%)	10 (18.5%)	7 (43.8%)	12 (42.9%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-deter-mf.pdf 29AUG2023: 9:44

Table 2.7208: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 11)	RUX (N = 12)	p-value
SF3602-Mental Component Summary at Week 24			
Responder, n(%)	0	3 (25.0%)	
Unadjusted Relative Risk (95% CI)	0.15 (0.01, 2.70)		
p-value [1]	0.20		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Unadjusted Odds Ratio (95% CI)	0.12 (0.01, 2.58)		
p-value [1]	0.17		
Unadjusted Absolute Risk Difference (95% CI)	-0.23 (-0.49, 0.04)		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Non-Responder, n(%)	11 (100.0%)	9 (75.0%)	
Non-missing	7 (63.6%)	4 (33.3%)	
Missing	4 (36.4%)	5 (41.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-deter-mf.pdf 29AUG2023: 9:44

Table 2.7203: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 50)	RUX (N = 56)	MMB (N = 36)	RUX (N = 38)	p-value
SF3602-Physical Functioning: NBS at Week 24					
Responder, n(%)	7 (14.0%)	5 (8.9%)	1 (2.8%)	4 (10.5%)	
Unadjusted Relative Risk (95% CI)	1.57 (0.53, 4.63)		0.26 (0.03, 2.25)		
p-value [1]	0.42		0.22		
Unadjusted interaction test for Treatment*Gender [3]					0.11
Unadjusted Odds Ratio (95% CI)	1.66 (0.49, 5.61)		0.24 (0.03, 2.28)		
p-value [1]	0.41		0.22		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.07, 0.17)		-0.08 (-0.19, 0.03)		
Adjusted Relative Risk (95% CI) [2]	1.70 (0.57, 5.10)		NE		
p-value [2]	0.34		NE		
Adjusted interaction test for Treatment*Gender [3]					0.10
Non-Responder, n(%)	43 (86.0%)	51 (91.1%)	35 (97.2%)	34 (89.5%)	
Non-missing	28 (56.0%)	36 (64.3%)	22 (61.1%)	22 (57.9%)	
Missing	15 (30.0%)	15 (26.8%)	13 (36.1%)	12 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7203: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 50)	RUX (N = 56)	MMB (N = 36)	RUX (N = 38)	p-value
SF3602-Role Physical: NBS at Week 24					
Responder, n(%)	7 (14.0%)	9 (16.1%)	3 (8.3%)	6 (15.8%)	
Unadjusted Relative Risk (95% CI)	0.87 (0.35, 2.17)		0.53 (0.14, 1.95)		
p-value [1]	0.77		0.34		
Unadjusted interaction test for Treatment*Gender [3]					0.53
Unadjusted Odds Ratio (95% CI)	0.85 (0.29, 2.48)		0.48 (0.11, 2.11)		
p-value [1]	0.77		0.33		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.16, 0.12)		-0.07 (-0.22, 0.07)		
Adjusted Relative Risk (95% CI) [2]	1.07 (0.44, 2.61)		NE		
p-value [2]	0.88		NE		
Adjusted interaction test for Treatment*Gender [3]					0.45
Non-Responder, n(%)	43 (86.0%)	47 (83.9%)	33 (91.7%)	32 (84.2%)	
Non-missing	28 (56.0%)	32 (57.1%)	20 (55.6%)	20 (52.6%)	
Missing	15 (30.0%)	15 (26.8%)	13 (36.1%)	12 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7203: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 50)	RUX (N = 56)	MMB (N = 36)	RUX (N = 38)	p-value
SF3602-Bodily Pain: NBS at Week 24					
Responder, n(%)	7 (14.0%)	4 (7.1%)	3 (8.3%)	5 (13.2%)	
Unadjusted Relative Risk (95% CI)	1.96 (0.61, 6.30)		0.63 (0.16, 2.46)		
p-value [1]	0.26		0.51		
Unadjusted interaction test for Treatment*Gender [3]					0.21
Unadjusted Odds Ratio (95% CI)	2.12 (0.58, 7.71)		0.60 (0.13, 2.72)		
p-value [1]	0.26		0.51		
Unadjusted Absolute Risk Difference (95% CI)	0.07 (-0.05, 0.19)		-0.05 (-0.19, 0.09)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Gender [3]					NE
Non-Responder, n(%)	43 (86.0%)	52 (92.9%)	33 (91.7%)	33 (86.8%)	
Non-missing	28 (56.0%)	37 (66.1%)	20 (55.6%)	21 (55.3%)	
Missing	15 (30.0%)	15 (26.8%)	13 (36.1%)	12 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7203: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 50)	RUX (N = 56)	MMB (N = 36)	RUX (N = 38)	p-value
SF3602-General Health: NBS at Week 24					
Responder, n(%)	2 (4.0%)	10 (17.9%)	1 (2.8%)	3 (7.9%)	
Unadjusted Relative Risk (95% CI)	0.22 (0.05, 0.97)		0.35 (0.04, 3.23)		
p-value [1]	0.046		0.36		
Unadjusted interaction test for Treatment*Gender [3]					0.76
Unadjusted Odds Ratio (95% CI)	0.19 (0.04, 0.92)		0.33 (0.03, 3.36)		
p-value [1]	0.039		0.35		
Unadjusted Absolute Risk Difference (95% CI)	-0.14 (-0.25, -0.02)		-0.05 (-0.15, 0.05)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Gender [3]					NE
Non-Responder, n(%)	48 (96.0%)	46 (82.1%)	35 (97.2%)	35 (92.1%)	
Non-missing	33 (66.0%)	31 (55.4%)	22 (61.1%)	23 (60.5%)	
Missing	15 (30.0%)	15 (26.8%)	13 (36.1%)	12 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7203: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 50)	RUX (N = 56)	MMB (N = 36)	RUX (N = 38)	p-value
SF3602-Vitality: NBS at Week 24					
Responder, n(%)	3 (6.0%)	5 (8.9%)	3 (8.3%)	3 (7.9%)	
Unadjusted Relative Risk (95% CI)	0.67 (0.17, 2.67)		1.06 (0.23, 4.89)		
p-value [1]	0.57		0.94		
Unadjusted interaction test for Treatment*Gender [3]					NA
Unadjusted Odds Ratio (95% CI)	0.65 (0.15, 2.88)		1.06 (0.20, 5.63)		
p-value [1]	0.57		0.94		
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.13, 0.07)		0.00 (-0.12, 0.13)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Gender [3]					NA
Non-Responder, n(%)	47 (94.0%)	51 (91.1%)	33 (91.7%)	35 (92.1%)	
Non-missing	32 (64.0%)	36 (64.3%)	20 (55.6%)	23 (60.5%)	
Missing	15 (30.0%)	15 (26.8%)	13 (36.1%)	12 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7203: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 50)	RUX (N = 56)	MMB (N = 36)	RUX (N = 38)	p-value
SF3602-Social Functioning: NBS at Week 24					
Responder, n(%)	5 (10.0%)	5 (8.9%)	2 (5.6%)	2 (5.3%)	
Unadjusted Relative Risk (95% CI)	1.12 (0.34, 3.64)		1.06 (0.16, 7.10)		
p-value [1]	0.85		0.96		
Unadjusted interaction test for Treatment*Gender [3]					0.96
Unadjusted Odds Ratio (95% CI)	1.13 (0.31, 4.17)		1.06 (0.14, 7.94)		
p-value [1]	0.85		0.96		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.10, 0.12)		0.00 (-0.10, 0.11)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Gender [3]					NE
Non-Responder, n(%)	45 (90.0%)	51 (91.1%)	34 (94.4%)	36 (94.7%)	
Non-missing	30 (60.0%)	36 (64.3%)	21 (58.3%)	24 (63.2%)	
Missing	15 (30.0%)	15 (26.8%)	13 (36.1%)	12 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7203: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 50)	RUX (N = 56)	MMB (N = 36)	RUX (N = 38)	p-value
SF3602-Role Emotional: NBS at Week 24					
Responder, n(%)	8 (16.0%)	8 (14.3%)	3 (8.3%)	5 (13.2%)	
Unadjusted Relative Risk (95% CI)	1.12 (0.45, 2.76)		0.63 (0.16, 2.46)		
p-value [1]	0.81		0.51		
Unadjusted interaction test for Treatment*Gender [3]					0.49
Unadjusted Odds Ratio (95% CI)	1.14 (0.39, 3.31)		0.60 (0.13, 2.72)		
p-value [1]	0.81		0.51		
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.12, 0.15)		-0.05 (-0.19, 0.09)		
Adjusted Relative Risk (95% CI) [2]	1.33 (0.54, 3.27)		NE		
p-value [2]	0.54		NE		
Adjusted interaction test for Treatment*Gender [3]					0.33
Non-Responder, n(%)	42 (84.0%)	48 (85.7%)	33 (91.7%)	33 (86.8%)	
Non-missing	27 (54.0%)	33 (58.9%)	20 (55.6%)	21 (55.3%)	
Missing	15 (30.0%)	15 (26.8%)	13 (36.1%)	12 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7203: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 50)	RUX (N = 56)	MMB (N = 36)	RUX (N = 38)	p-value
SF3602-Mental Health: NBS at Week 24					
Responder, n(%)	6 (12.0%)	6 (10.7%)	1 (2.8%)	3 (7.9%)	
Unadjusted Relative Risk (95% CI)	1.12 (0.39, 3.25)		0.35 (0.04, 3.23)		
p-value [1]	0.83		0.36		
Unadjusted interaction test for Treatment*Gender [3]					0.33
Unadjusted Odds Ratio (95% CI)	1.14 (0.34, 3.78)		0.33 (0.03, 3.36)		
p-value [1]	0.83		0.35		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.11, 0.13)		-0.05 (-0.15, 0.05)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Gender [3]					NE
Non-Responder, n(%)	44 (88.0%)	50 (89.3%)	35 (97.2%)	35 (92.1%)	
Non-missing	29 (58.0%)	35 (62.5%)	22 (61.1%)	23 (60.5%)	
Missing	15 (30.0%)	15 (26.8%)	13 (36.1%)	12 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7203: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 50)	RUX (N = 56)	MMB (N = 36)	RUX (N = 38)	p-value
SF3602-Physical Component Summary at Week 24					
Responder, n(%)	1 (2.0%)	2 (3.6%)	1 (2.8%)	3 (7.9%)	
Unadjusted Relative Risk (95% CI)	0.56 (0.05, 5.99)		0.35 (0.04, 3.23)		
p-value [1]	0.63		0.36		
Unadjusted interaction test for Treatment*Gender [3]					NA
Unadjusted Odds Ratio (95% CI)	0.55 (0.05, 6.27)		0.33 (0.03, 3.36)		
p-value [1]	0.63		0.35		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.08, 0.05)		-0.05 (-0.15, 0.05)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Gender [3]					NA
Non-Responder, n(%)	49 (98.0%)	54 (96.4%)	35 (97.2%)	35 (92.1%)	
Non-missing	34 (68.0%)	39 (69.6%)	22 (61.1%)	23 (60.5%)	
Missing	15 (30.0%)	15 (26.8%)	13 (36.1%)	12 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-deter-sex.pdf 29AUG2023: 9:44

Table 2.7203: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 50)	RUX (N = 56)	MMB (N = 36)	RUX (N = 38)	p-value
SF3602-Mental Component Summary at Week 24					
Responder, n(%)	3 (6.0%)	3 (5.4%)	1 (2.8%)	2 (5.3%)	
Unadjusted Relative Risk (95% CI)	1.12 (0.24, 5.30)		0.53 (0.05, 5.57)		
p-value [1]	0.89		0.60		
Unadjusted interaction test for Treatment*Gender [3]					NA
Unadjusted Odds Ratio (95% CI)	1.13 (0.22, 5.86)		0.51 (0.04, 5.93)		
p-value [1]	0.89		0.59		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.08, 0.09)		-0.02 (-0.11, 0.06)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Gender [3]					NA
Non-Responder, n(%)	47 (94.0%)	53 (94.6%)	35 (97.2%)	36 (94.7%)	
Non-missing	32 (64.0%)	38 (67.9%)	22 (61.1%)	24 (63.2%)	
Missing	15 (30.0%)	15 (26.8%)	13 (36.1%)	12 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-deter-sex.pdf 29AUG2023: 9:44

Table 2.7210: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N = 47)	RUX (N = 43)	MMB (N = 39)	RUX (N = 51)	p-value
SF3602-Physical Functioning: NBS at Week 24					
Responder, n(%)	7 (14.9%)	4 (9.3%)	1 (2.6%)	5 (9.8%)	
Unadjusted Relative Risk (95% CI)	1.60 (0.50, 5.09)		0.26 (0.03, 2.15)		
p-value [1]	0.43		0.21		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.092
Unadjusted Odds Ratio (95% CI)	1.71 (0.46, 6.29)		0.24 (0.03, 2.16)		
p-value [1]	0.42		0.20		
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.08, 0.19)		-0.07 (-0.17, 0.02)		
Adjusted Relative Risk (95% CI) [2]	NE		0.24 (0.02, 2.69)		
p-value [2]	NE		0.24		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.15
Non-Responder, n(%)	40 (85.1%)	39 (90.7%)	38 (97.4%)	46 (90.2%)	
Non-missing	27 (57.4%)	27 (62.8%)	23 (59.0%)	31 (60.8%)	
Missing	13 (27.7%)	12 (27.9%)	15 (38.5%)	15 (29.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7210: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N = 47)	RUX (N = 43)	MMB (N = 39)	RUX (N = 51)	p-value
SF3602-Role Physical: NBS at Week 24					
Responder, n(%)	7 (14.9%)	5 (11.6%)	3 (7.7%)	10 (19.6%)	
Unadjusted Relative Risk (95% CI)	1.28 (0.44, 3.74)		0.39 (0.12, 1.33)		
p-value [1]	0.65		0.13		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.13
Unadjusted Odds Ratio (95% CI)	1.33 (0.39, 4.55)		0.34 (0.09, 1.34)		
p-value [1]	0.65		0.12		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.11, 0.17)		-0.12 (-0.26, 0.02)		
Adjusted Relative Risk (95% CI) [2]	NE		0.41 (0.12, 1.40)		
p-value [2]	NE		0.15		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.22
Non-Responder, n(%)	40 (85.1%)	38 (88.4%)	36 (92.3%)	41 (80.4%)	
Non-missing	27 (57.4%)	26 (60.5%)	21 (53.8%)	26 (51.0%)	
Missing	13 (27.7%)	12 (27.9%)	15 (38.5%)	15 (29.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-deter-svb.pdf 29AUG2023: 9:45

Table 2.7210: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N = 47)	RUX (N = 43)	MMB (N = 39)	RUX (N = 51)	p-value
SF3602-Bodily Pain: NBS at Week 24					
Responder, n(%)	7 (14.9%)	3 (7.0%)	3 (7.7%)	6 (11.8%)	
Unadjusted Relative Risk (95% CI)	2.13 (0.59, 7.74)		0.65 (0.17, 2.45)		
p-value [1]	0.25		0.53		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.19
Unadjusted Odds Ratio (95% CI)	2.33 (0.56, 9.67)		0.63 (0.15, 2.67)		
p-value [1]	0.24		0.53		
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.05, 0.21)		-0.04 (-0.16, 0.08)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NE
Non-Responder, n(%)	40 (85.1%)	40 (93.0%)	36 (92.3%)	45 (88.2%)	
Non-missing	27 (57.4%)	28 (65.1%)	21 (53.8%)	30 (58.8%)	
Missing	13 (27.7%)	12 (27.9%)	15 (38.5%)	15 (29.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7210: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N = 47)	RUX (N = 43)	MMB (N = 39)	RUX (N = 51)	p-value
SF3602-General Health: NBS at Week 24					
Responder, n(%)	1 (2.1%)	6 (14.0%)	2 (5.1%)	7 (13.7%)	
Unadjusted Relative Risk (95% CI)	0.15 (0.02, 1.22)		0.37 (0.08, 1.70)		
p-value [1]	0.076		0.20		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Odds Ratio (95% CI)	0.13 (0.02, 1.16)		0.34 (0.07, 1.74)		
p-value [1]	0.068		0.19		
Unadjusted Absolute Risk Difference (95% CI)	-0.12 (-0.23, -0.01)		-0.09 (-0.20, 0.03)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Non-Responder, n(%)	46 (97.9%)	37 (86.0%)	37 (94.9%)	44 (86.3%)	
Non-missing	33 (70.2%)	25 (58.1%)	22 (56.4%)	29 (56.9%)	
Missing	13 (27.7%)	12 (27.9%)	15 (38.5%)	15 (29.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-deter-svb.pdf 29AUG2023: 9:45

Table 2.7210: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N = 47)	RUX (N = 43)	MMB (N = 39)	RUX (N = 51)	p-value
SF3602-Vitality: NBS at Week 24					
Responder, n(%)	4 (8.5%)	4 (9.3%)	2 (5.1%)	4 (7.8%)	
Unadjusted Relative Risk (95% CI)	0.91 (0.24, 3.43)		0.65 (0.13, 3.39)		
p-value [1]	0.90		0.61		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Odds Ratio (95% CI)	0.91 (0.21, 3.87)		0.64 (0.11, 3.66)		
p-value [1]	0.90		0.61		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.13, 0.11)		-0.03 (-0.13, 0.07)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Non-Responder, n(%)	43 (91.5%)	39 (90.7%)	37 (94.9%)	47 (92.2%)	
Non-missing	30 (63.8%)	27 (62.8%)	22 (56.4%)	32 (62.7%)	
Missing	13 (27.7%)	12 (27.9%)	15 (38.5%)	15 (29.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7210: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N = 47)	RUX (N = 43)	MMB (N = 39)	RUX (N = 51)	p-value
SF3602-Social Functioning: NBS at Week 24					
Responder, n(%)	4 (8.5%)	3 (7.0%)	3 (7.7%)	4 (7.8%)	
Unadjusted Relative Risk (95% CI)	1.22 (0.29, 5.14)		0.98 (0.23, 4.13)		
p-value [1]	0.79		0.98		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Odds Ratio (95% CI)	1.24 (0.26, 5.89)		0.98 (0.21, 4.65)		
p-value [1]	0.79		0.98		
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.09, 0.13)		0.00 (-0.11, 0.11)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Non-Responder, n(%)	43 (91.5%)	40 (93.0%)	36 (92.3%)	47 (92.2%)	
Non-missing	30 (63.8%)	28 (65.1%)	21 (53.8%)	32 (62.7%)	
Missing	13 (27.7%)	12 (27.9%)	15 (38.5%)	15 (29.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-deter-svb.pdf 29AUG2023: 9:45

Table 2.7210: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N = 47)	RUX (N = 43)	MMB (N = 39)	RUX (N = 51)	p-value
SF3602-Role Emotional: NBS at Week 24					
Responder, n(%)	7 (14.9%)	6 (14.0%)	4 (10.3%)	7 (13.7%)	
Unadjusted Relative Risk (95% CI)	1.07 (0.39, 2.93)		0.75 (0.24, 2.37)		
p-value [1]	0.90		0.62		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.64
Unadjusted Odds Ratio (95% CI)	1.08 (0.33, 3.51)		0.72 (0.19, 2.65)		
p-value [1]	0.90		0.62		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.14, 0.15)		-0.03 (-0.17, 0.10)		
Adjusted Relative Risk (95% CI) [2]	NE		0.92 (0.26, 3.29)		
p-value [2]	NE		0.90		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.87
Non-Responder, n(%)	40 (85.1%)	37 (86.0%)	35 (89.7%)	44 (86.3%)	
Non-missing	27 (57.4%)	25 (58.1%)	20 (51.3%)	29 (56.9%)	
Missing	13 (27.7%)	12 (27.9%)	15 (38.5%)	15 (29.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-deter-svb.pdf 29AUG2023: 9:45

Table 2.7210: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N = 47)	RUX (N = 43)	MMB (N = 39)	RUX (N = 51)	p-value
SF3602-Mental Health: NBS at Week 24					
Responder, n(%)	4 (8.5%)	4 (9.3%)	3 (7.7%)	5 (9.8%)	
Unadjusted Relative Risk (95% CI)	0.91 (0.24, 3.43)		0.78 (0.20, 3.09)		
p-value [1]	0.90		0.73		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Odds Ratio (95% CI)	0.91 (0.21, 3.87)		0.77 (0.17, 3.42)		
p-value [1]	0.90		0.73		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.13, 0.11)		-0.02 (-0.14, 0.10)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Non-Responder, n(%)	43 (91.5%)	39 (90.7%)	36 (92.3%)	46 (90.2%)	
Non-missing	30 (63.8%)	27 (62.8%)	21 (53.8%)	31 (60.8%)	
Missing	13 (27.7%)	12 (27.9%)	15 (38.5%)	15 (29.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7210: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N = 47)	RUX (N = 43)	MMB (N = 39)	RUX (N = 51)	p-value
SF3602-Physical Component Summary at Week 24					
Responder, n(%)	1 (2.1%)	2 (4.7%)	1 (2.6%)	3 (5.9%)	
Unadjusted Relative Risk (95% CI)	0.46 (0.04, 4.87)		0.44 (0.05, 4.03)		
p-value [1]	0.52		0.46		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Odds Ratio (95% CI)	0.45 (0.04, 5.10)		0.42 (0.04, 4.21)		
p-value [1]	0.52		0.46		
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.10, 0.05)		-0.03 (-0.11, 0.05)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Non-Responder, n(%)	46 (97.9%)	41 (95.3%)	38 (97.4%)	48 (94.1%)	
Non-missing	33 (70.2%)	29 (67.4%)	23 (59.0%)	33 (64.7%)	
Missing	13 (27.7%)	12 (27.9%)	15 (38.5%)	15 (29.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7210: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N = 47)	RUX (N = 43)	MMB (N = 39)	RUX (N = 51)	p-value
SF3602-Mental Component Summary at Week 24					
Responder, n(%)	1 (2.1%)	2 (4.7%)	3 (7.7%)	3 (5.9%)	
Unadjusted Relative Risk (95% CI)	0.46 (0.04, 4.87)		1.31 (0.28, 6.13)		
p-value [1]	0.52		0.73		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Odds Ratio (95% CI)	0.45 (0.04, 5.10)		1.33 (0.25, 7.00)		
p-value [1]	0.52		0.73		
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.10, 0.05)		0.02 (-0.09, 0.12)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Non-Responder, n(%)	46 (97.9%)	41 (95.3%)	36 (92.3%)	48 (94.1%)	
Non-missing	33 (70.2%)	29 (67.4%)	21 (53.8%)	33 (64.7%)	
Missing	13 (27.7%)	12 (27.9%)	15 (38.5%)	15 (29.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7209: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline TSS
Double-Blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 44)	RUX (N = 55)	MMB (N = 41)	RUX (N = 38)	p-value
SF3602-Physical Functioning: NBS at Week 24					
Responder, n(%)	6 (13.6%)	5 (9.1%)	2 (4.9%)	4 (10.5%)	
Unadjusted Relative Risk (95% CI)	1.50 (0.49, 4.59)		0.46 (0.09, 2.39)		
p-value [1]	0.48		0.36		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.24
Unadjusted Odds Ratio (95% CI)	1.58 (0.45, 5.56)		0.44 (0.08, 2.53)		
p-value [1]	0.48		0.35		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.08, 0.17)		-0.06 (-0.17, 0.06)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					0.21
Non-Responder, n(%)	38 (86.4%)	50 (90.9%)	39 (95.1%)	34 (89.5%)	
Non-missing	29 (65.9%)	36 (65.5%)	20 (48.8%)	21 (55.3%)	
Missing	9 (20.5%)	14 (25.5%)	19 (46.3%)	13 (34.2%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7209: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline TSS
Double-Blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 44)	RUX (N = 55)	MMB (N = 41)	RUX (N = 38)	p-value
SF3602-Role Physical: NBS at Week 24					
Responder, n(%)	8 (18.2%)	10 (18.2%)	2 (4.9%)	5 (13.2%)	
Unadjusted Relative Risk (95% CI)	1.00 (0.43, 2.32)		0.37 (0.08, 1.80)		
p-value [1]	1.00		0.22		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.26
Unadjusted Odds Ratio (95% CI)	1.00 (0.36, 2.80)		0.34 (0.06, 1.86)		
p-value [1]	1.00		0.21		
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.15, 0.15)		-0.08 (-0.21, 0.04)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					0.24
Non-Responder, n(%)	36 (81.8%)	45 (81.8%)	39 (95.1%)	33 (86.8%)	
Non-missing	27 (61.4%)	31 (56.4%)	20 (48.8%)	20 (52.6%)	
Missing	9 (20.5%)	14 (25.5%)	19 (46.3%)	13 (34.2%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7209: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline TSS
Double-Blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 44)	RUX (N = 55)	MMB (N = 41)	RUX (N = 38)	p-value
SF3602-Bodily Pain: NBS at Week 24					
Responder, n(%)	8 (18.2%)	6 (10.9%)	2 (4.9%)	3 (7.9%)	
Unadjusted Relative Risk (95% CI)	1.67 (0.62, 4.45)		0.62 (0.11, 3.50)		
p-value [1]	0.31		0.59		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.34
Unadjusted Odds Ratio (95% CI)	1.81 (0.58, 5.69)		0.60 (0.09, 3.79)		
p-value [1]	0.31		0.59		
Unadjusted Absolute Risk Difference (95% CI)	0.07 (-0.07, 0.21)		-0.03 (-0.14, 0.08)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NE
Non-Responder, n(%)	36 (81.8%)	49 (89.1%)	39 (95.1%)	35 (92.1%)	
Non-missing	27 (61.4%)	35 (63.6%)	20 (48.8%)	22 (57.9%)	
Missing	9 (20.5%)	14 (25.5%)	19 (46.3%)	13 (34.2%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7209: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline TSS
Double-Blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 44)	RUX (N = 55)	MMB (N = 41)	RUX (N = 38)	p-value
SF3602-General Health: NBS at Week 24					
Responder, n(%)	3 (6.8%)	11 (20.0%)	0	2 (5.3%)	
Unadjusted Relative Risk (95% CI)	0.34 (0.10, 1.15)		0.19 (0.01, 3.75)		
p-value [1]	0.082		0.27		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					NE
Unadjusted Odds Ratio (95% CI)	0.29 (0.08, 1.12)		0.18 (0.01, 3.78)		
p-value [1]	0.074		0.27		
Unadjusted Absolute Risk Difference (95% CI)	-0.13 (-0.26, 0.00)		-0.05 (-0.14, 0.03)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NE
Non-Responder, n(%)	41 (93.2%)	44 (80.0%)	41 (100.0%)	36 (94.7%)	
Non-missing	32 (72.7%)	30 (54.5%)	22 (53.7%)	23 (60.5%)	
Missing	9 (20.5%)	14 (25.5%)	19 (46.3%)	13 (34.2%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7209: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline TSS
Double-Blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 44)	RUX (N = 55)	MMB (N = 41)	RUX (N = 38)	p-value
SF3602-Vitality: NBS at Week 24					
Responder, n(%)	4 (9.1%)	8 (14.5%)	2 (4.9%)	0	
Unadjusted Relative Risk (95% CI)	0.63 (0.20, 1.94)		4.64 (0.23, 93.72)		
p-value [1]	0.42		0.32		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					NE
Unadjusted Odds Ratio (95% CI)	0.59 (0.16, 2.10)		4.87 (0.23, 104.85)		
p-value [1]	0.41		0.31		
Unadjusted Absolute Risk Difference (95% CI)	-0.05 (-0.18, 0.07)		0.05 (-0.03, 0.13)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NE
Non-Responder, n(%)	40 (90.9%)	47 (85.5%)	39 (95.1%)	38 (100.0%)	
Non-missing	31 (70.5%)	33 (60.0%)	20 (48.8%)	25 (65.8%)	
Missing	9 (20.5%)	14 (25.5%)	19 (46.3%)	13 (34.2%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7209: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline TSS
Double-Blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 44)	RUX (N = 55)	MMB (N = 41)	RUX (N = 38)	p-value
SF3602-Social Functioning: NBS at Week 24					
Responder, n(%)	4 (9.1%)	3 (5.5%)	3 (7.3%)	4 (10.5%)	
Unadjusted Relative Risk (95% CI)	1.67 (0.39, 7.06)		0.70 (0.17, 2.91)		
p-value [1]	0.49		0.62		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Unadjusted Odds Ratio (95% CI)	1.73 (0.37, 8.19)		0.67 (0.14, 3.22)		
p-value [1]	0.49		0.62		
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.07, 0.14)		-0.03 (-0.16, 0.09)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Non-Responder, n(%)	40 (90.9%)	52 (94.5%)	38 (92.7%)	34 (89.5%)	
Non-missing	31 (70.5%)	38 (69.1%)	19 (46.3%)	21 (55.3%)	
Missing	9 (20.5%)	14 (25.5%)	19 (46.3%)	13 (34.2%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7209: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline TSS
Double-Blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 44)	RUX (N = 55)	MMB (N = 41)	RUX (N = 38)	p-value
SF3602-Role Emotional: NBS at Week 24					
Responder, n(%)	7 (15.9%)	7 (12.7%)	4 (9.8%)	6 (15.8%)	
Unadjusted Relative Risk (95% CI)	1.25 (0.47, 3.30)		0.62 (0.19, 2.02)		
p-value [1]	0.65		0.43		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.37
Unadjusted Odds Ratio (95% CI)	1.30 (0.42, 4.02)		0.58 (0.15, 2.23)		
p-value [1]	0.65		0.42		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.11, 0.17)		-0.06 (-0.21, 0.09)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					0.33
Non-Responder, n(%)	37 (84.1%)	48 (87.3%)	37 (90.2%)	32 (84.2%)	
Non-missing	28 (63.6%)	34 (61.8%)	18 (43.9%)	19 (50.0%)	
Missing	9 (20.5%)	14 (25.5%)	19 (46.3%)	13 (34.2%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7209: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline TSS
Double-Blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 44)	RUX (N = 55)	MMB (N = 41)	RUX (N = 38)	p-value
SF3602-Mental Health: NBS at Week 24					
Responder, n(%)	5 (11.4%)	6 (10.9%)	2 (4.9%)	3 (7.9%)	
Unadjusted Relative Risk (95% CI)	1.04 (0.34, 3.19)		0.62 (0.11, 3.50)		
p-value [1]	0.94		0.59		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.62
Unadjusted Odds Ratio (95% CI)	1.05 (0.30, 3.69)		0.60 (0.09, 3.79)		
p-value [1]	0.94		0.59		
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.12, 0.13)		-0.03 (-0.14, 0.08)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NE
Non-Responder, n(%)	39 (88.6%)	49 (89.1%)	39 (95.1%)	35 (92.1%)	
Non-missing	30 (68.2%)	35 (63.6%)	20 (48.8%)	22 (57.9%)	
Missing	9 (20.5%)	14 (25.5%)	19 (46.3%)	13 (34.2%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7209: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline TSS
Double-Blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 44)	RUX (N = 55)	MMB (N = 41)	RUX (N = 38)	p-value
SF3602-Physical Component Summary at Week 24					
Responder, n(%)	2 (4.5%)	4 (7.3%)	0	1 (2.6%)	
Unadjusted Relative Risk (95% CI)	0.63 (0.12, 3.26)		0.31 (0.01, 7.38)		
p-value [1]	0.58		0.47		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Unadjusted Odds Ratio (95% CI)	0.61 (0.11, 3.48)		0.30 (0.01, 7.62)		
p-value [1]	0.58		0.47		
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.12, 0.06)		-0.03 (-0.10, 0.04)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Non-Responder, n(%)	42 (95.5%)	51 (92.7%)	41 (100.0%)	37 (97.4%)	
Non-missing	33 (75.0%)	37 (67.3%)	22 (53.7%)	24 (63.2%)	
Missing	9 (20.5%)	14 (25.5%)	19 (46.3%)	13 (34.2%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7209: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline TSS
Double-Blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 44)	RUX (N = 55)	MMB (N = 41)	RUX (N = 38)	p-value
SF3602-Mental Component Summary at Week 24					
Responder, n(%)	2 (4.5%)	4 (7.3%)	2 (4.9%)	1 (2.6%)	
Unadjusted Relative Risk (95% CI)	0.63 (0.12, 3.26)		1.85 (0.18, 19.62)		
p-value [1]	0.58		0.61		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Unadjusted Odds Ratio (95% CI)	0.61 (0.11, 3.48)		1.90 (0.17, 21.82)		
p-value [1]	0.58		0.61		
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.12, 0.06)		0.02 (-0.06, 0.11)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Non-Responder, n(%)	42 (95.5%)	51 (92.7%)	39 (95.1%)	37 (97.4%)	
Non-missing	33 (75.0%)	37 (67.3%)	20 (48.8%)	24 (63.2%)	
Missing	9 (20.5%)	14 (25.5%)	19 (46.3%)	13 (34.2%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7102: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	RUX (N = 36)	MMB (N = 62)	RUX (N = 58)	p-value
SF3602-Physical Functioning: NBS at Week 24					
Responder, n(%)	5 (20.8%)	8 (22.2%)	17 (27.4%)	16 (27.6%)	
Unadjusted Inverse Relative Risk (95% CI)	1.07 (0.40, 2.87)		1.01 (0.56, 1.80)		
p-value [1]	0.90		0.98		
Unadjusted interaction test for Treatment*Age Group [3]					0.92
Unadjusted Inverse Odds Ratio (95% CI)	1.09 (0.31, 3.83)		1.01 (0.45, 2.25)		
p-value [1]	0.90		0.98		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.23, 0.20)		0.00 (-0.16, 0.16)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		1.02 (0.57, 1.82)		
p-value [2]	NE		0.95		
Adjusted interaction test for Treatment*Age Group [3]					0.92
Non-Responder, n(%)	19 (79.2%)	28 (77.8%)	45 (72.6%)	42 (72.4%)	
Non-missing	10 (41.7%)	17 (47.2%)	26 (41.9%)	26 (44.8%)	
Missing	9 (37.5%)	11 (30.6%)	19 (30.6%)	16 (27.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7102: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	RUX (N = 36)	MMB (N = 62)	RUX (N = 58)	p-value
SF3602-Role Physical: NBS at Week 24					
Responder, n(%)	6 (25.0%)	4 (11.1%)	14 (22.6%)	13 (22.4%)	
Unadjusted Inverse Relative Risk (95% CI)	0.44 (0.14, 1.41)		0.99 (0.51, 1.93)		
p-value [1]	0.17		0.98		
Unadjusted interaction test for Treatment*Age Group [3]					0.24
Unadjusted Inverse Odds Ratio (95% CI)	0.38 (0.09, 1.51)		0.99 (0.42, 2.33)		
p-value [1]	0.17		0.98		
Unadjusted Absolute Risk Difference (95% CI)	0.14 (-0.06, 0.34)		0.00 (-0.15, 0.15)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Age Group [3]					NE
Non-Responder, n(%)	18 (75.0%)	32 (88.9%)	48 (77.4%)	45 (77.6%)	
Non-missing	9 (37.5%)	21 (58.3%)	29 (46.8%)	29 (50.0%)	
Missing	9 (37.5%)	11 (30.6%)	19 (30.6%)	16 (27.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7102: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	RUX (N = 36)	MMB (N = 62)	RUX (N = 58)	p-value
SF3602-Bodily Pain: NBS at Week 24					
Responder, n(%)	7 (29.2%)	9 (25.0%)	11 (17.7%)	13 (22.4%)	
Unadjusted Inverse Relative Risk (95% CI)	0.86 (0.37, 1.99)		1.26 (0.62, 2.59)		
p-value [1]	0.72		0.52		
Unadjusted interaction test for Treatment*Age Group [3]					0.50
Unadjusted Inverse Odds Ratio (95% CI)	0.81 (0.25, 2.58)		1.34 (0.55, 3.29)		
p-value [1]	0.72		0.52		
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.19, 0.27)		-0.05 (-0.19, 0.10)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		1.28 (0.62, 2.65)		
p-value [2]	NE		0.51		
Adjusted interaction test for Treatment*Age Group [3]					0.43
Non-Responder, n(%)	17 (70.8%)	27 (75.0%)	51 (82.3%)	45 (77.6%)	
Non-missing	8 (33.3%)	16 (44.4%)	32 (51.6%)	29 (50.0%)	
Missing	9 (37.5%)	11 (30.6%)	19 (30.6%)	16 (27.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
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Table 2.7102: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	RUX (N = 36)	MMB (N = 62)	RUX (N = 58)	p-value
SF3602-General Health: NBS at Week 24					
Responder, n(%)	5 (20.8%)	7 (19.4%)	16 (25.8%)	12 (20.7%)	
Unadjusted Inverse Relative Risk (95% CI)	0.93 (0.33, 2.60)		0.80 (0.42, 1.55)		
p-value [1]	0.90		0.51		
Unadjusted interaction test for Treatment*Age Group [3]					0.81
Unadjusted Inverse Odds Ratio (95% CI)	0.92 (0.25, 3.32)		0.75 (0.32, 1.76)		
p-value [1]	0.90		0.51		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.19, 0.22)		0.05 (-0.10, 0.20)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Age Group [3]					NE
Non-Responder, n(%)	19 (79.2%)	29 (80.6%)	46 (74.2%)	46 (79.3%)	
Non-missing	10 (41.7%)	18 (50.0%)	27 (43.5%)	30 (51.7%)	
Missing	9 (37.5%)	11 (30.6%)	19 (30.6%)	16 (27.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7102: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	RUX (N = 36)	MMB (N = 62)	RUX (N = 58)	p-value
SF3602-Vitality: NBS at Week 24					
Responder, n(%)	4 (16.7%)	8 (22.2%)	9 (14.5%)	16 (27.6%)	
Unadjusted Inverse Relative Risk (95% CI)	1.33 (0.45, 3.94)		1.90 (0.91, 3.96)		
p-value [1]	0.60		0.086		
Unadjusted interaction test for Treatment*Age Group [3]					0.61
Unadjusted Inverse Odds Ratio (95% CI)	1.43 (0.38, 5.40)		2.24 (0.90, 5.58)		
p-value [1]	0.60		0.082		
Unadjusted Absolute Risk Difference (95% CI)	-0.06 (-0.26, 0.15)		-0.13 (-0.28, 0.01)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Age Group [3]					NE
Non-Responder, n(%)	20 (83.3%)	28 (77.8%)	53 (85.5%)	42 (72.4%)	
Non-missing	11 (45.8%)	17 (47.2%)	34 (54.8%)	26 (44.8%)	
Missing	9 (37.5%)	11 (30.6%)	19 (30.6%)	16 (27.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7102: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	RUX (N = 36)	MMB (N = 62)	RUX (N = 58)	p-value
SF3602-Social Functioning: NBS at Week 24					
Responder, n(%)	1 (4.2%)	7 (19.4%)	11 (17.7%)	10 (17.2%)	
Unadjusted Inverse Relative Risk (95% CI)	4.67 (0.61, 35.56)		0.97 (0.45, 2.12)		
p-value [1]	0.14		0.94		
Unadjusted interaction test for Treatment*Age Group [3]					0.081
Unadjusted Inverse Odds Ratio (95% CI)	5.55 (0.64, 48.41)		0.97 (0.38, 2.48)		
p-value [1]	0.12		0.94		
Unadjusted Absolute Risk Difference (95% CI)	-0.15 (-0.30, 0.00)		0.01 (-0.13, 0.14)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Age Group [3]					NE
Non-Responder, n(%)	23 (95.8%)	29 (80.6%)	51 (82.3%)	48 (82.8%)	
Non-missing	14 (58.3%)	18 (50.0%)	32 (51.6%)	32 (55.2%)	
Missing	9 (37.5%)	11 (30.6%)	19 (30.6%)	16 (27.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-improv-age.pdf 29AUG2023: 9:41

Table 2.7102: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	RUX (N = 36)	MMB (N = 62)	RUX (N = 58)	p-value
SF3602-Role Emotional: NBS at Week 24					
Responder, n(%)	2 (8.3%)	6 (16.7%)	11 (17.7%)	12 (20.7%)	
Unadjusted Inverse Relative Risk (95% CI)	2.00 (0.44, 9.10)		1.17 (0.56, 2.43)		
p-value [1]	0.37		0.68		
Unadjusted interaction test for Treatment*Age Group [3]					0.50
Unadjusted Inverse Odds Ratio (95% CI)	2.20 (0.41, 11.95)		1.21 (0.49, 3.00)		
p-value [1]	0.36		0.68		
Unadjusted Absolute Risk Difference (95% CI)	-0.08 (-0.25, 0.08)		-0.03 (-0.17, 0.11)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Age Group [3]					NE
Non-Responder, n(%)	22 (91.7%)	30 (83.3%)	51 (82.3%)	46 (79.3%)	
Non-missing	13 (54.2%)	19 (52.8%)	32 (51.6%)	30 (51.7%)	
Missing	9 (37.5%)	11 (30.6%)	19 (30.6%)	16 (27.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7102: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	RUX (N = 36)	MMB (N = 62)	RUX (N = 58)	p-value
SF3602-Mental Health: NBS at Week 24					
Responder, n(%)	5 (20.8%)	5 (13.9%)	11 (17.7%)	11 (19.0%)	
Unadjusted Inverse Relative Risk (95% CI)	0.67 (0.22, 2.06)		1.07 (0.50, 2.27)		
p-value [1]	0.48		0.86		
Unadjusted interaction test for Treatment*Age Group [3]					0.50
Unadjusted Inverse Odds Ratio (95% CI)	0.61 (0.16, 2.40)		1.09 (0.43, 2.74)		
p-value [1]	0.48		0.86		
Unadjusted Absolute Risk Difference (95% CI)	0.07 (-0.13, 0.27)		-0.01 (-0.15, 0.13)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Age Group [3]					NE
Non-Responder, n(%)	19 (79.2%)	31 (86.1%)	51 (82.3%)	47 (81.0%)	
Non-missing	10 (41.7%)	20 (55.6%)	32 (51.6%)	31 (53.4%)	
Missing	9 (37.5%)	11 (30.6%)	19 (30.6%)	16 (27.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7102: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	RUX (N = 36)	MMB (N = 62)	RUX (N = 58)	p-value
SF3602-Physical Component Summary at Week 24					
Responder, n(%)	4 (16.7%)	1 (2.8%)	9 (14.5%)	8 (13.8%)	
Unadjusted Inverse Relative Risk (95% CI)	0.17 (0.02, 1.40)		0.95 (0.39, 2.30)		
p-value [1]	0.099		0.91		
Unadjusted interaction test for Treatment*Age Group [3]					0.11
Unadjusted Inverse Odds Ratio (95% CI)	0.14 (0.01, 1.37)		0.94 (0.34, 2.63)		
p-value [1]	0.091		0.91		
Unadjusted Absolute Risk Difference (95% CI)	0.14 (-0.02, 0.30)		0.01 (-0.12, 0.13)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.96 (0.38, 2.47)		
p-value [2]	NE		0.94		
Adjusted interaction test for Treatment*Age Group [3]					0.12
Non-Responder, n(%)	20 (83.3%)	35 (97.2%)	53 (85.5%)	50 (86.2%)	
Non-missing	11 (45.8%)	24 (66.7%)	34 (54.8%)	34 (58.6%)	
Missing	9 (37.5%)	11 (30.6%)	19 (30.6%)	16 (27.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-improv-age.pdf 29AUG2023: 9:41

Table 2.7102: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	RUX (N = 36)	MMB (N = 62)	RUX (N = 58)	p-value
SF3602-Mental Component Summary at Week 24					
Responder, n(%)	1 (4.2%)	5 (13.9%)	5 (8.1%)	5 (8.6%)	
Unadjusted Inverse Relative Risk (95% CI)	3.33 (0.41, 26.79)		1.07 (0.33, 3.50)		
p-value [1]	0.26		0.91		
Unadjusted interaction test for Treatment*Age Group [3]					0.30
Unadjusted Inverse Odds Ratio (95% CI)	3.71 (0.41, 33.94)		1.08 (0.29, 3.93)		
p-value [1]	0.25		0.91		
Unadjusted Absolute Risk Difference (95% CI)	-0.10 (-0.24, 0.04)		-0.01 (-0.10, 0.09)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Age Group [3]					NE
Non-Responder, n(%)	23 (95.8%)	31 (86.1%)	57 (91.9%)	53 (91.4%)	
Non-missing	14 (58.3%)	20 (55.6%)	38 (61.3%)	37 (63.8%)	
Missing	9 (37.5%)	11 (30.6%)	19 (30.6%)	16 (27.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7104: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Region
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N = 53)	RUX (N = 51)	MMB (N = 33)	RUX (N = 43)	p-value
SF3602-Physical Functioning: NBS at Week 24					
Responder, n(%)	12 (22.6%)	9 (17.6%)	10 (30.3%)	15 (34.9%)	
Unadjusted Inverse Relative Risk (95% CI)	0.78 (0.36, 1.69)		1.15 (0.60, 2.23)		
p-value [1]	0.53		0.68		
Unadjusted interaction test for Treatment*Region [3]					0.45
Unadjusted Inverse Odds Ratio (95% CI)	0.73 (0.28, 1.92)		1.23 (0.47, 3.26)		
p-value [1]	0.53		0.67		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.10, 0.20)		-0.05 (-0.26, 0.17)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.84 (0.42, 1.70)		NE		
p-value [2]	0.63		NE		
Adjusted interaction test for Treatment*Region [3]					0.38
Non-Responder, n(%)	41 (77.4%)	42 (82.4%)	23 (69.7%)	28 (65.1%)	
Non-missing	19 (35.8%)	23 (45.1%)	17 (51.5%)	20 (46.5%)	
Missing	22 (41.5%)	19 (37.3%)	6 (18.2%)	8 (18.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
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Table 2.7104: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Region
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N = 53)	RUX (N = 51)	MMB (N = 33)	RUX (N = 43)	p-value
SF3602-Role Physical: NBS at Week 24					
Responder, n(%)	6 (11.3%)	7 (13.7%)	14 (42.4%)	10 (23.3%)	
Unadjusted Inverse Relative Risk (95% CI)	1.21 (0.44, 3.36)		0.55 (0.28, 1.07)		
p-value [1]	0.71		0.080		
Unadjusted interaction test for Treatment*Region [3]					0.21
Unadjusted Inverse Odds Ratio (95% CI)	1.25 (0.39, 4.00)		0.41 (0.15, 1.11)		
p-value [1]	0.71		0.078		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.15, 0.10)		0.19 (-0.02, 0.40)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Region [3]					NE
Non-Responder, n(%)	47 (88.7%)	44 (86.3%)	19 (57.6%)	33 (76.7%)	
Non-missing	25 (47.2%)	25 (49.0%)	13 (39.4%)	25 (58.1%)	
Missing	22 (41.5%)	19 (37.3%)	6 (18.2%)	8 (18.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7104: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Region
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N = 53)	RUX (N = 51)	MMB (N = 33)	RUX (N = 43)	p-value
SF3602-Bodily Pain: NBS at Week 24					
Responder, n(%)	7 (13.2%)	8 (15.7%)	11 (33.3%)	14 (32.6%)	
Unadjusted Inverse Relative Risk (95% CI)	1.19 (0.46, 3.04)		0.98 (0.51, 1.86)		
p-value [1]	0.72		0.94		
Unadjusted interaction test for Treatment*Region [3]					0.74
Unadjusted Inverse Odds Ratio (95% CI)	1.22 (0.41, 3.66)		0.97 (0.37, 2.53)		
p-value [1]	0.72		0.94		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.16, 0.11)		0.01 (-0.21, 0.22)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.34 (0.54, 3.32)		NE		
p-value [2]	0.53		NE		
Adjusted interaction test for Treatment*Region [3]					0.66
Non-Responder, n(%)	46 (86.8%)	43 (84.3%)	22 (66.7%)	29 (67.4%)	
Non-missing	24 (45.3%)	24 (47.1%)	16 (48.5%)	21 (48.8%)	
Missing	22 (41.5%)	19 (37.3%)	6 (18.2%)	8 (18.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
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Table 2.7104: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Region
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N = 53)	RUX (N = 51)	MMB (N = 33)	RUX (N = 43)	p-value
SF3602-General Health: NBS at Week 24					
Responder, n(%)	12 (22.6%)	7 (13.7%)	9 (27.3%)	12 (27.9%)	
Unadjusted Inverse Relative Risk (95% CI)	0.61 (0.26, 1.42)		1.02 (0.49, 2.14)		
p-value [1]	0.25		0.95		
Unadjusted interaction test for Treatment*Region [3]					0.35
Unadjusted Inverse Odds Ratio (95% CI)	0.54 (0.20, 1.51)		1.03 (0.37, 2.85)		
p-value [1]	0.24		0.95		
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.06, 0.24)		-0.01 (-0.21, 0.20)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Region [3]					NE
Non-Responder, n(%)	41 (77.4%)	44 (86.3%)	24 (72.7%)	31 (72.1%)	
Non-missing	19 (35.8%)	25 (49.0%)	18 (54.5%)	23 (53.5%)	
Missing	22 (41.5%)	19 (37.3%)	6 (18.2%)	8 (18.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
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Table 2.7104: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Region
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N = 53)	RUX (N = 51)	MMB (N = 33)	RUX (N = 43)	p-value
SF3602-Vitality: NBS at Week 24					
Responder, n(%)	7 (13.2%)	9 (17.6%)	6 (18.2%)	15 (34.9%)	
Unadjusted Inverse Relative Risk (95% CI)	1.34 (0.54, 3.32)		1.92 (0.84, 4.40)		
p-value [1]	0.53		0.12		
Unadjusted interaction test for Treatment*Region [3]					0.56
Unadjusted Inverse Odds Ratio (95% CI)	1.41 (0.48, 4.12)		2.41 (0.82, 7.13)		
p-value [1]	0.53		0.11		
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.18, 0.09)		-0.17 (-0.36, 0.03)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Region [3]					NE
Non-Responder, n(%)	46 (86.8%)	42 (82.4%)	27 (81.8%)	28 (65.1%)	
Non-missing	24 (45.3%)	23 (45.1%)	21 (63.6%)	20 (46.5%)	
Missing	22 (41.5%)	19 (37.3%)	6 (18.2%)	8 (18.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
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Table 2.7104: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Region
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N = 53)	RUX (N = 51)	MMB (N = 33)	RUX (N = 43)	p-value
SF3602-Social Functioning: NBS at Week 24					
Responder, n(%)	8 (15.1%)	7 (13.7%)	4 (12.1%)	10 (23.3%)	
Unadjusted Inverse Relative Risk (95% CI)	0.91 (0.36, 2.32)		1.92 (0.66, 5.58)		
p-value [1]	0.84		0.23		
Unadjusted interaction test for Treatment*Region [3]					0.29
Unadjusted Inverse Odds Ratio (95% CI)	0.89 (0.30, 2.68)		2.20 (0.62, 7.76)		
p-value [1]	0.84		0.22		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.12, 0.15)		-0.11 (-0.28, 0.06)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Region [3]					NE
Non-Responder, n(%)	45 (84.9%)	44 (86.3%)	29 (87.9%)	33 (76.7%)	
Non-missing	23 (43.4%)	25 (49.0%)	23 (69.7%)	25 (58.1%)	
Missing	22 (41.5%)	19 (37.3%)	6 (18.2%)	8 (18.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7104: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Region
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N = 53)	RUX (N = 51)	MMB (N = 33)	RUX (N = 43)	p-value
SF3602-Role Emotional: NBS at Week 24					
Responder, n(%)	8 (15.1%)	8 (15.7%)	5 (15.2%)	10 (23.3%)	
Unadjusted Inverse Relative Risk (95% CI)	1.04 (0.42, 2.56)		1.53 (0.58, 4.06)		
p-value [1]	0.93		0.39		
Unadjusted interaction test for Treatment*Region [3]					0.56
Unadjusted Inverse Odds Ratio (95% CI)	1.05 (0.36, 3.04)		1.70 (0.52, 5.55)		
p-value [1]	0.93		0.38		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.14, 0.13)		-0.08 (-0.26, 0.09)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Region [3]					NE
Non-Responder, n(%)	45 (84.9%)	43 (84.3%)	28 (84.8%)	33 (76.7%)	
Non-missing	23 (43.4%)	24 (47.1%)	22 (66.7%)	25 (58.1%)	
Missing	22 (41.5%)	19 (37.3%)	6 (18.2%)	8 (18.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
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Table 2.7104: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Region
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N = 53)	RUX (N = 51)	MMB (N = 33)	RUX (N = 43)	p-value
SF3602-Mental Health: NBS at Week 24					
Responder, n(%)	9 (17.0%)	7 (13.7%)	7 (21.2%)	9 (20.9%)	
Unadjusted Inverse Relative Risk (95% CI)	0.81 (0.33, 2.01)		0.99 (0.41, 2.37)		
p-value [1]	0.65		0.98		
Unadjusted interaction test for Treatment*Region [3]					0.76
Unadjusted Inverse Odds Ratio (95% CI)	0.78 (0.27, 2.27)		0.98 (0.32, 2.99)		
p-value [1]	0.65		0.98		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.11, 0.17)		0.00 (-0.18, 0.19)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Region [3]					NE
Non-Responder, n(%)	44 (83.0%)	44 (86.3%)	26 (78.8%)	34 (79.1%)	
Non-missing	22 (41.5%)	25 (49.0%)	20 (60.6%)	26 (60.5%)	
Missing	22 (41.5%)	19 (37.3%)	6 (18.2%)	8 (18.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-improv-geo.pdf 29AUG2023: 9:41

Table 2.7104: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Region
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N = 53)	RUX (N = 51)	MMB (N = 33)	RUX (N = 43)	p-value
SF3602-Physical Component Summary at Week 24					
Responder, n(%)	6 (11.3%)	5 (9.8%)	7 (21.2%)	4 (9.3%)	
Unadjusted Inverse Relative Risk (95% CI)	0.87 (0.28, 2.66)		0.44 (0.14, 1.37)		
p-value [1]	0.80		0.16		
Unadjusted interaction test for Treatment*Region [3]					0.41
Unadjusted Inverse Odds Ratio (95% CI)	0.85 (0.24, 2.99)		0.38 (0.10, 1.43)		
p-value [1]	0.80		0.15		
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.10, 0.13)		0.12 (-0.05, 0.28)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.03 (0.36, 2.92)		NE		
p-value [2]	0.96		NE		
Adjusted interaction test for Treatment*Region [3]					0.34
Non-Responder, n(%)	47 (88.7%)	46 (90.2%)	26 (78.8%)	39 (90.7%)	
Non-missing	25 (47.2%)	27 (52.9%)	20 (60.6%)	31 (72.1%)	
Missing	22 (41.5%)	19 (37.3%)	6 (18.2%)	8 (18.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-improv-geo.pdf 29AUG2023: 9:41

Table 2.7104: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Region
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N = 53)	RUX (N = 51)	MMB (N = 33)	RUX (N = 43)	p-value
SF3602-Mental Component Summary at Week 24					
Responder, n(%)	4 (7.5%)	3 (5.9%)	2 (6.1%)	7 (16.3%)	
Unadjusted Inverse Relative Risk (95% CI)	0.78 (0.18, 3.31)		2.69 (0.60, 12.09)		
p-value [1]	0.74		0.20		
Unadjusted interaction test for Treatment*Region [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.77 (0.16, 3.60)		3.01 (0.58, 15.59)		
p-value [1]	0.74		0.19		
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.08, 0.11)		-0.10 (-0.24, 0.03)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Region [3]					NA
Non-Responder, n(%)	49 (92.5%)	48 (94.1%)	31 (93.9%)	36 (83.7%)	
Non-missing	27 (50.9%)	29 (56.9%)	25 (75.8%)	28 (65.1%)	
Missing	22 (41.5%)	19 (37.3%)	6 (18.2%)	8 (18.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
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Table 2.7107: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 28)	RUX (N = 21)	MMB (N = 58)	RUX (N = 73)	p-value
SF3602-Physical Functioning: NBS at Week 24					
Responder, n(%)	9 (32.1%)	5 (23.8%)	13 (22.4%)	19 (26.0%)	
Unadjusted Inverse Relative Risk (95% CI)	0.74 (0.29, 1.89)		1.16 (0.63, 2.15)		
p-value [1]	0.53		0.63		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.42
Unadjusted Inverse Odds Ratio (95% CI)	0.66 (0.18, 2.37)		1.22 (0.54, 2.73)		
p-value [1]	0.52		0.63		
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.17, 0.33)		-0.04 (-0.18, 0.11)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.71 (0.30, 1.69)		NE		
p-value [2]	0.44		NE		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.36
Non-Responder, n(%)	19 (67.9%)	16 (76.2%)	45 (77.6%)	54 (74.0%)	
Non-missing	9 (32.1%)	11 (52.4%)	27 (46.6%)	32 (43.8%)	
Missing	10 (35.7%)	5 (23.8%)	18 (31.0%)	22 (30.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7107: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 28)	RUX (N = 21)	MMB (N = 58)	RUX (N = 73)	p-value
SF3602-Role Physical: NBS at Week 24					
Responder, n(%)	8 (28.6%)	4 (19.0%)	12 (20.7%)	13 (17.8%)	
Unadjusted Inverse Relative Risk (95% CI)	0.67 (0.23, 1.92)		0.86 (0.43, 1.74)		
p-value [1]	0.45		0.68		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.69
Unadjusted Inverse Odds Ratio (95% CI)	0.59 (0.15, 2.30)		0.83 (0.35, 1.99)		
p-value [1]	0.45		0.68		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.14, 0.33)		0.03 (-0.11, 0.17)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.66 (0.22, 1.92)		NE		
p-value [2]	0.44		NE		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE
Non-Responder, n(%)	20 (71.4%)	17 (81.0%)	46 (79.3%)	60 (82.2%)	
Non-missing	10 (35.7%)	12 (57.1%)	28 (48.3%)	38 (52.1%)	
Missing	10 (35.7%)	5 (23.8%)	18 (31.0%)	22 (30.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7107: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 28)	RUX (N = 21)	MMB (N = 58)	RUX (N = 73)	p-value
SF3602-Bodily Pain: NBS at Week 24					
Responder, n(%)	5 (17.9%)	7 (33.3%)	13 (22.4%)	15 (20.5%)	
Unadjusted Inverse Relative Risk (95% CI)	1.87 (0.69, 5.07)		0.92 (0.47, 1.77)		
p-value [1]	0.22		0.80		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.24
Unadjusted Inverse Odds Ratio (95% CI)	2.30 (0.61, 8.66)		0.90 (0.39, 2.07)		
p-value [1]	0.22		0.80		
Unadjusted Absolute Risk Difference (95% CI)	-0.15 (-0.40, 0.09)		0.02 (-0.12, 0.16)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.84 (0.68, 4.93)		0.98 (0.52, 1.85)		
p-value [2]	0.23		0.94		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.29
Non-Responder, n(%)	23 (82.1%)	14 (66.7%)	45 (77.6%)	58 (79.5%)	
Non-missing	13 (46.4%)	9 (42.9%)	27 (46.6%)	36 (49.3%)	
Missing	10 (35.7%)	5 (23.8%)	18 (31.0%)	22 (30.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-improv-hgb.pdf 29AUG2023: 9:42

Table 2.7107: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 28)	RUX (N = 21)	MMB (N = 58)	RUX (N = 73)	p-value
SF3602-General Health: NBS at Week 24					
Responder, n(%)	9 (32.1%)	8 (38.1%)	12 (20.7%)	11 (15.1%)	
Unadjusted Inverse Relative Risk (95% CI)	1.19 (0.55, 2.55)		0.73 (0.35, 1.53)		
p-value [1]	0.66		0.40		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.38
Unadjusted Inverse Odds Ratio (95% CI)	1.30 (0.40, 4.25)		0.68 (0.28, 1.68)		
p-value [1]	0.67		0.40		
Unadjusted Absolute Risk Difference (95% CI)	-0.06 (-0.33, 0.21)		0.06 (-0.08, 0.19)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.18 (0.55, 2.51)		NE		
p-value [2]	0.67		NE		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE
Non-Responder, n(%)	19 (67.9%)	13 (61.9%)	46 (79.3%)	62 (84.9%)	
Non-missing	9 (32.1%)	8 (38.1%)	28 (48.3%)	40 (54.8%)	
Missing	10 (35.7%)	5 (23.8%)	18 (31.0%)	22 (30.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-improv-hgb.pdf 29AUG2023: 9:42

Table 2.7107: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 28)	RUX (N = 21)	MMB (N = 58)	RUX (N = 73)	p-value
SF3602-Vitality: NBS at Week 24					
Responder, n(%)	7 (25.0%)	7 (33.3%)	6 (10.3%)	17 (23.3%)	
Unadjusted Inverse Relative Risk (95% CI)	1.33 (0.55, 3.22)		2.25 (0.95, 5.34)		
p-value [1]	0.52		0.066		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.40
Unadjusted Inverse Odds Ratio (95% CI)	1.50 (0.43, 5.22)		2.63 (0.96, 7.18)		
p-value [1]	0.52		0.059		
Unadjusted Absolute Risk Difference (95% CI)	-0.08 (-0.34, 0.17)		-0.13 (-0.25, 0.00)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.31 (0.54, 3.15)		NE		
p-value [2]	0.55		NE		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE
Non-Responder, n(%)	21 (75.0%)	14 (66.7%)	52 (89.7%)	56 (76.7%)	
Non-missing	11 (39.3%)	9 (42.9%)	34 (58.6%)	34 (46.6%)	
Missing	10 (35.7%)	5 (23.8%)	18 (31.0%)	22 (30.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
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Table 2.7107: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 28)	RUX (N = 21)	MMB (N = 58)	RUX (N = 73)	p-value
SF3602-Social Functioning: NBS at Week 24					
Responder, n(%)	2 (7.1%)	2 (9.5%)	10 (17.2%)	15 (20.5%)	
Unadjusted Inverse Relative Risk (95% CI)	1.33 (0.20, 8.71)		1.19 (0.58, 2.45)		
p-value [1]	0.76		0.63		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.91
Unadjusted Inverse Odds Ratio (95% CI)	1.37 (0.18, 10.60)		1.24 (0.51, 3.01)		
p-value [1]	0.76		0.63		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.18, 0.13)		-0.03 (-0.17, 0.10)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.36 (0.21, 8.95)		NE		
p-value [2]	0.75		NE		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE
Non-Responder, n(%)	26 (92.9%)	19 (90.5%)	48 (82.8%)	58 (79.5%)	
Non-missing	16 (57.1%)	14 (66.7%)	30 (51.7%)	36 (49.3%)	
Missing	10 (35.7%)	5 (23.8%)	18 (31.0%)	22 (30.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

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Table 2.7107: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 28)	RUX (N = 21)	MMB (N = 58)	RUX (N = 73)	p-value
SF3602-Role Emotional: NBS at Week 24					
Responder, n(%)	5 (17.9%)	6 (28.6%)	8 (13.8%)	12 (16.4%)	
Unadjusted Inverse Relative Risk (95% CI)	1.60 (0.56, 4.54)		1.19 (0.52, 2.72)		
p-value [1]	0.38		0.68		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.66
Unadjusted Inverse Odds Ratio (95% CI)	1.84 (0.48, 7.12)		1.23 (0.47, 3.24)		
p-value [1]	0.38		0.68		
Unadjusted Absolute Risk Difference (95% CI)	-0.11 (-0.35, 0.13)		-0.03 (-0.15, 0.10)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.59 (0.55, 4.57)		NE		
p-value [2]	0.39		NE		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE
Non-Responder, n(%)	23 (82.1%)	15 (71.4%)	50 (86.2%)	61 (83.6%)	
Non-missing	13 (46.4%)	10 (47.6%)	32 (55.2%)	39 (53.4%)	
Missing	10 (35.7%)	5 (23.8%)	18 (31.0%)	22 (30.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

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Table 2.7107: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 28)	RUX (N = 21)	MMB (N = 58)	RUX (N = 73)	p-value
SF3602-Mental Health: NBS at Week 24					
Responder, n(%)	6 (21.4%)	6 (28.6%)	10 (17.2%)	10 (13.7%)	
Unadjusted Inverse Relative Risk (95% CI)	1.33 (0.50, 3.55)		0.79 (0.35, 1.78)		
p-value [1]	0.57		0.58		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.43
Unadjusted Inverse Odds Ratio (95% CI)	1.47 (0.40, 5.43)		0.76 (0.29, 1.98)		
p-value [1]	0.57		0.58		
Unadjusted Absolute Risk Difference (95% CI)	-0.07 (-0.32, 0.17)		0.04 (-0.09, 0.16)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.36 (0.52, 3.57)		NE		
p-value [2]	0.53		NE		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE
Non-Responder, n(%)	22 (78.6%)	15 (71.4%)	48 (82.8%)	63 (86.3%)	
Non-missing	12 (42.9%)	10 (47.6%)	30 (51.7%)	41 (56.2%)	
Missing	10 (35.7%)	5 (23.8%)	18 (31.0%)	22 (30.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

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Table 2.7107: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 28)	RUX (N = 21)	MMB (N = 58)	RUX (N = 73)	p-value
SF3602-Physical Component Summary at Week 24					
Responder, n(%)	5 (17.9%)	2 (9.5%)	8 (13.8%)	7 (9.6%)	
Unadjusted Inverse Relative Risk (95% CI)	0.53 (0.11, 2.49)		0.70 (0.27, 1.80)		
p-value [1]	0.42		0.46		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.77
Unadjusted Inverse Odds Ratio (95% CI)	0.48 (0.08, 2.78)		0.66 (0.23, 1.95)		
p-value [1]	0.42		0.46		
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.11, 0.27)		0.04 (-0.07, 0.15)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.52 (0.11, 2.35)		NE		
p-value [2]	0.40		NE		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.72
Non-Responder, n(%)	23 (82.1%)	19 (90.5%)	50 (86.2%)	66 (90.4%)	
Non-missing	13 (46.4%)	14 (66.7%)	32 (55.2%)	44 (60.3%)	
Missing	10 (35.7%)	5 (23.8%)	18 (31.0%)	22 (30.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7107: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Hemoglobin Level
Double-Blind Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 28)	RUX (N = 21)	MMB (N = 58)	RUX (N = 73)	p-value
SF3602-Mental Component Summary at Week 24					
Responder, n(%)	3 (10.7%)	4 (19.0%)	3 (5.2%)	6 (8.2%)	
Unadjusted Inverse Relative Risk (95% CI)	1.78 (0.44, 7.11)		1.59 (0.42, 6.08)		
p-value [1]	0.42		0.50		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	1.96 (0.39, 9.90)		1.64 (0.39, 6.87)		
p-value [1]	0.41		0.50		
Unadjusted Absolute Risk Difference (95% CI)	-0.08 (-0.29, 0.12)		-0.03 (-0.12, 0.05)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Non-Responder, n(%)	25 (89.3%)	17 (81.0%)	55 (94.8%)	67 (91.8%)	
Non-missing	15 (53.6%)	12 (57.1%)	37 (63.8%)	45 (61.6%)	
Missing	10 (35.7%)	5 (23.8%)	18 (31.0%)	22 (30.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

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Table 2.7106: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Two-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 28)	RUX (N = 24)	MMB (N = 58)	RUX (N = 70)	p-value
SF3602-Physical Functioning: NBS at Week 24					
Responder, n(%)	4 (14.3%)	6 (25.0%)	18 (31.0%)	18 (25.7%)	
Unadjusted Inverse Relative Risk (95% CI)	1.75 (0.56, 5.48)		0.83 (0.48, 1.44)		
p-value [1]	0.34		0.51		
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.25
Unadjusted Inverse Odds Ratio (95% CI)	2.00 (0.49, 8.15)		0.77 (0.36, 1.67)		
p-value [1]	0.33		0.51		
Unadjusted Absolute Risk Difference (95% CI)	-0.11 (-0.32, 0.11)		0.05 (-0.10, 0.21)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.84 (0.48, 1.47)		
p-value [2]	NE		0.54		
Adjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.28
Non-Responder, n(%)	24 (85.7%)	18 (75.0%)	40 (69.0%)	52 (74.3%)	
Non-missing	14 (50.0%)	11 (45.8%)	22 (37.9%)	32 (45.7%)	
Missing	10 (35.7%)	7 (29.2%)	18 (31.0%)	20 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7106: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Two-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 28)	RUX (N = 24)	MMB (N = 58)	RUX (N = 70)	p-value
SF3602-Role Physical: NBS at Week 24					
Responder, n(%)	3 (10.7%)	2 (8.3%)	17 (29.3%)	15 (21.4%)	
Unadjusted Inverse Relative Risk (95% CI)	0.78 (0.14, 4.28)		0.73 (0.40, 1.33)		
p-value [1]	0.77		0.31		
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.95
Unadjusted Inverse Odds Ratio (95% CI)	0.76 (0.12, 4.96)		0.66 (0.29, 1.47)		
p-value [1]	0.77		0.31		
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.14, 0.18)		0.08 (-0.07, 0.23)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*IPSS 2-Level Risk [3]					NE
Non-Responder, n(%)	25 (89.3%)	22 (91.7%)	41 (70.7%)	55 (78.6%)	
Non-missing	15 (53.6%)	15 (62.5%)	23 (39.7%)	35 (50.0%)	
Missing	10 (35.7%)	7 (29.2%)	18 (31.0%)	20 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7106: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Two-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 28)	RUX (N = 24)	MMB (N = 58)	RUX (N = 70)	p-value
SF3602-Bodily Pain: NBS at Week 24					
Responder, n(%)	4 (14.3%)	5 (20.8%)	14 (24.1%)	17 (24.3%)	
Unadjusted Inverse Relative Risk (95% CI)	1.46 (0.44, 4.82)		1.01 (0.54, 1.86)		
p-value [1]	0.54		0.98		
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.59
Unadjusted Inverse Odds Ratio (95% CI)	1.58 (0.37, 6.70)		1.01 (0.45, 2.27)		
p-value [1]	0.54		0.98		
Unadjusted Absolute Risk Difference (95% CI)	-0.07 (-0.27, 0.14)		0.00 (-0.15, 0.15)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		1.04 (0.55, 1.95)		
p-value [2]	NE		0.90		
Adjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.61
Non-Responder, n(%)	24 (85.7%)	19 (79.2%)	44 (75.9%)	53 (75.7%)	
Non-missing	14 (50.0%)	12 (50.0%)	26 (44.8%)	33 (47.1%)	
Missing	10 (35.7%)	7 (29.2%)	18 (31.0%)	20 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7106: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Two-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 28)	RUX (N = 24)	MMB (N = 58)	RUX (N = 70)	p-value
SF3602-General Health: NBS at Week 24					
Responder, n(%)	4 (14.3%)	2 (8.3%)	17 (29.3%)	17 (24.3%)	
Unadjusted Inverse Relative Risk (95% CI)	0.58 (0.12, 2.91)		0.83 (0.47, 1.47)		
p-value [1]	0.51		0.52		
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.68
Unadjusted Inverse Odds Ratio (95% CI)	0.55 (0.09, 3.28)		0.77 (0.35, 1.70)		
p-value [1]	0.51		0.52		
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.11, 0.23)		0.05 (-0.10, 0.20)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*IPSS 2-Level Risk [3]					NE
Non-Responder, n(%)	24 (85.7%)	22 (91.7%)	41 (70.7%)	53 (75.7%)	
Non-missing	14 (50.0%)	15 (62.5%)	23 (39.7%)	33 (47.1%)	
Missing	10 (35.7%)	7 (29.2%)	18 (31.0%)	20 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7106: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Two-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 28)	RUX (N = 24)	MMB (N = 58)	RUX (N = 70)	p-value
SF3602-Vitality: NBS at Week 24					
Responder, n(%)	4 (14.3%)	6 (25.0%)	9 (15.5%)	18 (25.7%)	
Unadjusted Inverse Relative Risk (95% CI)	1.75 (0.56, 5.48)		1.66 (0.81, 3.41)		
p-value [1]	0.34		0.17		
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.94
Unadjusted Inverse Odds Ratio (95% CI)	2.00 (0.49, 8.15)		1.88 (0.77, 4.59)		
p-value [1]	0.33		0.16		
Unadjusted Absolute Risk Difference (95% CI)	-0.11 (-0.32, 0.11)		-0.10 (-0.24, 0.04)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*IPSS 2-Level Risk [3]					NE
Non-Responder, n(%)	24 (85.7%)	18 (75.0%)	49 (84.5%)	52 (74.3%)	
Non-missing	14 (50.0%)	11 (45.8%)	31 (53.4%)	32 (45.7%)	
Missing	10 (35.7%)	7 (29.2%)	18 (31.0%)	20 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7106: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Two-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 28)	RUX (N = 24)	MMB (N = 58)	RUX (N = 70)	p-value
SF3602-Social Functioning: NBS at Week 24					
Responder, n(%)	2 (7.1%)	5 (20.8%)	10 (17.2%)	12 (17.1%)	
Unadjusted Inverse Relative Risk (95% CI)	2.92 (0.62, 13.69)		0.99 (0.46, 2.13)		
p-value [1]	0.17		0.99		
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.20
Unadjusted Inverse Odds Ratio (95% CI)	3.42 (0.60, 19.56)		0.99 (0.39, 2.50)		
p-value [1]	0.17		0.99		
Unadjusted Absolute Risk Difference (95% CI)	-0.14 (-0.33, 0.05)		0.00 (-0.13, 0.13)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*IPSS 2-Level Risk [3]					NE
Non-Responder, n(%)	26 (92.9%)	19 (79.2%)	48 (82.8%)	58 (82.9%)	
Non-missing	16 (57.1%)	12 (50.0%)	30 (51.7%)	38 (54.3%)	
Missing	10 (35.7%)	7 (29.2%)	18 (31.0%)	20 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7106: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Two-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 28)	RUX (N = 24)	MMB (N = 58)	RUX (N = 70)	p-value
SF3602-Role Emotional: NBS at Week 24					
Responder, n(%)	2 (7.1%)	4 (16.7%)	11 (19.0%)	14 (20.0%)	
Unadjusted Inverse Relative Risk (95% CI)	2.33 (0.47, 11.64)		1.05 (0.52, 2.14)		
p-value [1]	0.30		0.88		
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.36
Unadjusted Inverse Odds Ratio (95% CI)	2.60 (0.43, 15.65)		1.07 (0.44, 2.57)		
p-value [1]	0.30		0.88		
Unadjusted Absolute Risk Difference (95% CI)	-0.10 (-0.27, 0.08)		-0.01 (-0.15, 0.13)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*IPSS 2-Level Risk [3]					NE
Non-Responder, n(%)	26 (92.9%)	20 (83.3%)	47 (81.0%)	56 (80.0%)	
Non-missing	16 (57.1%)	13 (54.2%)	29 (50.0%)	36 (51.4%)	
Missing	10 (35.7%)	7 (29.2%)	18 (31.0%)	20 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7106: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Two-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 28)	RUX (N = 24)	MMB (N = 58)	RUX (N = 70)	p-value
SF3602-Mental Health: NBS at Week 24					
Responder, n(%)	6 (21.4%)	3 (12.5%)	10 (17.2%)	13 (18.6%)	
Unadjusted Inverse Relative Risk (95% CI)	0.58 (0.16, 2.09)		1.08 (0.51, 2.27)		
p-value [1]	0.41		0.85		
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.40
Unadjusted Inverse Odds Ratio (95% CI)	0.52 (0.12, 2.37)		1.09 (0.44, 2.72)		
p-value [1]	0.40		0.85		
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.11, 0.29)		-0.01 (-0.15, 0.12)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*IPSS 2-Level Risk [3]					NE
Non-Responder, n(%)	22 (78.6%)	21 (87.5%)	48 (82.8%)	57 (81.4%)	
Non-missing	12 (42.9%)	14 (58.3%)	30 (51.7%)	37 (52.9%)	
Missing	10 (35.7%)	7 (29.2%)	18 (31.0%)	20 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7106: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Two-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 28)	RUX (N = 24)	MMB (N = 58)	RUX (N = 70)	p-value
SF3602-Physical Component Summary at Week 24					
Responder, n(%)	2 (7.1%)	1 (4.2%)	11 (19.0%)	8 (11.4%)	
Unadjusted Inverse Relative Risk (95% CI)	0.58 (0.06, 6.04)		0.60 (0.26, 1.40)		
p-value [1]	0.65		0.24		
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.98
Unadjusted Inverse Odds Ratio (95% CI)	0.57 (0.05, 6.65)		0.55 (0.21, 1.48)		
p-value [1]	0.65		0.24		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.09, 0.15)		0.08 (-0.05, 0.20)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.57 (0.23, 1.40)		
p-value [2]	NE		0.22		
Adjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.96
Non-Responder, n(%)	26 (92.9%)	23 (95.8%)	47 (81.0%)	62 (88.6%)	
Non-missing	16 (57.1%)	16 (66.7%)	29 (50.0%)	42 (60.0%)	
Missing	10 (35.7%)	7 (29.2%)	18 (31.0%)	20 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7106: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Two-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 28)	RUX (N = 24)	MMB (N = 58)	RUX (N = 70)	p-value
SF3602-Mental Component Summary at Week 24					
Responder, n(%)	2 (7.1%)	3 (12.5%)	4 (6.9%)	7 (10.0%)	
Unadjusted Inverse Relative Risk (95% CI)	1.75 (0.32, 9.62)		1.45 (0.45, 4.71)		
p-value [1]	0.52		0.54		
Unadjusted interaction test for Treatment*IPSS 2-Level Risk [3]					0.86
Unadjusted Inverse Odds Ratio (95% CI)	1.86 (0.28, 12.16)		1.50 (0.42, 5.40)		
p-value [1]	0.52		0.54		
Unadjusted Absolute Risk Difference (95% CI)	-0.05 (-0.22, 0.11)		-0.03 (-0.13, 0.06)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*IPSS 2-Level Risk [3]					NE
Non-Responder, n(%)	26 (92.9%)	21 (87.5%)	54 (93.1%)	63 (90.0%)	
Non-missing	16 (57.1%)	14 (58.3%)	36 (62.1%)	43 (61.4%)	
Missing	10 (35.7%)	7 (29.2%)	18 (31.0%)	20 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7105: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 2)	RUX (N = 4)	MMB (N = 26)	RUX (N = 20)
SF3602-Physical Functioning: NBS at Week 24				
Responder, n(%)	0	0	4 (15.4%)	6 (30.0%)
Unadjusted Inverse Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Non-Responder, n(%)	2 (100.0%)	4 (100.0%)	22 (84.6%)	14 (70.0%)
Non-missing	1 (50.0%)	3 (75.0%)	13 (50.0%)	8 (40.0%)
Missing	1 (50.0%)	1 (25.0%)	9 (34.6%)	6 (30.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-improv-ip3.pdf 29AUG2023: 9:41

Table 2.7105: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 58)	RUX (N = 70)	p-value
SF3602-Physical Functioning: NBS at Week 24			
Responder, n(%)	18 (31.0%)	18 (25.7%)	
Unadjusted Inverse Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	40 (69.0%)	52 (74.3%)	
Non-missing	22 (37.9%)	32 (45.7%)	
Missing	18 (31.0%)	20 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-improv-ip3.pdf 29AUG2023: 9:41

Table 2.7105: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 2)	RUX (N = 4)	MMB (N = 26)	RUX (N = 20)
SF3602-Role Physical: NBS at Week 24				
Responder, n(%)	0	0	3 (11.5%)	2 (10.0%)
Unadjusted Inverse Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Non-Responder, n(%)	2 (100.0%)	4 (100.0%)	23 (88.5%)	18 (90.0%)
Non-missing	1 (50.0%)	3 (75.0%)	14 (53.8%)	12 (60.0%)
Missing	1 (50.0%)	1 (25.0%)	9 (34.6%)	6 (30.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.7105: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 58)	RUX (N = 70)	p-value
SF3602-Role Physical: NBS at Week 24			
Responder, n(%)	17 (29.3%)	15 (21.4%)	
Unadjusted Inverse Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	41 (70.7%)	55 (78.6%)	
Non-missing	23 (39.7%)	35 (50.0%)	
Missing	18 (31.0%)	20 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-improv-ip3.pdf 29AUG2023: 9:41

Table 2.7105: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 2)	RUX (N = 4)	MMB (N = 26)	RUX (N = 20)
SF3602-Bodily Pain: NBS at Week 24				
Responder, n(%)	0	0	4 (15.4%)	5 (25.0%)
Unadjusted Inverse Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Non-Responder, n(%)	2 (100.0%)	4 (100.0%)	22 (84.6%)	15 (75.0%)
Non-missing	1 (50.0%)	3 (75.0%)	13 (50.0%)	9 (45.0%)
Missing	1 (50.0%)	1 (25.0%)	9 (34.6%)	6 (30.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.7105: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 58)	RUX (N = 70)	p-value
SF3602-Bodily Pain: NBS at Week 24			
Responder, n(%)	14 (24.1%)	17 (24.3%)	
Unadjusted Inverse Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	44 (75.9%)	53 (75.7%)	
Non-missing	26 (44.8%)	33 (47.1%)	
Missing	18 (31.0%)	20 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
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Table 2.7105: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 2)	RUX (N = 4)	MMB (N = 26)	RUX (N = 20)
SF3602-General Health: NBS at Week 24				
Responder, n(%)	0	0	4 (15.4%)	2 (10.0%)
Unadjusted Inverse Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Non-Responder, n(%)	2 (100.0%)	4 (100.0%)	22 (84.6%)	18 (90.0%)
Non-missing	1 (50.0%)	3 (75.0%)	13 (50.0%)	12 (60.0%)
Missing	1 (50.0%)	1 (25.0%)	9 (34.6%)	6 (30.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

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Table 2.7105: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 58)	RUX (N = 70)	p-value
SF3602-General Health: NBS at Week 24			
Responder, n(%)	17 (29.3%)	17 (24.3%)	
Unadjusted Inverse Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	41 (70.7%)	53 (75.7%)	
Non-missing	23 (39.7%)	33 (47.1%)	
Missing	18 (31.0%)	20 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

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Table 2.7105: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 2)	RUX (N = 4)	MMB (N = 26)	RUX (N = 20)
SF3602-Vitality: NBS at Week 24				
Responder, n(%)	0	0	4 (15.4%)	6 (30.0%)
Unadjusted Inverse Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Non-Responder, n(%)	2 (100.0%)	4 (100.0%)	22 (84.6%)	14 (70.0%)
Non-missing	1 (50.0%)	3 (75.0%)	13 (50.0%)	8 (40.0%)
Missing	1 (50.0%)	1 (25.0%)	9 (34.6%)	6 (30.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.7105: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 58)	RUX (N = 70)	p-value
SF3602-Vitality: NBS at Week 24			
Responder, n(%)	9 (15.5%)	18 (25.7%)	
Unadjusted Inverse Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	49 (84.5%)	52 (74.3%)	
Non-missing	31 (53.4%)	32 (45.7%)	
Missing	18 (31.0%)	20 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

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Table 2.7105: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 2)	RUX (N = 4)	MMB (N = 26)	RUX (N = 20)
SF3602-Social Functioning: NBS at Week 24				
Responder, n(%)	0	0	2 (7.7%)	5 (25.0%)
Unadjusted Inverse Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Non-Responder, n(%)	2 (100.0%)	4 (100.0%)	24 (92.3%)	15 (75.0%)
Non-missing	1 (50.0%)	3 (75.0%)	15 (57.7%)	9 (45.0%)
Missing	1 (50.0%)	1 (25.0%)	9 (34.6%)	6 (30.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

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Table 2.7105: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 58)	RUX (N = 70)	p-value
SF3602-Social Functioning: NBS at Week 24			
Responder, n(%)	10 (17.2%)	12 (17.1%)	
Unadjusted Inverse Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	48 (82.8%)	58 (82.9%)	
Non-missing	30 (51.7%)	38 (54.3%)	
Missing	18 (31.0%)	20 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

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Table 2.7105: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 2)	RUX (N = 4)	MMB (N = 26)	RUX (N = 20)
SF3602-Role Emotional: NBS at Week 24				
Responder, n(%)	0	1 (25.0%)	2 (7.7%)	3 (15.0%)
Unadjusted Inverse Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Non-Responder, n(%)	2 (100.0%)	3 (75.0%)	24 (92.3%)	17 (85.0%)
Non-missing	1 (50.0%)	2 (50.0%)	15 (57.7%)	11 (55.0%)
Missing	1 (50.0%)	1 (25.0%)	9 (34.6%)	6 (30.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.7105: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 58)	RUX (N = 70)	p-value
SF3602-Role Emotional: NBS at Week 24			
Responder, n(%)	11 (19.0%)	14 (20.0%)	
Unadjusted Inverse Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	47 (81.0%)	56 (80.0%)	
Non-missing	29 (50.0%)	36 (51.4%)	
Missing	18 (31.0%)	20 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

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Table 2.7105: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 2)	RUX (N = 4)	MMB (N = 26)	RUX (N = 20)
SF3602-Mental Health: NBS at Week 24				
Responder, n(%)	0	1 (25.0%)	6 (23.1%)	2 (10.0%)
Unadjusted Inverse Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Non-Responder, n(%)	2 (100.0%)	3 (75.0%)	20 (76.9%)	18 (90.0%)
Non-missing	1 (50.0%)	2 (50.0%)	11 (42.3%)	12 (60.0%)
Missing	1 (50.0%)	1 (25.0%)	9 (34.6%)	6 (30.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.7105: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 58)	RUX (N = 70)	p-value
SF3602-Mental Health: NBS at Week 24			
Responder, n(%)	10 (17.2%)	13 (18.6%)	
Unadjusted Inverse Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	48 (82.8%)	57 (81.4%)	
Non-missing	30 (51.7%)	37 (52.9%)	
Missing	18 (31.0%)	20 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

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Table 2.7105: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 2)	RUX (N = 4)	MMB (N = 26)	RUX (N = 20)
SF3602-Physical Component Summary at Week 24				
Responder, n(%)	0	0	2 (7.7%)	1 (5.0%)
Unadjusted Inverse Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Non-Responder, n(%)	2 (100.0%)	4 (100.0%)	24 (92.3%)	19 (95.0%)
Non-missing	1 (50.0%)	3 (75.0%)	15 (57.7%)	13 (65.0%)
Missing	1 (50.0%)	1 (25.0%)	9 (34.6%)	6 (30.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

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Table 2.7105: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 58)	RUX (N = 70)	p-value
SF3602-Physical Component Summary at Week 24			
Responder, n(%)	11 (19.0%)	8 (11.4%)	
Unadjusted Inverse Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	47 (81.0%)	62 (88.6%)	
Non-missing	29 (50.0%)	42 (60.0%)	
Missing	18 (31.0%)	20 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

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Table 2.7105: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 2)	RUX (N = 4)	MMB (N = 26)	RUX (N = 20)
SF3602-Mental Component Summary at Week 24				
Responder, n(%)	0	1 (25.0%)	2 (7.7%)	2 (10.0%)
Unadjusted Inverse Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]				
Non-Responder, n(%)	2 (100.0%)	3 (75.0%)	24 (92.3%)	18 (90.0%)
Non-missing	1 (50.0%)	2 (50.0%)	15 (57.7%)	12 (60.0%)
Missing	1 (50.0%)	1 (25.0%)	9 (34.6%)	6 (30.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019

Table 2.7105: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline IPSS Three-Level Risk
Double-Blind Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 58)	RUX (N = 70)	p-value
SF3602-Mental Component Summary at Week 24			
Responder, n(%)	4 (6.9%)	7 (10.0%)	
Unadjusted Inverse Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*IPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	54 (93.1%)	63 (90.0%)	
Non-missing	36 (62.1%)	43 (61.4%)	
Missing	18 (31.0%)	20 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-improv-ip3.pdf 29AUG2023: 9:41

Table 2.7108: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 59)	RUX (N = 54)	MMB (N = 16)	RUX (N = 28)
SF3602-Physical Functioning: NBS at Week 24				
Responder, n(%)	17 (28.8%)	18 (33.3%)	2 (12.5%)	5 (17.9%)
Unadjusted Inverse Relative Risk (95% CI)	1.16 (0.67, 2.01)		1.43 (0.31, 6.53)	
p-value [1]	0.60		0.65	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	1.24 (0.56, 2.75)		1.52 (0.26, 8.93)	
p-value [1]	0.60		0.64	
Unadjusted Absolute Risk Difference (95% CI)	-0.05 (-0.22, 0.13)		-0.05 (-0.27, 0.16)	
Adjusted Inverse Relative Risk (95% CI) [2]	1.25 (0.73, 2.14)		NE	
p-value [2]	0.42		NE	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	42 (71.2%)	36 (66.7%)	14 (87.5%)	23 (82.1%)
Non-missing	25 (42.4%)	26 (48.1%)	7 (43.8%)	11 (39.3%)
Missing	17 (28.8%)	10 (18.5%)	7 (43.8%)	12 (42.9%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-improv-mf.pdf 29AUG2023: 9:43

Table 2.7108: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 11)	RUX (N = 12)	p-value
SF3602-Physical Functioning: NBS at Week 24			
Responder, n(%)	3 (27.3%)	1 (8.3%)	
Unadjusted Inverse Relative Risk (95% CI)	0.31 (0.04, 2.52)		
p-value [1]	0.27		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.42
Unadjusted Inverse Odds Ratio (95% CI)	0.24 (0.02, 2.78)		
p-value [1]	0.25		
Unadjusted Absolute Risk Difference (95% CI)	0.19 (-0.12, 0.50)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.42
Non-Responder, n(%)	8 (72.7%)	11 (91.7%)	
Non-missing	4 (36.4%)	6 (50.0%)	
Missing	4 (36.4%)	5 (41.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-improv-mf.pdf 29AUG2023: 9:43

Table 2.7108: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 59)	RUX (N = 54)	MMB (N = 16)	RUX (N = 28)
SF3602-Role Physical: NBS at Week 24				
Responder, n(%)	14 (23.7%)	10 (18.5%)	3 (18.8%)	4 (14.3%)
Unadjusted Inverse Relative Risk (95% CI)	0.78 (0.38, 1.61)		0.76 (0.19, 2.98)	
p-value [1]	0.50		0.70	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	0.73 (0.29, 1.82)		0.72 (0.14, 3.73)	
p-value [1]	0.50		0.70	
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.10, 0.20)		0.04 (-0.19, 0.28)	
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE	
p-value [2]	NE		NE	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	45 (76.3%)	44 (81.5%)	13 (81.3%)	24 (85.7%)
Non-missing	28 (47.5%)	34 (63.0%)	6 (37.5%)	12 (42.9%)
Missing	17 (28.8%)	10 (18.5%)	7 (43.8%)	12 (42.9%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-improv-mf.pdf 29AUG2023: 9:43

Table 2.7108: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 11)	RUX (N = 12)	p-value
SF3602-Role Physical: NBS at Week 24			
Responder, n(%)	3 (27.3%)	3 (25.0%)	
Unadjusted Inverse Relative Risk (95% CI)	0.92 (0.23, 3.63)		
p-value [1]	0.90		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.98
Unadjusted Inverse Odds Ratio (95% CI)	0.89 (0.14, 5.72)		
p-value [1]	0.90		
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.34, 0.38)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NE
Non-Responder, n(%)	8 (72.7%)	9 (75.0%)	
Non-missing	4 (36.4%)	4 (33.3%)	
Missing	4 (36.4%)	5 (41.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-improv-mf.pdf 29AUG2023: 9:43

Table 2.7108: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 59)	RUX (N = 54)	MMB (N = 16)	RUX (N = 28)
SF3602-Bodily Pain: NBS at Week 24				
Responder, n(%)	11 (18.6%)	17 (31.5%)	4 (25.0%)	4 (14.3%)
Unadjusted Inverse Relative Risk (95% CI)	1.69 (0.87, 3.28)		0.57 (0.16, 1.98)	
p-value [1]	0.12		0.38	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	2.00 (0.84, 4.79)		0.50 (0.11, 2.35)	
p-value [1]	0.12		0.38	
Unadjusted Absolute Risk Difference (95% CI)	-0.13 (-0.29, 0.03)		0.11 (-0.14, 0.36)	
Adjusted Inverse Relative Risk (95% CI) [2]	1.83 (0.97, 3.48)		NE	
p-value [2]	0.064		NE	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	48 (81.4%)	37 (68.5%)	12 (75.0%)	24 (85.7%)
Non-missing	31 (52.5%)	27 (50.0%)	5 (31.3%)	12 (42.9%)
Missing	17 (28.8%)	10 (18.5%)	7 (43.8%)	12 (42.9%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-improv-mf.pdf 29AUG2023: 9:43

Table 2.7108: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 11)	RUX (N = 12)	p-value
SF3602-Bodily Pain: NBS at Week 24			
Responder, n(%)	3 (27.3%)	1 (8.3%)	
Unadjusted Inverse Relative Risk (95% CI)	0.31 (0.04, 2.52)		
p-value [1]	0.27		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.14
Unadjusted Inverse Odds Ratio (95% CI)	0.24 (0.02, 2.78)		
p-value [1]	0.25		
Unadjusted Absolute Risk Difference (95% CI)	0.19 (-0.12, 0.50)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.12
Non-Responder, n(%)	8 (72.7%)	11 (91.7%)	
Non-missing	4 (36.4%)	6 (50.0%)	
Missing	4 (36.4%)	5 (41.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-improv-mf.pdf 29AUG2023: 9:43

Table 2.7108: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 59)	RUX (N = 54)	MMB (N = 16)	RUX (N = 28)
SF3602-General Health: NBS at Week 24				
Responder, n(%)	17 (28.8%)	15 (27.8%)	2 (12.5%)	3 (10.7%)
Unadjusted Inverse Relative Risk (95% CI)	0.96 (0.54, 1.74)		0.86 (0.16, 4.60)	
p-value [1]	0.90		0.86	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	0.95 (0.42, 2.16)		0.84 (0.12, 5.64)	
p-value [1]	0.90		0.86	
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.16, 0.18)		0.02 (-0.18, 0.22)	
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE	
p-value [2]	NE		NE	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	42 (71.2%)	39 (72.2%)	14 (87.5%)	25 (89.3%)
Non-missing	25 (42.4%)	29 (53.7%)	7 (43.8%)	13 (46.4%)
Missing	17 (28.8%)	10 (18.5%)	7 (43.8%)	12 (42.9%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-improv-mf.pdf 29AUG2023: 9:43

Table 2.7108: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 11)	RUX (N = 12)	p-value
SF3602-General Health: NBS at Week 24			
Responder, n(%)	2 (18.2%)	1 (8.3%)	
Unadjusted Inverse Relative Risk (95% CI)	0.46 (0.05, 4.38)		
p-value [1]	0.50		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.81
Unadjusted Inverse Odds Ratio (95% CI)	0.41 (0.03, 5.28)		
p-value [1]	0.49		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.18, 0.37)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NE
Non-Responder, n(%)	9 (81.8%)	11 (91.7%)	
Non-missing	5 (45.5%)	6 (50.0%)	
Missing	4 (36.4%)	5 (41.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-improv-mf.pdf 29AUG2023: 9:43

Table 2.7108: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 59)	RUX (N = 54)	MMB (N = 16)	RUX (N = 28)
SF3602-Vitality: NBS at Week 24				
Responder, n(%)	9 (15.3%)	18 (33.3%)	2 (12.5%)	4 (14.3%)
Unadjusted Inverse Relative Risk (95% CI)	2.19 (1.07, 4.44)		1.14 (0.23, 5.56)	
p-value [1]	0.031		0.87	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	2.78 (1.12, 6.88)		1.17 (0.19, 7.21)	
p-value [1]	0.027		0.87	
Unadjusted Absolute Risk Difference (95% CI)	-0.18 (-0.34, -0.03		-0.02 (-0.23, 0.19)	
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE	
p-value [2]	NE		NE	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	50 (84.7%)	36 (66.7%)	14 (87.5%)	24 (85.7%)
Non-missing	33 (55.9%)	26 (48.1%)	7 (43.8%)	12 (42.9%)
Missing	17 (28.8%)	10 (18.5%)	7 (43.8%)	12 (42.9%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-improv-mf.pdf 29AUG2023: 9:43

Table 2.7108: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 11)	RUX (N = 12)	p-value
SF3602-Vitality: NBS at Week 24			
Responder, n(%)	2 (18.2%)	2 (16.7%)	
Unadjusted Inverse Relative Risk (95% CI)	0.92 (0.15, 5.44)		
p-value [1]	0.92		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.61
Unadjusted Inverse Odds Ratio (95% CI)	0.90 (0.10, 7.78)		
p-value [1]	0.92		
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.30, 0.33)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NE
Non-Responder, n(%)	9 (81.8%)	10 (83.3%)	
Non-missing	5 (45.5%)	5 (41.7%)	
Missing	4 (36.4%)	5 (41.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-improv-mf.pdf 29AUG2023: 9:43

Table 2.7108: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 59)	RUX (N = 54)	MMB (N = 16)	RUX (N = 28)
SF3602-Social Functioning: NBS at Week 24				
Responder, n(%)	8 (13.6%)	13 (24.1%)	2 (12.5%)	3 (10.7%)
Unadjusted Inverse Relative Risk (95% CI)	1.78 (0.80, 3.95)		0.86 (0.16, 4.60)	
p-value [1]	0.16		0.86	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	2.02 (0.76, 5.34)		0.84 (0.12, 5.64)	
p-value [1]	0.16		0.86	
Unadjusted Absolute Risk Difference (95% CI)	-0.11 (-0.25, 0.04)		0.02 (-0.18, 0.22)	
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE	
p-value [2]	NE		NE	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	51 (86.4%)	41 (75.9%)	14 (87.5%)	25 (89.3%)
Non-missing	34 (57.6%)	31 (57.4%)	7 (43.8%)	13 (46.4%)
Missing	17 (28.8%)	10 (18.5%)	7 (43.8%)	12 (42.9%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-improv-mf.pdf 29AUG2023: 9:43

Table 2.7108: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 11)	RUX (N = 12)	p-value
SF3602-Social Functioning: NBS at Week 24			
Responder, n(%)	2 (18.2%)	1 (8.3%)	
Unadjusted Inverse Relative Risk (95% CI)	0.46 (0.05, 4.38)		
p-value [1]	0.50		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.48
Unadjusted Inverse Odds Ratio (95% CI)	0.41 (0.03, 5.28)		
p-value [1]	0.49		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.18, 0.37)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NE
Non-Responder, n(%)	9 (81.8%)	11 (91.7%)	
Non-missing	5 (45.5%)	6 (50.0%)	
Missing	4 (36.4%)	5 (41.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-improv-mf.pdf 29AUG2023: 9:43

Table 2.7108: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 59)	RUX (N = 54)	MMB (N = 16)	RUX (N = 28)
SF3602-Role Emotional: NBS at Week 24				
Responder, n(%)	11 (18.6%)	12 (22.2%)	1 (6.3%)	5 (17.9%)
Unadjusted Inverse Relative Risk (95% CI)	1.19 (0.57, 2.47)		2.86 (0.37, 22.36)	
p-value [1]	0.64		0.32	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	1.25 (0.50, 3.12)		3.26 (0.35, 30.74)	
p-value [1]	0.64		0.30	
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.18, 0.11)		-0.12 (-0.30, 0.07)	
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE	
p-value [2]	NE		NE	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	48 (81.4%)	42 (77.8%)	15 (93.8%)	23 (82.1%)
Non-missing	31 (52.5%)	32 (59.3%)	8 (50.0%)	11 (39.3%)
Missing	17 (28.8%)	10 (18.5%)	7 (43.8%)	12 (42.9%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-improv-mf.pdf 29AUG2023: 9:43

Table 2.7108: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 11)	RUX (N = 12)	p-value
SF3602-Role Emotional: NBS at Week 24			
Responder, n(%)	1 (9.1%)	1 (8.3%)	
Unadjusted Inverse Relative Risk (95% CI)	0.92 (0.06, 12.95)		
p-value [1]	0.95		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.63
Unadjusted Inverse Odds Ratio (95% CI)	0.91 (0.05, 16.54)		
p-value [1]	0.95		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.22, 0.24)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NE
Non-Responder, n(%)	10 (90.9%)	11 (91.7%)	
Non-missing	6 (54.5%)	6 (50.0%)	
Missing	4 (36.4%)	5 (41.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-improv-mf.pdf 29AUG2023: 9:43

Table 2.7108: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 59)	RUX (N = 54)	MMB (N = 16)	RUX (N = 28)
SF3602-Mental Health: NBS at Week 24				
Responder, n(%)	9 (15.3%)	12 (22.2%)	3 (18.8%)	4 (14.3%)
Unadjusted Inverse Relative Risk (95% CI)	1.46 (0.67, 3.18)		0.76 (0.19, 2.98)	
p-value [1]	0.35		0.70	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	1.59 (0.61, 4.13)		0.72 (0.14, 3.73)	
p-value [1]	0.34		0.70	
Unadjusted Absolute Risk Difference (95% CI)	-0.07 (-0.21, 0.07)		0.04 (-0.19, 0.28)	
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE	
p-value [2]	NE		NE	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	50 (84.7%)	42 (77.8%)	13 (81.3%)	24 (85.7%)
Non-missing	33 (55.9%)	32 (59.3%)	6 (37.5%)	12 (42.9%)
Missing	17 (28.8%)	10 (18.5%)	7 (43.8%)	12 (42.9%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
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Table 2.7108: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 11)	RUX (N = 12)	p-value
SF3602-Mental Health: NBS at Week 24			
Responder, n(%)	4 (36.4%)	0	
Unadjusted Inverse Relative Risk (95% CI)	0.10 (0.01, 1.71)		
p-value [1]	0.11		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NE
Unadjusted Inverse Odds Ratio (95% CI)	0.07 (0.00, 1.42)		
p-value [1]	0.083		
Unadjusted Absolute Risk Difference (95% CI)	0.34 (0.04, 0.63)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NE
Non-Responder, n(%)	7 (63.6%)	12 (100.0%)	
Non-missing	3 (27.3%)	7 (58.3%)	
Missing	4 (36.4%)	5 (41.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

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Table 2.7108: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 59)	RUX (N = 54)	MMB (N = 16)	RUX (N = 28)
SF3602-Physical Component Summary at Week 24				
Responder, n(%)	7 (11.9%)	6 (11.1%)	3 (18.8%)	2 (7.1%)
Unadjusted Inverse Relative Risk (95% CI)	0.94 (0.34, 2.61)		0.38 (0.07, 2.05)	
p-value [1]	0.90		0.26	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	0.93 (0.29, 2.96)		0.33 (0.05, 2.25)	
p-value [1]	0.90		0.26	
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.11, 0.13)		0.12 (-0.10, 0.33)	
Adjusted Inverse Relative Risk (95% CI) [2]	0.92 (0.31, 2.71)		NE	
p-value [2]	0.88		NE	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	52 (88.1%)	48 (88.9%)	13 (81.3%)	26 (92.9%)
Non-missing	35 (59.3%)	38 (70.4%)	6 (37.5%)	14 (50.0%)
Missing	17 (28.8%)	10 (18.5%)	7 (43.8%)	12 (42.9%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
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Table 2.7108: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 11)	RUX (N = 12)	p-value
SF3602-Physical Component Summary at Week 24			
Responder, n(%)	3 (27.3%)	1 (8.3%)	
Unadjusted Inverse Relative Risk (95% CI)	0.31 (0.04, 2.52)		
p-value [1]	0.27		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.49
Unadjusted Inverse Odds Ratio (95% CI)	0.24 (0.02, 2.78)		
p-value [1]	0.25		
Unadjusted Absolute Risk Difference (95% CI)	0.19 (-0.12, 0.50)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.56
Non-Responder, n(%)	8 (72.7%)	11 (91.7%)	
Non-missing	4 (36.4%)	6 (50.0%)	
Missing	4 (36.4%)	5 (41.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
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Table 2.7108: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 59)	RUX (N = 54)	MMB (N = 16)	RUX (N = 28)
SF3602-Mental Component Summary at Week 24				
Responder, n(%)	4 (6.8%)	7 (13.0%)	1 (6.3%)	3 (10.7%)
Unadjusted Inverse Relative Risk (95% CI)	1.91 (0.59, 6.17)		1.71 (0.19, 15.14)	
p-value [1]	0.28		0.63	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	2.05 (0.56, 7.43)		1.80 (0.17, 18.91)	
p-value [1]	0.28		0.62	
Unadjusted Absolute Risk Difference (95% CI)	-0.06 (-0.17, 0.05)		-0.04 (-0.21, 0.12)	
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE	
p-value [2]	NE		NE	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	55 (93.2%)	47 (87.0%)	15 (93.8%)	25 (89.3%)
Non-missing	38 (64.4%)	37 (68.5%)	8 (50.0%)	13 (46.4%)
Missing	17 (28.8%)	10 (18.5%)	7 (43.8%)	12 (42.9%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-improv-mf.pdf 29AUG2023: 9:43

Table 2.7108: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Double-Blind Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 11)	RUX (N = 12)	p-value
SF3602-Mental Component Summary at Week 24			
Responder, n(%)	1 (9.1%)	0	
Unadjusted Inverse Relative Risk (95% CI)	0.31 (0.01, 6.85)		
p-value [1]	0.46		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NE
Unadjusted Inverse Odds Ratio (95% CI)	0.28 (0.01, 7.62)		
p-value [1]	0.45		
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.13, 0.30)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NE
Non-Responder, n(%)	10 (90.9%)	12 (100.0%)	
Non-missing	6 (54.5%)	7 (58.3%)	
Missing	4 (36.4%)	5 (41.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-improv-mf.pdf 29AUG2023: 9:43

Table 2.7103: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 50)	RUX (N = 56)	MMB (N = 36)	RUX (N = 38)	p-value
SF3602-Physical Functioning: NBS at Week 24					
Responder, n(%)	14 (28.0%)	12 (21.4%)	8 (22.2%)	12 (31.6%)	
Unadjusted Inverse Relative Risk (95% CI)	0.77 (0.39, 1.50)		1.42 (0.66, 3.07)		
p-value [1]	0.43		0.37		
Unadjusted interaction test for Treatment*Gender [3]					0.23
Unadjusted Inverse Odds Ratio (95% CI)	0.70 (0.29, 1.70)		1.62 (0.57, 4.58)		
p-value [1]	0.43		0.37		
Unadjusted Absolute Risk Difference (95% CI)	0.07 (-0.10, 0.23)		-0.09 (-0.29, 0.11)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		1.35 (0.63, 2.90)		
p-value [2]	NE		0.44		
Adjusted interaction test for Treatment*Gender [3]					0.32
Non-Responder, n(%)	36 (72.0%)	44 (78.6%)	28 (77.8%)	26 (68.4%)	
Non-missing	21 (42.0%)	29 (51.8%)	15 (41.7%)	14 (36.8%)	
Missing	15 (30.0%)	15 (26.8%)	13 (36.1%)	12 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-improv-sex.pdf 29AUG2023: 9:41

Table 2.7103: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 50)	RUX (N = 56)	MMB (N = 36)	RUX (N = 38)	p-value
SF3602-Role Physical: NBS at Week 24					
Responder, n(%)	12 (24.0%)	9 (16.1%)	8 (22.2%)	8 (21.1%)	
Unadjusted Inverse Relative Risk (95% CI)	0.67 (0.31, 1.45)		0.95 (0.40, 2.26)		
p-value [1]	0.31		0.90		
Unadjusted interaction test for Treatment*Gender [3]					0.56
Unadjusted Inverse Odds Ratio (95% CI)	0.61 (0.23, 1.59)		0.93 (0.31, 2.82)		
p-value [1]	0.31		0.90		
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.07, 0.23)		0.01 (-0.18, 0.20)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Gender [3]					NE
Non-Responder, n(%)	38 (76.0%)	47 (83.9%)	28 (77.8%)	30 (78.9%)	
Non-missing	23 (46.0%)	32 (57.1%)	15 (41.7%)	18 (47.4%)	
Missing	15 (30.0%)	15 (26.8%)	13 (36.1%)	12 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7103: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 50)	RUX (N = 56)	MMB (N = 36)	RUX (N = 38)	p-value
SF3602-Bodily Pain: NBS at Week 24					
Responder, n(%)	12 (24.0%)	12 (21.4%)	6 (16.7%)	10 (26.3%)	
Unadjusted Inverse Relative Risk (95% CI)	0.89 (0.44, 1.80)		1.58 (0.64, 3.90)		
p-value [1]	0.75		0.32		
Unadjusted interaction test for Treatment*Gender [3]					0.32
Unadjusted Inverse Odds Ratio (95% CI)	0.86 (0.35, 2.15)		1.79 (0.57, 5.56)		
p-value [1]	0.75		0.32		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.13, 0.19)		-0.10 (-0.28, 0.09)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		1.60 (0.70, 3.64)		
p-value [2]	NE		0.27		
Adjusted interaction test for Treatment*Gender [3]					0.34
Non-Responder, n(%)	38 (76.0%)	44 (78.6%)	30 (83.3%)	28 (73.7%)	
Non-missing	23 (46.0%)	29 (51.8%)	17 (47.2%)	16 (42.1%)	
Missing	15 (30.0%)	15 (26.8%)	13 (36.1%)	12 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7103: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 50)	RUX (N = 56)	MMB (N = 36)	RUX (N = 38)	p-value
SF3602-General Health: NBS at Week 24					
Responder, n(%)	13 (26.0%)	13 (23.2%)	8 (22.2%)	6 (15.8%)	
Unadjusted Inverse Relative Risk (95% CI)	0.89 (0.46, 1.74)		0.71 (0.27, 1.85)		
p-value [1]	0.74		0.48		
Unadjusted interaction test for Treatment*Gender [3]					0.70
Unadjusted Inverse Odds Ratio (95% CI)	0.86 (0.35, 2.09)		0.66 (0.20, 2.12)		
p-value [1]	0.74		0.48		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.14, 0.19)		0.06 (-0.11, 0.24)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Gender [3]					NE
Non-Responder, n(%)	37 (74.0%)	43 (76.8%)	28 (77.8%)	32 (84.2%)	
Non-missing	22 (44.0%)	28 (50.0%)	15 (41.7%)	20 (52.6%)	
Missing	15 (30.0%)	15 (26.8%)	13 (36.1%)	12 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7103: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 50)	RUX (N = 56)	MMB (N = 36)	RUX (N = 38)	p-value
SF3602-Vitality: NBS at Week 24					
Responder, n(%)	8 (16.0%)	12 (21.4%)	5 (13.9%)	12 (31.6%)	
Unadjusted Inverse Relative Risk (95% CI)	1.34 (0.60, 3.01)		2.27 (0.89, 5.81)		
p-value [1]	0.48		0.086		
Unadjusted interaction test for Treatment*Gender [3]					0.40
Unadjusted Inverse Odds Ratio (95% CI)	1.43 (0.53, 3.85)		2.86 (0.89, 9.19)		
p-value [1]	0.48		0.077		
Unadjusted Absolute Risk Difference (95% CI)	-0.05 (-0.20, 0.09)		-0.18 (-0.36, 0.01)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Gender [3]					NE
Non-Responder, n(%)	42 (84.0%)	44 (78.6%)	31 (86.1%)	26 (68.4%)	
Non-missing	27 (54.0%)	29 (51.8%)	18 (50.0%)	14 (36.8%)	
Missing	15 (30.0%)	15 (26.8%)	13 (36.1%)	12 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7103: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 50)	RUX (N = 56)	MMB (N = 36)	RUX (N = 38)	p-value
SF3602-Social Functioning: NBS at Week 24					
Responder, n(%)	7 (14.0%)	8 (14.3%)	5 (13.9%)	9 (23.7%)	
Unadjusted Inverse Relative Risk (95% CI)	1.02 (0.40, 2.61)		1.71 (0.63, 4.61)		
p-value [1]	0.97		0.29		
Unadjusted interaction test for Treatment*Gender [3]					0.46
Unadjusted Inverse Odds Ratio (95% CI)	1.02 (0.34, 3.06)		1.92 (0.58, 6.42)		
p-value [1]	0.97		0.29		
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.14, 0.13)		-0.10 (-0.27, 0.08)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Gender [3]					NE
Non-Responder, n(%)	43 (86.0%)	48 (85.7%)	31 (86.1%)	29 (76.3%)	
Non-missing	28 (56.0%)	33 (58.9%)	18 (50.0%)	17 (44.7%)	
Missing	15 (30.0%)	15 (26.8%)	13 (36.1%)	12 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7103: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 50)	RUX (N = 56)	MMB (N = 36)	RUX (N = 38)	p-value
SF3602-Role Emotional: NBS at Week 24					
Responder, n(%)	8 (16.0%)	10 (17.9%)	5 (13.9%)	8 (21.1%)	
Unadjusted Inverse Relative Risk (95% CI)	1.12 (0.48, 2.61)		1.52 (0.55, 4.20)		
p-value [1]	0.80		0.42		
Unadjusted interaction test for Treatment*Gender [3]					0.65
Unadjusted Inverse Odds Ratio (95% CI)	1.14 (0.41, 3.16)		1.65 (0.49, 5.63)		
p-value [1]	0.80		0.42		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.16, 0.12)		-0.07 (-0.24, 0.10)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Gender [3]					NE
Non-Responder, n(%)	42 (84.0%)	46 (82.1%)	31 (86.1%)	30 (78.9%)	
Non-missing	27 (54.0%)	31 (55.4%)	18 (50.0%)	18 (47.4%)	
Missing	15 (30.0%)	15 (26.8%)	13 (36.1%)	12 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7103: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 50)	RUX (N = 56)	MMB (N = 36)	RUX (N = 38)	p-value
SF3602-Mental Health: NBS at Week 24					
Responder, n(%)	12 (24.0%)	9 (16.1%)	4 (11.1%)	7 (18.4%)	
Unadjusted Inverse Relative Risk (95% CI)	0.67 (0.31, 1.45)		1.66 (0.53, 5.19)		
p-value [1]	0.31		0.39		
Unadjusted interaction test for Treatment*Gender [3]					0.19
Unadjusted Inverse Odds Ratio (95% CI)	0.61 (0.23, 1.59)		1.81 (0.48, 6.79)		
p-value [1]	0.31		0.38		
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.07, 0.23)		-0.07 (-0.23, 0.09)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Gender [3]					NE
Non-Responder, n(%)	38 (76.0%)	47 (83.9%)	32 (88.9%)	31 (81.6%)	
Non-missing	23 (46.0%)	32 (57.1%)	19 (52.8%)	19 (50.0%)	
Missing	15 (30.0%)	15 (26.8%)	13 (36.1%)	12 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7103: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 50)	RUX (N = 56)	MMB (N = 36)	RUX (N = 38)	p-value
SF3602-Physical Component Summary at Week 24					
Responder, n(%)	7 (14.0%)	4 (7.1%)	6 (16.7%)	5 (13.2%)	
Unadjusted Inverse Relative Risk (95% CI)	0.51 (0.16, 1.64)		0.79 (0.26, 2.36)		
p-value [1]	0.26		0.67		
Unadjusted interaction test for Treatment*Gender [3]					0.59
Unadjusted Inverse Odds Ratio (95% CI)	0.47 (0.13, 1.72)		0.76 (0.21, 2.74)		
p-value [1]	0.26		0.67		
Unadjusted Absolute Risk Difference (95% CI)	0.07 (-0.05, 0.19)		0.04 (-0.13, 0.20)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.83 (0.28, 2.44)		
p-value [2]	NE		0.73		
Adjusted interaction test for Treatment*Gender [3]					0.74
Non-Responder, n(%)	43 (86.0%)	52 (92.9%)	30 (83.3%)	33 (86.8%)	
Non-missing	28 (56.0%)	37 (66.1%)	17 (47.2%)	21 (55.3%)	
Missing	15 (30.0%)	15 (26.8%)	13 (36.1%)	12 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-improv-sex.pdf 29AUG2023: 9:41

Table 2.7103: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 50)	RUX (N = 56)	MMB (N = 36)	RUX (N = 38)	p-value
SF3602-Mental Component Summary at Week 24					
Responder, n(%)	4 (8.0%)	6 (10.7%)	2 (5.6%)	4 (10.5%)	
Unadjusted Inverse Relative Risk (95% CI)	1.34 (0.40, 4.47)		1.89 (0.37, 9.72)		
p-value [1]	0.64		0.44		
Unadjusted interaction test for Treatment*Gender [3]					0.73
Unadjusted Inverse Odds Ratio (95% CI)	1.38 (0.37, 5.20)		2.00 (0.34, 11.66)		
p-value [1]	0.63		0.44		
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.14, 0.08)		-0.05 (-0.17, 0.07)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Gender [3]					NE
Non-Responder, n(%)	46 (92.0%)	50 (89.3%)	34 (94.4%)	34 (89.5%)	
Non-missing	31 (62.0%)	35 (62.5%)	21 (58.3%)	22 (57.9%)	
Missing	15 (30.0%)	15 (26.8%)	13 (36.1%)	12 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7110: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N = 47)	RUX (N = 43)	MMB (N = 39)	RUX (N = 51)	p-value
SF3602-Physical Functioning: NBS at Week 24					
Responder, n(%)	13 (27.7%)	13 (30.2%)	9 (23.1%)	11 (21.6%)	
Unadjusted Inverse Relative Risk (95% CI)	1.09 (0.57, 2.09)		0.93 (0.43, 2.03)		
p-value [1]	0.79		0.86		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.76
Unadjusted Inverse Odds Ratio (95% CI)	1.13 (0.46, 2.82)		0.92 (0.34, 2.49)		
p-value [1]	0.79		0.86		
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.21, 0.16)		0.02 (-0.16, 0.19)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.98 (0.44, 2.17)		
p-value [2]	NE		0.96		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.86
Non-Responder, n(%)	34 (72.3%)	30 (69.8%)	30 (76.9%)	40 (78.4%)	
Non-missing	21 (44.7%)	18 (41.9%)	15 (38.5%)	25 (49.0%)	
Missing	13 (27.7%)	12 (27.9%)	15 (38.5%)	15 (29.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-improv-svb.pdf 29AUG2023: 9:43

Table 2.7110: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N = 47)	RUX (N = 43)	MMB (N = 39)	RUX (N = 51)	p-value
SF3602-Role Physical: NBS at Week 24					
Responder, n(%)	10 (21.3%)	8 (18.6%)	10 (25.6%)	9 (17.6%)	
Unadjusted Inverse Relative Risk (95% CI)	0.87 (0.38, 2.01)		0.69 (0.31, 1.53)		
p-value [1]	0.75		0.36		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.69
Unadjusted Inverse Odds Ratio (95% CI)	0.85 (0.30, 2.39)		0.62 (0.22, 1.72)		
p-value [1]	0.75		0.36		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.14, 0.19)		0.08 (-0.09, 0.25)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NE
Non-Responder, n(%)	37 (78.7%)	35 (81.4%)	29 (74.4%)	42 (82.4%)	
Non-missing	24 (51.1%)	23 (53.5%)	14 (35.9%)	27 (52.9%)	
Missing	13 (27.7%)	12 (27.9%)	15 (38.5%)	15 (29.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7110: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N = 47)	RUX (N = 43)	MMB (N = 39)	RUX (N = 51)	p-value
SF3602-Bodily Pain: NBS at Week 24					
Responder, n(%)	11 (23.4%)	10 (23.3%)	7 (17.9%)	12 (23.5%)	
Unadjusted Inverse Relative Risk (95% CI)	0.99 (0.47, 2.10)		1.31 (0.57, 3.02)		
p-value [1]	0.99		0.52		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.63
Unadjusted Inverse Odds Ratio (95% CI)	0.99 (0.37, 2.64)		1.41 (0.50, 3.99)		
p-value [1]	0.99		0.52		
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.17, 0.18)		-0.06 (-0.22, 0.11)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		1.36 (0.60, 3.08)		
p-value [2]	NE		0.46		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.77
Non-Responder, n(%)	36 (76.6%)	33 (76.7%)	32 (82.1%)	39 (76.5%)	
Non-missing	23 (48.9%)	21 (48.8%)	17 (43.6%)	24 (47.1%)	
Missing	13 (27.7%)	12 (27.9%)	15 (38.5%)	15 (29.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7110: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N = 47)	RUX (N = 43)	MMB (N = 39)	RUX (N = 51)	p-value
SF3602-General Health: NBS at Week 24					
Responder, n(%)	15 (31.9%)	8 (18.6%)	6 (15.4%)	11 (21.6%)	
Unadjusted Inverse Relative Risk (95% CI)	0.58 (0.27, 1.24)		1.40 (0.57, 3.46)		
p-value [1]	0.16		0.46		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.13
Unadjusted Inverse Odds Ratio (95% CI)	0.49 (0.18, 1.30)		1.51 (0.51, 4.53)		
p-value [1]	0.15		0.46		
Unadjusted Absolute Risk Difference (95% CI)	0.13 (-0.04, 0.31)		-0.06 (-0.22, 0.10)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NE
Non-Responder, n(%)	32 (68.1%)	35 (81.4%)	33 (84.6%)	40 (78.4%)	
Non-missing	19 (40.4%)	23 (53.5%)	18 (46.2%)	25 (49.0%)	
Missing	13 (27.7%)	12 (27.9%)	15 (38.5%)	15 (29.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-improv-svb.pdf 29AUG2023: 9:43

Table 2.7110: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N = 47)	RUX (N = 43)	MMB (N = 39)	RUX (N = 51)	p-value
SF3602-Vitality: NBS at Week 24					
Responder, n(%)	8 (17.0%)	13 (30.2%)	5 (12.8%)	11 (21.6%)	
Unadjusted Inverse Relative Risk (95% CI)	1.78 (0.82, 3.87)		1.68 (0.64, 4.44)		
p-value [1]	0.15		0.29		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.93
Unadjusted Inverse Odds Ratio (95% CI)	2.11 (0.78, 5.75)		1.87 (0.59, 5.92)		
p-value [1]	0.14		0.29		
Unadjusted Absolute Risk Difference (95% CI)	-0.13 (-0.31, 0.04)		-0.09 (-0.24, 0.07)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NE
Non-Responder, n(%)	39 (83.0%)	30 (69.8%)	34 (87.2%)	40 (78.4%)	
Non-missing	26 (55.3%)	18 (41.9%)	19 (48.7%)	25 (49.0%)	
Missing	13 (27.7%)	12 (27.9%)	15 (38.5%)	15 (29.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7110: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N = 47)	RUX (N = 43)	MMB (N = 39)	RUX (N = 51)	p-value
SF3602-Social Functioning: NBS at Week 24					
Responder, n(%)	8 (17.0%)	9 (20.9%)	4 (10.3%)	8 (15.7%)	
Unadjusted Inverse Relative Risk (95% CI)	1.23 (0.52, 2.90)		1.53 (0.50, 4.71)		
p-value [1]	0.64		0.46		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.76
Unadjusted Inverse Odds Ratio (95% CI)	1.29 (0.45, 3.72)		1.63 (0.45, 5.86)		
p-value [1]	0.64		0.46		
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.20, 0.12)		-0.05 (-0.19, 0.08)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NE
Non-Responder, n(%)	39 (83.0%)	34 (79.1%)	35 (89.7%)	43 (84.3%)	
Non-missing	26 (55.3%)	22 (51.2%)	20 (51.3%)	28 (54.9%)	
Missing	13 (27.7%)	12 (27.9%)	15 (38.5%)	15 (29.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-improv-svb.pdf 29AUG2023: 9:43

Table 2.7110: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N = 47)	RUX (N = 43)	MMB (N = 39)	RUX (N = 51)	p-value
SF3602-Role Emotional: NBS at Week 24					
Responder, n(%)	6 (12.8%)	11 (25.6%)	7 (17.9%)	7 (13.7%)	
Unadjusted Inverse Relative Risk (95% CI)	2.00 (0.81, 4.95)		0.76 (0.29, 2.00)		
p-value [1]	0.13		0.58		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.16
Unadjusted Inverse Odds Ratio (95% CI)	2.35 (0.78, 7.04)		0.73 (0.23, 2.28)		
p-value [1]	0.13		0.58		
Unadjusted Absolute Risk Difference (95% CI)	-0.13 (-0.29, 0.03)		0.04 (-0.11, 0.20)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NE
Non-Responder, n(%)	41 (87.2%)	32 (74.4%)	32 (82.1%)	44 (86.3%)	
Non-missing	28 (59.6%)	20 (46.5%)	17 (43.6%)	29 (56.9%)	
Missing	13 (27.7%)	12 (27.9%)	15 (38.5%)	15 (29.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7110: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N = 47)	RUX (N = 43)	MMB (N = 39)	RUX (N = 51)	p-value
SF3602-Mental Health: NBS at Week 24					
Responder, n(%)	9 (19.1%)	8 (18.6%)	7 (17.9%)	8 (15.7%)	
Unadjusted Inverse Relative Risk (95% CI)	0.97 (0.41, 2.29)		0.87 (0.35, 2.20)		
p-value [1]	0.95		0.78		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.87
Unadjusted Inverse Odds Ratio (95% CI)	0.97 (0.34, 2.78)		0.85 (0.28, 2.59)		
p-value [1]	0.95		0.78		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.16, 0.17)		0.02 (-0.13, 0.18)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NE
Non-Responder, n(%)	38 (80.9%)	35 (81.4%)	32 (82.1%)	43 (84.3%)	
Non-missing	25 (53.2%)	23 (53.5%)	17 (43.6%)	28 (54.9%)	
Missing	13 (27.7%)	12 (27.9%)	15 (38.5%)	15 (29.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-improv-svb.pdf 29AUG2023: 9:43

Table 2.7110: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N = 47)	RUX (N = 43)	MMB (N = 39)	RUX (N = 51)	p-value
SF3602-Physical Component Summary at Week 24					
Responder, n(%)	9 (19.1%)	4 (9.3%)	4 (10.3%)	5 (9.8%)	
Unadjusted Inverse Relative Risk (95% CI)	0.49 (0.16, 1.46)		0.96 (0.27, 3.33)		
p-value [1]	0.20		0.94		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.42
Unadjusted Inverse Odds Ratio (95% CI)	0.43 (0.12, 1.53)		0.95 (0.24, 3.80)		
p-value [1]	0.19		0.94		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.04, 0.24)		0.00 (-0.12, 0.13)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.27
Non-Responder, n(%)	38 (80.9%)	39 (90.7%)	35 (89.7%)	46 (90.2%)	
Non-missing	25 (53.2%)	27 (62.8%)	20 (51.3%)	31 (60.8%)	
Missing	13 (27.7%)	12 (27.9%)	15 (38.5%)	15 (29.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7110: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Spleen Volume
Double-Blind Phase
ITT-Anemic Analysis Set

	<Median 1837.09 cm^3		>=Median 1837.09 cm^3		
	MMB (N = 47)	RUX (N = 43)	MMB (N = 39)	RUX (N = 51)	p-value
SF3602-Mental Component Summary at Week 24					
Responder, n(%)	3 (6.4%)	5 (11.6%)	3 (7.7%)	5 (9.8%)	
Unadjusted Inverse Relative Risk (95% CI)	1.82 (0.46, 7.17)		1.27 (0.32, 5.01)		
p-value [1]	0.39		0.73		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	1.93 (0.43, 8.61)		1.30 (0.29, 5.82)		
p-value [1]	0.39		0.73		
Unadjusted Absolute Risk Difference (95% CI)	-0.05 (-0.17, 0.07)		-0.02 (-0.14, 0.10)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Non-Responder, n(%)	44 (93.6%)	38 (88.4%)	36 (92.3%)	46 (90.2%)	
Non-missing	31 (66.0%)	26 (60.5%)	21 (53.8%)	31 (60.8%)	
Missing	13 (27.7%)	12 (27.9%)	15 (38.5%)	15 (29.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7109: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline TSS
Double-Blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 44)	RUX (N = 55)	MMB (N = 41)	RUX (N = 38)	p-value
SF3602-Physical Functioning: NBS at Week 24					
Responder, n(%)	8 (18.2%)	10 (18.2%)	14 (34.1%)	13 (34.2%)	
Unadjusted Inverse Relative Risk (95% CI)	1.00 (0.43, 2.32)		1.00 (0.54, 1.85)		
p-value [1]	1.00		1.00		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					1.00
Unadjusted Inverse Odds Ratio (95% CI)	1.00 (0.36, 2.80)		1.00 (0.40, 2.54)		
p-value [1]	1.00		1.00		
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.15, 0.15)		0.00 (-0.21, 0.21)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		1.07 (0.60, 1.90)		
p-value [2]	NE		0.82		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					0.96
Non-Responder, n(%)	36 (81.8%)	45 (81.8%)	27 (65.9%)	25 (65.8%)	
Non-missing	27 (61.4%)	31 (56.4%)	8 (19.5%)	12 (31.6%)	
Missing	9 (20.5%)	14 (25.5%)	19 (46.3%)	13 (34.2%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7109: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline TSS
Double-Blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 44)	RUX (N = 55)	MMB (N = 41)	RUX (N = 38)	p-value
SF3602-Role Physical: NBS at Week 24					
Responder, n(%)	8 (18.2%)	4 (7.3%)	12 (29.3%)	12 (31.6%)	
Unadjusted Inverse Relative Risk (95% CI)	0.40 (0.13, 1.24)		1.08 (0.55, 2.10)		
p-value [1]	0.11		0.82		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.13
Unadjusted Inverse Odds Ratio (95% CI)	0.35 (0.10, 1.26)		1.12 (0.43, 2.91)		
p-value [1]	0.11		0.82		
Unadjusted Absolute Risk Difference (95% CI)	0.11 (-0.02, 0.24)		-0.02 (-0.23, 0.18)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NE
Non-Responder, n(%)	36 (81.8%)	51 (92.7%)	29 (70.7%)	26 (68.4%)	
Non-missing	27 (61.4%)	37 (67.3%)	10 (24.4%)	13 (34.2%)	
Missing	9 (20.5%)	14 (25.5%)	19 (46.3%)	13 (34.2%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 2.7109: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline TSS
Double-Blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 44)	RUX (N = 55)	MMB (N = 41)	RUX (N = 38)	p-value
SF3602-Bodily Pain: NBS at Week 24					
Responder, n(%)	6 (13.6%)	8 (14.5%)	11 (26.8%)	13 (34.2%)	
Unadjusted Inverse Relative Risk (95% CI)	1.07 (0.40, 2.85)		1.28 (0.65, 2.49)		
p-value [1]	0.90		0.48		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.77
Unadjusted Inverse Odds Ratio (95% CI)	1.08 (0.34, 3.38)		1.42 (0.54, 3.71)		
p-value [1]	0.90		0.48		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.15, 0.13)		-0.07 (-0.28, 0.13)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		1.39 (0.73, 2.64)		
p-value [2]	NE		0.32		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					0.78
Non-Responder, n(%)	38 (86.4%)	47 (85.5%)	30 (73.2%)	25 (65.8%)	
Non-missing	29 (65.9%)	33 (60.0%)	11 (26.8%)	12 (31.6%)	
Missing	9 (20.5%)	14 (25.5%)	19 (46.3%)	13 (34.2%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
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Table 2.7109: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline TSS
Double-Blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 44)	RUX (N = 55)	MMB (N = 41)	RUX (N = 38)	p-value
SF3602-General Health: NBS at Week 24					
Responder, n(%)	8 (18.2%)	7 (12.7%)	12 (29.3%)	11 (28.9%)	
Unadjusted Inverse Relative Risk (95% CI)	0.70 (0.28, 1.78)		0.99 (0.50, 1.97)		
p-value [1]	0.45		0.97		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.56
Unadjusted Inverse Odds Ratio (95% CI)	0.66 (0.22, 1.98)		0.98 (0.37, 2.60)		
p-value [1]	0.45		0.97		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.09, 0.20)		0.00 (-0.20, 0.20)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NE
Non-Responder, n(%)	36 (81.8%)	48 (87.3%)	29 (70.7%)	27 (71.1%)	
Non-missing	27 (61.4%)	34 (61.8%)	10 (24.4%)	14 (36.8%)	
Missing	9 (20.5%)	14 (25.5%)	19 (46.3%)	13 (34.2%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

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Table 2.7109: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline TSS
Double-Blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 44)	RUX (N = 55)	MMB (N = 41)	RUX (N = 38)	p-value
SF3602-Vitality: NBS at Week 24					
Responder, n(%)	5 (11.4%)	8 (14.5%)	8 (19.5%)	15 (39.5%)	
Unadjusted Inverse Relative Risk (95% CI)	1.28 (0.45, 3.64)		2.02 (0.97, 4.22)		
p-value [1]	0.64		0.061		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.50
Unadjusted Inverse Odds Ratio (95% CI)	1.33 (0.40, 4.39)		2.69 (0.98, 7.38)		
p-value [1]	0.64		0.055		
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.16, 0.10)		-0.20 (-0.40, 0.00)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NE
Non-Responder, n(%)	39 (88.6%)	47 (85.5%)	33 (80.5%)	23 (60.5%)	
Non-missing	30 (68.2%)	33 (60.0%)	14 (34.1%)	10 (26.3%)	
Missing	9 (20.5%)	14 (25.5%)	19 (46.3%)	13 (34.2%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

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Table 2.7109: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline TSS
Double-Blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 44)	RUX (N = 55)	MMB (N = 41)	RUX (N = 38)	p-value
SF3602-Social Functioning: NBS at Week 24					
Responder, n(%)	8 (18.2%)	8 (14.5%)	4 (9.8%)	8 (21.1%)	
Unadjusted Inverse Relative Risk (95% CI)	0.80 (0.33, 1.96)		2.16 (0.71, 6.59)		
p-value [1]	0.63		0.18		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.17
Unadjusted Inverse Odds Ratio (95% CI)	0.77 (0.26, 2.24)		2.47 (0.68, 8.99)		
p-value [1]	0.63		0.17		
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.11, 0.18)		-0.11 (-0.27, 0.05)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NE
Non-Responder, n(%)	36 (81.8%)	47 (85.5%)	37 (90.2%)	30 (78.9%)	
Non-missing	27 (61.4%)	33 (60.0%)	18 (43.9%)	17 (44.7%)	
Missing	9 (20.5%)	14 (25.5%)	19 (46.3%)	13 (34.2%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

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Table 2.7109: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline TSS
Double-Blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 44)	RUX (N = 55)	MMB (N = 41)	RUX (N = 38)	p-value
SF3602-Role Emotional: NBS at Week 24					
Responder, n(%)	6 (13.6%)	10 (18.2%)	7 (17.1%)	7 (18.4%)	
Unadjusted Inverse Relative Risk (95% CI)	1.33 (0.53, 3.38)		1.08 (0.42, 2.79)		
p-value [1]	0.54		0.88		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.75
Unadjusted Inverse Odds Ratio (95% CI)	1.41 (0.47, 4.23)		1.10 (0.35, 3.48)		
p-value [1]	0.54		0.88		
Unadjusted Absolute Risk Difference (95% CI)	-0.05 (-0.19, 0.10)		-0.01 (-0.18, 0.16)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NE
Non-Responder, n(%)	38 (86.4%)	45 (81.8%)	34 (82.9%)	31 (81.6%)	
Non-missing	29 (65.9%)	31 (56.4%)	15 (36.6%)	18 (47.4%)	
Missing	9 (20.5%)	14 (25.5%)	19 (46.3%)	13 (34.2%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-improv-tss.pdf 29AUG2023: 9:43

Table 2.7109: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline TSS
Double-Blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 44)	RUX (N = 55)	MMB (N = 41)	RUX (N = 38)	p-value
SF3602-Mental Health: NBS at Week 24					
Responder, n(%)	9 (20.5%)	9 (16.4%)	7 (17.1%)	6 (15.8%)	
Unadjusted Inverse Relative Risk (95% CI)	0.80 (0.35, 1.84)		0.92 (0.34, 2.51)		
p-value [1]	0.60		0.88		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.83
Unadjusted Inverse Odds Ratio (95% CI)	0.76 (0.27, 2.12)		0.91 (0.28, 3.00)		
p-value [1]	0.60		0.88		
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.11, 0.20)		0.01 (-0.15, 0.18)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NE
Non-Responder, n(%)	35 (79.5%)	46 (83.6%)	34 (82.9%)	32 (84.2%)	
Non-missing	26 (59.1%)	32 (58.2%)	15 (36.6%)	19 (50.0%)	
Missing	9 (20.5%)	14 (25.5%)	19 (46.3%)	13 (34.2%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-improv-tss.pdf 29AUG2023: 9:43

Table 2.7109: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline TSS
Double-Blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 44)	RUX (N = 55)	MMB (N = 41)	RUX (N = 38)	p-value
SF3602-Physical Component Summary at Week 24					
Responder, n(%)	5 (11.4%)	2 (3.6%)	8 (19.5%)	6 (15.8%)	
Unadjusted Inverse Relative Risk (95% CI)	0.32 (0.07, 1.57)		0.81 (0.31, 2.12)		
p-value [1]	0.16		0.67		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.31
Unadjusted Inverse Odds Ratio (95% CI)	0.29 (0.05, 1.60)		0.77 (0.24, 2.48)		
p-value [1]	0.16		0.67		
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.03, 0.18)		0.04 (-0.13, 0.21)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.87 (0.34, 2.25)		
p-value [2]	NE		0.78		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					0.32
Non-Responder, n(%)	39 (88.6%)	53 (96.4%)	33 (80.5%)	32 (84.2%)	
Non-missing	30 (68.2%)	39 (70.9%)	14 (34.1%)	19 (50.0%)	
Missing	9 (20.5%)	14 (25.5%)	19 (46.3%)	13 (34.2%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-improv-tss.pdf 29AUG2023: 9:43

Table 2.7109: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline TSS
Double-Blind Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 44)	RUX (N = 55)	MMB (N = 41)	RUX (N = 38)	p-value
SF3602-Mental Component Summary at Week 24					
Responder, n(%)	2 (4.5%)	5 (9.1%)	4 (9.8%)	4 (10.5%)	
Unadjusted Inverse Relative Risk (95% CI)	2.00 (0.41, 9.82)		1.08 (0.29, 4.01)		
p-value [1]	0.39		0.91		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	2.10 (0.39, 11.39)		1.09 (0.25, 4.70)		
p-value [1]	0.39		0.91		
Unadjusted Absolute Risk Difference (95% CI)	-0.05 (-0.14, 0.05)		-0.01 (-0.14, 0.13)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Non-Responder, n(%)	42 (95.5%)	50 (90.9%)	37 (90.2%)	34 (89.5%)	
Non-missing	33 (75.0%)	36 (65.5%)	18 (43.9%)	21 (55.3%)	
Missing	9 (20.5%)	14 (25.5%)	19 (46.3%)	13 (34.2%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no), and baseline platelet count (<100, 100-200, >200 10^9/L) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 01JUL2019

Table 3.0102: TEAEs: Overall Summary by Age
Double-Blind Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
TEAE					
Number of subjects, n(%)	21 (87.5%)	33 (91.7%)	60 (96.8%)	58 (100.0%)	
Unadjusted Relative Risk (95% CI)	0.95 (0.80, 1.14)		0.97 (0.92, 1.02)		
p-value [1]	0.61		0.26		
Unadjusted Odds Ratio (95% CI)	0.64 (0.12, 3.45)		0.21 (0.01, 4.40)		
p-value [1]	0.60		0.31		
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.20, 0.12)		-0.03 (-0.08, 0.02)		
Interaction test for Treatment*Age Group [2]					0.88
TEAE with Grade >=3					
Number of subjects, n(%)	9 (37.5%)	18 (50.0%)	33 (53.2%)	34 (58.6%)	
Unadjusted Relative Risk (95% CI)	0.75 (0.41, 1.38)		0.91 (0.66, 1.25)		
p-value [1]	0.36		0.55		
Unadjusted Odds Ratio (95% CI)	0.60 (0.21, 1.72)		0.80 (0.39, 1.65)		
p-value [1]	0.34		0.55		
Unadjusted Absolute Risk Difference (95% CI)	-0.13 (-0.38, 0.13)		-0.05 (-0.23, 0.12)		
Interaction test for Treatment*Age Group [2]					0.58

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test. [2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Modified Poisson regression model did not converge for some categories so these values are presented as NE.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-sub-gba.sas V.03.05 Output file: t-aesum-gba-age.pdf 24AUG2023:12:46

Table 3.0102: TEAEs: Overall Summary by Age
Double-Blind Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
TEAE with Grade 3 or 4					
Number of subjects, n(%)	9 (37.5%)	18 (50.0%)	32 (51.6%)	34 (58.6%)	
Unadjusted Relative Risk (95% CI)	0.75 (0.41, 1.38)		0.88 (0.64, 1.22)		
p-value [1]	0.36		0.44		
Unadjusted Odds Ratio (95% CI)	0.60 (0.21, 1.72)		0.75 (0.37, 1.55)		
p-value [1]	0.34		0.44		
Unadjusted Absolute Risk Difference (95% CI)	-0.13 (-0.38, 0.13)		-0.07 (-0.25, 0.11)		
Interaction test for Treatment*Age Group [2]					0.64
TEAE Related to Study Drug					
Number of subjects, n(%)	16 (66.7%)	23 (63.9%)	42 (67.7%)	36 (62.1%)	
Unadjusted Relative Risk (95% CI)	1.04 (0.72, 1.52)		1.09 (0.84, 1.42)		
p-value [1]	0.82		0.52		
Unadjusted Odds Ratio (95% CI)	1.13 (0.38, 3.35)		1.28 (0.61, 2.72)		
p-value [1]	0.83		0.52		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.22, 0.27)		0.06 (-0.11, 0.23)		
Interaction test for Treatment*Age Group [2]					0.85

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test. [2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Modified Poisson regression model did not converge for some categories so these values are presented as NE.

Data Extracted: CRF data: 01JUL2019
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Table 3.0102: TEAEs: Overall Summary by Age
Double-Blind Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
TEAE Related to Study Drug with Grade >=3					
Number of subjects, n(%)	5 (20.8%)	16 (44.4%)	19 (30.6%)	15 (25.9%)	
Unadjusted Relative Risk (95% CI)	0.47 (0.20, 1.11)		1.18 (0.67, 2.10)		
p-value [1]	0.085		0.56		
Unadjusted Odds Ratio (95% CI)	0.33 (0.10, 1.08)		1.27 (0.57, 2.81)		
p-value [1]	0.066		0.56		
Unadjusted Absolute Risk Difference (95% CI)	-0.24 (-0.47, -0.01)		0.05 (-0.11, 0.21)		
Interaction test for Treatment*Age Group [2]					0.059
Serious TEAE					
Number of subjects, n(%)	3 (12.5%)	5 (13.9%)	23 (37.1%)	18 (31.0%)	
Unadjusted Relative Risk (95% CI)	0.90 (0.24, 3.42)		1.20 (0.72, 1.98)		
p-value [1]	0.88		0.49		
Unadjusted Odds Ratio (95% CI)	0.89 (0.19, 4.11)		1.31 (0.61, 2.80)		
p-value [1]	0.88		0.48		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.19, 0.16)		0.06 (-0.11, 0.23)		
Interaction test for Treatment*Age Group [2]					0.69

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test. [2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Modified Poisson regression model did not converge for some categories so these values are presented as NE.

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Table 3.0102: TEAEs: Overall Summary by Age
Double-Blind Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Serious TEAE Related to Study Drug					
Number of subjects, n(%)	0	4 (11.1%)	10 (16.1%)	4 (6.9%)	
Unadjusted Relative Risk (95% CI)	0.16 (0.01, 2.92)		2.34 (0.78, 7.05)		
p-value [1]	0.22		0.13		
Unadjusted Odds Ratio (95% CI)	0.15 (0.01, 2.87)		2.60 (0.77, 8.80)		
p-value [1]	0.21		0.13		
Unadjusted Absolute Risk Difference (95% CI)	-0.10 (-0.22, 0.02)		0.09 (-0.02, 0.20)		
Interaction test for Treatment*Age Group [2]					NE
Non-Fatal SAEs					
Number of subjects, n(%)	2 (8.3%)	5 (13.9%)	22 (35.5%)	18 (31.0%)	
Unadjusted Relative Risk (95% CI)	0.60 (0.13, 2.84)		1.14 (0.69, 1.90)		
p-value [1]	0.52		0.61		
Unadjusted Odds Ratio (95% CI)	0.56 (0.10, 3.17)		1.22 (0.57, 2.62)		
p-value [1]	0.52		0.61		
Unadjusted Absolute Risk Difference (95% CI)	-0.06 (-0.21, 0.10)		0.04 (-0.12, 0.21)		
Interaction test for Treatment*Age Group [2]					0.41

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test. [2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Modified Poisson regression model did not converge for some categories so these values are presented as NE.

Data Extracted: CRF data: 01JUL2019
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Table 3.0102: TEAEs: Overall Summary by Age
Double-Blind Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
TEAE Leading to Premature Discontinuation of Study Drug of MMB\MMB Matched Placebo					
Number of subjects, n(%)	2 (8.3%)	3 (8.3%)	15 (24.2%)	2 (3.4%)	
Unadjusted Relative Risk (95% CI)	1.00 (0.18, 5.55)		7.02 (1.68, 29.36)		
p-value [1]	>0.99		0.008		
Unadjusted Odds Ratio (95% CI)	1.00 (0.15, 6.48)		8.94 (1.94, 41.08)		
p-value [1]	>0.99		0.005		
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.14, 0.14)		0.21 (0.09, 0.32)		
Interaction test for Treatment*Age Group [2]					0.12
TEAE Leading to Premature Discontinuation of Study Drug of RUX\RUX Matched Placebo					
Number of subjects, n(%)	2 (8.3%)	3 (8.3%)	15 (24.2%)	2 (3.4%)	
Unadjusted Relative Risk (95% CI)	1.00 (0.18, 5.55)		7.02 (1.68, 29.36)		
p-value [1]	>0.99		0.008		
Unadjusted Odds Ratio (95% CI)	1.00 (0.15, 6.48)		8.94 (1.94, 41.08)		
p-value [1]	>0.99		0.005		
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.14, 0.14)		0.21 (0.09, 0.32)		
Interaction test for Treatment*Age Group [2]					0.12

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test. [2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Modified Poisson regression model did not converge for some categories so these values are presented as NE.

Data Extracted: CRF data: 01JUL2019

Table 3.0102: TEAEs: Overall Summary by Age
Double-Blind Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
TEAE Leading to Dose Reduction or Temporary Interruption of Study Drug of MMB\MMB Matched Placebo					
Number of subjects, n(%)	3 (12.5%)	5 (13.9%)	16 (25.8%)	10 (17.2%)	
Unadjusted Relative Risk (95% CI)	0.90 (0.24, 3.42)		1.50 (0.74, 3.03)		
p-value [1]	0.88		0.26		
Unadjusted Odds Ratio (95% CI)	0.89 (0.19, 4.11)		1.67 (0.69, 4.06)		
p-value [1]	0.88		0.26		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.19, 0.16)		0.09 (-0.06, 0.23)		
Interaction test for Treatment*Age Group [2]					0.50
TEAE Leading to Dose Reduction or Temporary Interruption of Study Drug of RUX\RUX Matched Placebo					
Number of subjects, n(%)	6 (25.0%)	9 (25.0%)	20 (32.3%)	25 (43.1%)	
Unadjusted Relative Risk (95% CI)	1.00 (0.41, 2.45)		0.75 (0.47, 1.19)		
p-value [1]	>0.99		0.22		
Unadjusted Odds Ratio (95% CI)	1.00 (0.30, 3.30)		0.63 (0.30, 1.32)		
p-value [1]	>0.99		0.22		
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.22, 0.22)		-0.11 (-0.28, 0.06)		
Interaction test for Treatment*Age Group [2]					0.58

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test. [2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Modified Poisson regression model did not converge for some categories so these values are presented as NE.

Data Extracted: CRF data: 01JUL2019
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Table 3.0102: TEAEs: Overall Summary by Age
Double-Blind Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
TEAE Leading to Death					
Number of subjects, n(%)	2 (8.3%)	1 (2.8%)	2 (3.2%)	2 (3.4%)	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Age Group [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test. [2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Modified Poisson regression model did not converge for some categories so these values are presented as NE.

Data Extracted: CRF data: 01JUL2019

Table 3.0104: TEAEs: Overall Summary by Region
Double-Blind Phase
SAF-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
TEAE					
Number of subjects, n(%)	53 (100.0%)	51 (100.0%)	28 (84.8%)	40 (93.0%)	
Unadjusted Relative Risk (95% CI)	1.00 (0.96, 1.04)		0.91 (0.77, 1.08)		
p-value [1]	0.98		0.28		
Unadjusted Odds Ratio (95% CI)	1.04 (0.02, 53.34)		0.42 (0.09, 1.90)		
p-value [1]	0.98		0.26		
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.04, 0.04)		-0.08 (-0.23, 0.06)		
Interaction test for Treatment*Region [2]					0.27
TEAE with Grade >=3					
Number of subjects, n(%)	29 (54.7%)	27 (52.9%)	13 (39.4%)	25 (58.1%)	
Unadjusted Relative Risk (95% CI)	1.03 (0.72, 1.48)		0.68 (0.41, 1.11)		
p-value [1]	0.86		0.12		
Unadjusted Odds Ratio (95% CI)	1.07 (0.50, 2.32)		0.47 (0.19, 1.18)		
p-value [1]	0.86		0.11		
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.17, 0.21)		-0.19 (-0.41, 0.04)		
Interaction test for Treatment*Region [2]					0.16

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0104: TEAEs: Overall Summary by Region
Double-Blind Phase
SAF-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
TEAE with Grade 3 or 4					
Number of subjects, n(%)	29 (54.7%)	27 (52.9%)	12 (36.4%)	25 (58.1%)	
Unadjusted Relative Risk (95% CI)	1.03 (0.72, 1.48)		0.63 (0.37, 1.05)		
p-value [1]	0.86		0.076		
Unadjusted Odds Ratio (95% CI)	1.07 (0.50, 2.32)		0.41 (0.16, 1.05)		
p-value [1]	0.86		0.062		
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.17, 0.21)		-0.22 (-0.44, 0.00)		
Interaction test for Treatment*Region [2]					0.10
TEAE Related to Study Drug					
Number of subjects, n(%)	43 (81.1%)	33 (64.7%)	15 (45.5%)	26 (60.5%)	
Unadjusted Relative Risk (95% CI)	1.25 (0.99, 1.60)		0.75 (0.48, 1.17)		
p-value [1]	0.065		0.21		
Unadjusted Odds Ratio (95% CI)	2.35 (0.96, 5.75)		0.54 (0.22, 1.36)		
p-value [1]	0.062		0.19		
Unadjusted Absolute Risk Difference (95% CI)	0.16 (0.00, 0.33)		-0.15 (-0.37, 0.07)		
Interaction test for Treatment*Region [2]					0.041

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0104: TEAEs: Overall Summary by Region
Double-Blind Phase
SAF-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
TEAE Related to Study Drug with Grade >=3					
Number of subjects, n(%)	15 (28.3%)	12 (23.5%)	9 (27.3%)	19 (44.2%)	
Unadjusted Relative Risk (95% CI)	1.20 (0.63, 2.31)		0.62 (0.32, 1.18)		
p-value [1]	0.58		0.15		
Unadjusted Odds Ratio (95% CI)	1.28 (0.53, 3.10)		0.47 (0.18, 1.25)		
p-value [1]	0.58		0.13		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.12, 0.22)		-0.17 (-0.38, 0.04)		
Interaction test for Treatment*Region [2]					0.15
Serious TEAE					
Number of subjects, n(%)	18 (34.0%)	12 (23.5%)	8 (24.2%)	11 (25.6%)	
Unadjusted Relative Risk (95% CI)	1.44 (0.78, 2.69)		0.95 (0.43, 2.09)		
p-value [1]	0.25		0.89		
Unadjusted Odds Ratio (95% CI)	1.67 (0.71, 3.95)		0.93 (0.33, 2.66)		
p-value [1]	0.24		0.89		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.07, 0.28)		-0.01 (-0.21, 0.18)		
Interaction test for Treatment*Region [2]					0.41

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0104: TEAEs: Overall Summary by Region
Double-Blind Phase
SAF-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Serious TEAE Related to Study Drug					
Number of subjects, n(%)	7 (13.2%)	4 (7.8%)	3 (9.1%)	4 (9.3%)	
Unadjusted Relative Risk (95% CI)	1.68 (0.52, 5.41)		0.98 (0.23, 4.07)		
p-value [1]	0.38		0.97		
Unadjusted Odds Ratio (95% CI)	1.79 (0.49, 6.52)		0.98 (0.20, 4.69)		
p-value [1]	0.38		0.97		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.06, 0.17)		0.00 (-0.13, 0.13)		
Interaction test for Treatment*Region [2]					0.56
Non-Fatal SAEs					
Number of subjects, n(%)	18 (34.0%)	12 (23.5%)	6 (18.2%)	11 (25.6%)	
Unadjusted Relative Risk (95% CI)	1.44 (0.78, 2.69)		0.71 (0.29, 1.72)		
p-value [1]	0.25		0.45		
Unadjusted Odds Ratio (95% CI)	1.67 (0.71, 3.95)		0.65 (0.21, 1.98)		
p-value [1]	0.24		0.44		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.07, 0.28)		-0.07 (-0.26, 0.11)		
Interaction test for Treatment*Region [2]					0.19

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0104: TEAEs: Overall Summary by Region
Double-Blind Phase
SAF-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
TEAE Leading to Premature Discontinuation of Study Drug of MMB\MMB Matched Placebo					
Number of subjects, n(%)	12 (22.6%)	4 (7.8%)	5 (15.2%)	1 (2.3%)	
Unadjusted Relative Risk (95% CI)	2.89 (1.00, 8.37)		6.52 (0.80, 53.13)		
p-value [1]	0.051		0.080		
Unadjusted Odds Ratio (95% CI)	3.44 (1.03, 11.49)		7.50 (0.83, 67.67)		
p-value [1]	0.045		0.073		
Unadjusted Absolute Risk Difference (95% CI)	0.15 (0.01, 0.28)		0.13 (0.00, 0.26)		
Interaction test for Treatment*Region [2]					0.46
TEAE Leading to Premature Discontinuation of Study Drug of RUX\RUX Matched Placebo					
Number of subjects, n(%)	12 (22.6%)	4 (7.8%)	5 (15.2%)	1 (2.3%)	
Unadjusted Relative Risk (95% CI)	2.89 (1.00, 8.37)		6.52 (0.80, 53.13)		
p-value [1]	0.051		0.080		
Unadjusted Odds Ratio (95% CI)	3.44 (1.03, 11.49)		7.50 (0.83, 67.67)		
p-value [1]	0.045		0.073		
Unadjusted Absolute Risk Difference (95% CI)	0.15 (0.01, 0.28)		0.13 (0.00, 0.26)		
Interaction test for Treatment*Region [2]					0.46

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0104: TEAEs: Overall Summary by Region
Double-Blind Phase
SAF-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
TEAE Leading to Dose Reduction or Temporary Interruption of Study Drug of MMB\MMB Matched Placebo					
Number of subjects, n(%)	13 (24.5%)	9 (17.6%)	6 (18.2%)	6 (14.0%)	
Unadjusted Relative Risk (95% CI)	1.39 (0.65, 2.97)		1.30 (0.46, 3.67)		
p-value [1]	0.39		0.62		
Unadjusted Odds Ratio (95% CI)	1.52 (0.58, 3.94)		1.37 (0.40, 4.71)		
p-value [1]	0.39		0.62		
Unadjusted Absolute Risk Difference (95% CI)	0.07 (-0.09, 0.22)		0.04 (-0.13, 0.21)		
Interaction test for Treatment*Region [2]					0.92
TEAE Leading to Dose Reduction or Temporary Interruption of Study Drug of RUX\RUX Matched Placebo					
Number of subjects, n(%)	20 (37.7%)	19 (37.3%)	6 (18.2%)	15 (34.9%)	
Unadjusted Relative Risk (95% CI)	1.01 (0.62, 1.66)		0.52 (0.23, 1.20)		
p-value [1]	0.96		0.12		
Unadjusted Odds Ratio (95% CI)	1.02 (0.46, 2.26)		0.41 (0.14, 1.23)		
p-value [1]	0.96		0.11		
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.18, 0.19)		-0.17 (-0.36, 0.03)		
Interaction test for Treatment*Region [2]					0.16

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0104: TEAEs: Overall Summary by Region
Double-Blind Phase
SAF-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
TEAE Leading to Death					
Number of subjects, n(%)	2 (3.8%)	2 (3.9%)	2 (6.1%)	1 (2.3%)	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Region [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0107: TEAEs: Overall Summary by Baseline Hemoglobin Level
Double-Blind Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
TEAE					
Number of subjects, n(%)	26 (92.9%)	20 (95.2%)	55 (94.8%)	71 (97.3%)	
Unadjusted Relative Risk (95% CI)	0.98 (0.85, 1.12)		0.97 (0.91, 1.05)		
p-value [1]	0.72		0.49		
Unadjusted Odds Ratio (95% CI)	0.65 (0.05, 7.69)		0.52 (0.08, 3.20)		
p-value [1]	0.73		0.48		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.16, 0.11)		-0.02 (-0.09, 0.04)		
Interaction test for Treatment*Baseline Hemoglobin Level Group [2]					>0.99
TEAE with Grade >=3					
Number of subjects, n(%)	17 (60.7%)	13 (61.9%)	25 (43.1%)	39 (53.4%)	
Unadjusted Relative Risk (95% CI)	0.98 (0.63, 1.54)		0.81 (0.56, 1.16)		
p-value [1]	0.93		0.25		
Unadjusted Odds Ratio (95% CI)	0.95 (0.30, 3.04)		0.66 (0.33, 1.32)		
p-value [1]	0.93		0.24		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.29, 0.26)		-0.10 (-0.27, 0.07)		
Interaction test for Treatment*Baseline Hemoglobin Level Group [2]					0.51

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0107: TEAEs: Overall Summary by Baseline Hemoglobin Level
Double-Blind Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
TEAE with Grade 3 or 4					
Number of subjects, n(%)	17 (60.7%)	13 (61.9%)	24 (41.4%)	39 (53.4%)	
Unadjusted Relative Risk (95% CI)	0.98 (0.63, 1.54)		0.77 (0.53, 1.13)		
p-value [1]	0.93		0.18		
Unadjusted Odds Ratio (95% CI)	0.95 (0.30, 3.04)		0.62 (0.31, 1.23)		
p-value [1]	0.93		0.17		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.29, 0.26)		-0.12 (-0.29, 0.05)		
Interaction test for Treatment*Baseline Hemoglobin Level Group [2]					0.43
TEAE Related to Study Drug					
Number of subjects, n(%)	19 (67.9%)	14 (66.7%)	39 (67.2%)	45 (61.6%)	
Unadjusted Relative Risk (95% CI)	1.02 (0.69, 1.51)		1.09 (0.85, 1.41)		
p-value [1]	0.93		0.50		
Unadjusted Odds Ratio (95% CI)	1.06 (0.32, 3.52)		1.28 (0.62, 2.63)		
p-value [1]	0.93		0.51		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.25, 0.28)		0.06 (-0.11, 0.22)		
Interaction test for Treatment*Baseline Hemoglobin Level Group [2]					0.77

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0107: TEAEs: Overall Summary by Baseline Hemoglobin Level
Double-Blind Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
TEAE Related to Study Drug with Grade >=3					
Number of subjects, n(%)	10 (35.7%)	6 (28.6%)	14 (24.1%)	25 (34.2%)	
Unadjusted Relative Risk (95% CI)	1.25 (0.54, 2.89)		0.70 (0.40, 1.23)		
p-value [1]	0.60		0.22		
Unadjusted Odds Ratio (95% CI)	1.39 (0.41, 4.72)		0.61 (0.28, 1.32)		
p-value [1]	0.60		0.21		
Unadjusted Absolute Risk Difference (95% CI)	0.07 (-0.19, 0.33)		-0.10 (-0.26, 0.05)		
Interaction test for Treatment*Baseline Hemoglobin Level Group [2]					0.26
Serious TEAE					
Number of subjects, n(%)	11 (39.3%)	6 (28.6%)	15 (25.9%)	17 (23.3%)	
Unadjusted Relative Risk (95% CI)	1.38 (0.61, 3.12)		1.11 (0.61, 2.03)		
p-value [1]	0.45		0.73		
Unadjusted Odds Ratio (95% CI)	1.62 (0.48, 5.44)		1.15 (0.52, 2.56)		
p-value [1]	0.44		0.73		
Unadjusted Absolute Risk Difference (95% CI)	0.11 (-0.16, 0.37)		0.03 (-0.12, 0.17)		
Interaction test for Treatment*Baseline Hemoglobin Level Group [2]					0.68

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0107: TEAEs: Overall Summary by Baseline Hemoglobin Level
Double-Blind Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Serious TEAE Related to Study Drug					
Number of subjects, n(%)	5 (17.9%)	2 (9.5%)	5 (8.6%)	6 (8.2%)	
Unadjusted Relative Risk (95% CI)	1.88 (0.40, 8.74)		1.05 (0.34, 3.27)		
p-value [1]	0.42		0.93		
Unadjusted Odds Ratio (95% CI)	2.07 (0.36, 11.87)		1.05 (0.30, 3.64)		
p-value [1]	0.42		0.93		
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.11, 0.27)		0.00 (-0.09, 0.10)		
Interaction test for Treatment*Baseline Hemoglobin Level Group [2]					0.54
Non-Fatal SAEs					
Number of subjects, n(%)	11 (39.3%)	6 (28.6%)	13 (22.4%)	17 (23.3%)	
Unadjusted Relative Risk (95% CI)	1.38 (0.61, 3.12)		0.96 (0.51, 1.82)		
p-value [1]	0.45		0.91		
Unadjusted Odds Ratio (95% CI)	1.62 (0.48, 5.44)		0.95 (0.42, 2.16)		
p-value [1]	0.44		0.91		
Unadjusted Absolute Risk Difference (95% CI)	0.11 (-0.16, 0.37)		-0.01 (-0.15, 0.14)		
Interaction test for Treatment*Baseline Hemoglobin Level Group [2]					0.49

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0107: TEAEs: Overall Summary by Baseline Hemoglobin Level
Double-Blind Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
TEAE Leading to Premature Discontinuation of Study Drug of MMB\MMB Matched Placebo					
Number of subjects, n(%)	7 (25.0%)	4 (19.0%)	10 (17.2%)	1 (1.4%)	
Unadjusted Relative Risk (95% CI)	1.31 (0.44, 3.91)		12.59 (1.66, 95.50)		
p-value [1]	0.62		0.014		
Unadjusted Odds Ratio (95% CI)	1.42 (0.35, 5.66)		15.00 (1.86, 121.01)		
p-value [1]	0.62		0.011		
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.17, 0.29)		0.16 (0.06, 0.26)		
Interaction test for Treatment*Baseline Hemoglobin Level Group [2]					0.048
TEAE Leading to Premature Discontinuation of Study Drug of RUX\RUX Matched Placebo					
Number of subjects, n(%)	7 (25.0%)	4 (19.0%)	10 (17.2%)	1 (1.4%)	
Unadjusted Relative Risk (95% CI)	1.31 (0.44, 3.91)		12.59 (1.66, 95.50)		
p-value [1]	0.62		0.014		
Unadjusted Odds Ratio (95% CI)	1.42 (0.35, 5.66)		15.00 (1.86, 121.01)		
p-value [1]	0.62		0.011		
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.17, 0.29)		0.16 (0.06, 0.26)		
Interaction test for Treatment*Baseline Hemoglobin Level Group [2]					0.048

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0107: TEAEs: Overall Summary by Baseline Hemoglobin Level
Double-Blind Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
TEAE Leading to Dose Reduction or Temporary Interruption of Study Drug of MMB\MMB Matched Placebo					
Number of subjects, n(%)	7 (25.0%)	2 (9.5%)	12 (20.7%)	13 (17.8%)	
Unadjusted Relative Risk (95% CI)	2.63 (0.61, 11.37)		1.16 (0.57, 2.35)		
p-value [1]	0.20		0.68		
Unadjusted Odds Ratio (95% CI)	3.17 (0.58, 17.15)		1.20 (0.50, 2.88)		
p-value [1]	0.18		0.68		
Unadjusted Absolute Risk Difference (95% CI)	0.15 (-0.05, 0.36)		0.03 (-0.11, 0.17)		
Interaction test for Treatment*Baseline Hemoglobin Level Group [2]					0.28
TEAE Leading to Dose Reduction or Temporary Interruption of Study Drug of RUX\RUX Matched Placebo					
Number of subjects, n(%)	9 (32.1%)	7 (33.3%)	17 (29.3%)	27 (37.0%)	
Unadjusted Relative Risk (95% CI)	0.96 (0.43, 2.17)		0.79 (0.48, 1.31)		
p-value [1]	0.93		0.36		
Unadjusted Odds Ratio (95% CI)	0.95 (0.28, 3.16)		0.71 (0.34, 1.48)		
p-value [1]	0.93		0.36		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.28, 0.25)		-0.08 (-0.24, 0.08)		
Interaction test for Treatment*Baseline Hemoglobin Level Group [2]					0.68

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0107: TEAEs: Overall Summary by Baseline Hemoglobin Level
Double-Blind Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
TEAE Leading to Death					
Number of subjects, n(%)	1 (3.6%)	3 (14.3%)	3 (5.2%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Baseline Hemoglobin Level Group [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0106: TEAEs: Overall Summary by Baseline IPSS Two-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
TEAE					
Number of subjects, n(%)	25 (89.3%)	24 (100.0%)	56 (96.6%)	67 (95.7%)	
Unadjusted Relative Risk (95% CI)	0.90 (0.78, 1.04)		1.01 (0.94, 1.08)		
p-value [1]	0.15		0.81		
Unadjusted Odds Ratio (95% CI)	0.15 (0.01, 3.03)		1.25 (0.20, 7.77)		
p-value [1]	0.22		0.81		
Unadjusted Absolute Risk Difference (95% CI)	-0.10 (-0.23, 0.03)		0.01 (-0.06, 0.08)		
Interaction test for Treatment*Baseline IPSS 2-Level Risk [2]					0.095
TEAE with Grade >=3					
Number of subjects, n(%)	10 (35.7%)	12 (50.0%)	32 (55.2%)	40 (57.1%)	
Unadjusted Relative Risk (95% CI)	0.71 (0.38, 1.35)		0.97 (0.71, 1.31)		
p-value [1]	0.30		0.82		
Unadjusted Odds Ratio (95% CI)	0.56 (0.18, 1.69)		0.92 (0.46, 1.86)		
p-value [1]	0.30		0.82		
Unadjusted Absolute Risk Difference (95% CI)	-0.14 (-0.41, 0.12)		-0.02 (-0.19, 0.15)		
Interaction test for Treatment*Baseline IPSS 2-Level Risk [2]					0.40

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0106: TEAEs: Overall Summary by Baseline IPSS Two-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
TEAE with Grade 3 or 4					
Number of subjects, n(%)	10 (35.7%)	12 (50.0%)	31 (53.4%)	40 (57.1%)	
Unadjusted Relative Risk (95% CI)	0.71 (0.38, 1.35)		0.94 (0.68, 1.28)		
p-value [1]	0.30		0.68		
Unadjusted Odds Ratio (95% CI)	0.56 (0.18, 1.69)		0.86 (0.43, 1.73)		
p-value [1]	0.30		0.68		
Unadjusted Absolute Risk Difference (95% CI)	-0.14 (-0.41, 0.12)		-0.04 (-0.21, 0.14)		
Interaction test for Treatment*Baseline IPSS 2-Level Risk [2]					0.45
TEAE Related to Study Drug					
Number of subjects, n(%)	20 (71.4%)	15 (62.5%)	38 (65.5%)	44 (62.9%)	
Unadjusted Relative Risk (95% CI)	1.14 (0.77, 1.69)		1.04 (0.80, 1.35)		
p-value [1]	0.50		0.75		
Unadjusted Odds Ratio (95% CI)	1.50 (0.47, 4.80)		1.12 (0.54, 2.32)		
p-value [1]	0.49		0.75		
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.17, 0.35)		0.03 (-0.14, 0.19)		
Interaction test for Treatment*Baseline IPSS 2-Level Risk [2]					0.70

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0106: TEAEs: Overall Summary by Baseline IPSS Two-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
TEAE Related to Study Drug with Grade >=3					
Number of subjects, n(%)	8 (28.6%)	9 (37.5%)	16 (27.6%)	22 (31.4%)	
Unadjusted Relative Risk (95% CI)	0.76 (0.35, 1.66)		0.88 (0.51, 1.51)		
p-value [1]	0.49		0.64		
Unadjusted Odds Ratio (95% CI)	0.67 (0.21, 2.14)		0.83 (0.39, 1.79)		
p-value [1]	0.49		0.64		
Unadjusted Absolute Risk Difference (95% CI)	-0.09 (-0.35, 0.17)		-0.04 (-0.20, 0.12)		
Interaction test for Treatment*Baseline IPSS 2-Level Risk [2]					0.77
Serious TEAE					
Number of subjects, n(%)	8 (28.6%)	4 (16.7%)	18 (31.0%)	19 (27.1%)	
Unadjusted Relative Risk (95% CI)	1.71 (0.59, 4.99)		1.14 (0.66, 1.97)		
p-value [1]	0.32		0.63		
Unadjusted Odds Ratio (95% CI)	2.00 (0.52, 7.72)		1.21 (0.56, 2.60)		
p-value [1]	0.31		0.63		
Unadjusted Absolute Risk Difference (95% CI)	0.12 (-0.11, 0.34)		0.04 (-0.12, 0.20)		
Interaction test for Treatment*Baseline IPSS 2-Level Risk [2]					0.49

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0106: TEAEs: Overall Summary by Baseline IPSS Two-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Serious TEAE Related to Study Drug					
Number of subjects, n(%)	5 (17.9%)	2 (8.3%)	5 (8.6%)	6 (8.6%)	
Unadjusted Relative Risk (95% CI)	2.14 (0.46, 10.06)		1.01 (0.32, 3.13)		
p-value [1]	0.33		>0.99		
Unadjusted Odds Ratio (95% CI)	2.39 (0.42, 13.64)		1.01 (0.29, 3.48)		
p-value [1]	0.33		>0.99		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.08, 0.28)		0.00 (-0.10, 0.10)		
Interaction test for Treatment*Baseline IPSS 2-Level Risk [2]					0.42
Non-Fatal SAEs					
Number of subjects, n(%)	7 (25.0%)	4 (16.7%)	17 (29.3%)	19 (27.1%)	
Unadjusted Relative Risk (95% CI)	1.50 (0.50, 4.51)		1.08 (0.62, 1.88)		
p-value [1]	0.47		0.79		
Unadjusted Odds Ratio (95% CI)	1.67 (0.42, 6.58)		1.11 (0.51, 2.41)		
p-value [1]	0.47		0.79		
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.14, 0.30)		0.02 (-0.14, 0.18)		
Interaction test for Treatment*Baseline IPSS 2-Level Risk [2]					0.59

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0106: TEAEs: Overall Summary by Baseline IPSS Two-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
TEAE Leading to Premature Discontinuation of Study Drug of MMB\MMB Matched Placebo					
Number of subjects, n(%)	3 (10.7%)	2 (8.3%)	14 (24.1%)	3 (4.3%)	
Unadjusted Relative Risk (95% CI)	1.29 (0.23, 7.07)		5.63 (1.70, 18.65)		
p-value [1]	0.77		0.005		
Unadjusted Odds Ratio (95% CI)	1.32 (0.20, 8.64)		7.11 (1.93, 26.17)		
p-value [1]	0.77		0.003		
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.14, 0.18)		0.20 (0.08, 0.32)		
Interaction test for Treatment*Baseline IPSS 2-Level Risk [2]					0.27
TEAE Leading to Premature Discontinuation of Study Drug of RUX\RUX Matched Placebo					
Number of subjects, n(%)	3 (10.7%)	2 (8.3%)	14 (24.1%)	3 (4.3%)	
Unadjusted Relative Risk (95% CI)	1.29 (0.23, 7.07)		5.63 (1.70, 18.65)		
p-value [1]	0.77		0.005		
Unadjusted Odds Ratio (95% CI)	1.32 (0.20, 8.64)		7.11 (1.93, 26.17)		
p-value [1]	0.77		0.003		
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.14, 0.18)		0.20 (0.08, 0.32)		
Interaction test for Treatment*Baseline IPSS 2-Level Risk [2]					0.27

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0106: TEAEs: Overall Summary by Baseline IPSS Two-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
TEAE Leading to Dose Reduction or Temporary Interruption of Study Drug of MMB\MMB Matched Placebo					
Number of subjects, n(%)	7 (25.0%)	2 (8.3%)	12 (20.7%)	13 (18.6%)	
Unadjusted Relative Risk (95% CI)	3.00 (0.69, 13.10)		1.11 (0.55, 2.25)		
p-value [1]	0.14		0.76		
Unadjusted Odds Ratio (95% CI)	3.67 (0.68, 19.70)		1.14 (0.48, 2.75)		
p-value [1]	0.13		0.76		
Unadjusted Absolute Risk Difference (95% CI)	0.17 (-0.03, 0.36)		0.02 (-0.12, 0.16)		
Interaction test for Treatment*Baseline IPSS 2-Level Risk [2]					0.19
TEAE Leading to Dose Reduction or Temporary Interruption of Study Drug of RUX\RUX Matched Placebo					
Number of subjects, n(%)	9 (32.1%)	5 (20.8%)	17 (29.3%)	29 (41.4%)	
Unadjusted Relative Risk (95% CI)	1.54 (0.60, 3.98)		0.71 (0.43, 1.15)		
p-value [1]	0.37		0.16		
Unadjusted Odds Ratio (95% CI)	1.80 (0.51, 6.38)		0.59 (0.28, 1.23)		
p-value [1]	0.36		0.16		
Unadjusted Absolute Risk Difference (95% CI)	0.11 (-0.12, 0.35)		-0.12 (-0.29, 0.04)		
Interaction test for Treatment*Baseline IPSS 2-Level Risk [2]					0.14

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0106: TEAEs: Overall Summary by Baseline IPSS Two-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
TEAE Leading to Death					
Number of subjects, n(%)	2 (7.1%)	1 (4.2%)	2 (3.4%)	2 (2.9%)	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Baseline IPSS 2-Level Risk [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.0105: TEAEs: Overall Summary by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
TEAE				
Number of subjects, n(%)	2 (100.0%)	4 (100.0%)	23 (88.5%)	20 (100.0%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]				
TEAE with Grade >=3				
Number of subjects, n(%)	1 (50.0%)	1 (25.0%)	9 (34.6%)	11 (55.0%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0105: TEAEs: Overall Summary by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=58)	BAT (N=70)	p-value
TEAE			
Number of subjects, n(%)	56 (96.6%)	67 (95.7%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]			NA
TEAE with Grade >=3			
Number of subjects, n(%)	32 (55.2%)	40 (57.1%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
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Table 3.0105: TEAEs: Overall Summary by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
TEAE with Grade 3 or 4				
Number of subjects, n(%)	1 (50.0%)	1 (25.0%)	9 (34.6%)	11 (55.0%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]				
TEAE Related to Study Drug				
Number of subjects, n(%)	2 (100.0%)	1 (25.0%)	18 (69.2%)	14 (70.0%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0105: TEAEs: Overall Summary by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=58)	BAT (N=70)	p-value
TEAE with Grade 3 or 4			
Number of subjects, n(%)	31 (53.4%)	40 (57.1%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]			NA
TEAE Related to Study Drug			
Number of subjects, n(%)	38 (65.5%)	44 (62.9%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0105: TEAEs: Overall Summary by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
TEAE Related to Study Drug with Grade >=3				
Number of subjects, n(%)	1 (50.0%)	0	7 (26.9%)	9 (45.0%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]				
Serious TEAE				
Number of subjects, n(%)	0	1 (25.0%)	8 (30.8%)	3 (15.0%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0105: TEAEs: Overall Summary by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=58)	BAT (N=70)	p-value
TEAE Related to Study Drug with Grade >=3			
Number of subjects, n(%)	16 (27.6%)	22 (31.4%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]			NA
Serious TEAE			
Number of subjects, n(%)	18 (31.0%)	19 (27.1%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0105: TEAEs: Overall Summary by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Serious TEAE Related to Study Drug				
Number of subjects, n(%)	0	0	5 (19.2%)	2 (10.0%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]				
Non-Fatal SAEs				
Number of subjects, n(%)	0	1 (25.0%)	7 (26.9%)	3 (15.0%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0105: TEAEs: Overall Summary by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=58)	BAT (N=70)	p-value
Serious TEAE Related to Study Drug			
Number of subjects, n(%)	5 (8.6%)	6 (8.6%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]			NA
Non-Fatal SAEs			
Number of subjects, n(%)	17 (29.3%)	19 (27.1%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0105: TEAEs: Overall Summary by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
TEAE Leading to Premature Discontinuation of Study Drug of MMB\MMB Matched Placebo				
Number of subjects, n(%)	0	0	3 (11.5%)	2 (10.0%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]				
TEAE Leading to Premature Discontinuation of Study Drug of RUX\RUX Matched Placebo				
Number of subjects, n(%)	0	0	3 (11.5%)	2 (10.0%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0105: TEAEs: Overall Summary by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=58)	BAT (N=70)	p-value
TEAE Leading to Premature Discontinuation of Study Drug of MMB\MMB Matched Placebo			
Number of subjects, n(%)	14 (24.1%)	3 (4.3%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]			NA
TEAE Leading to Premature Discontinuation of Study Drug of RUX\RUX Matched Placebo			
Number of subjects, n(%)	14 (24.1%)	3 (4.3%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0105: TEAEs: Overall Summary by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
TEAE Leading to Dose Reduction or Temporary Interruption of Study Drug of MMB\MMB Matched Placebo				
Number of subjects, n(%)	0	0	7 (26.9%)	2 (10.0%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]				
TEAE Leading to Dose Reduction or Temporary Interruption of Study Drug of RUX\RUX Matched Placebo				
Number of subjects, n(%)	0	0	9 (34.6%)	5 (25.0%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0105: TEAEs: Overall Summary by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=58)	BAT (N=70)	p-value
TEAE Leading to Dose Reduction or Temporary Interruption of Study Drug of MMB\MMB Matched Placebo			
Number of subjects, n(%)	12 (20.7%)	13 (18.6%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]			NA
TEAE Leading to Dose Reduction or Temporary Interruption of Study Drug of RUX\RUX Matched Placebo			
Number of subjects, n(%)	17 (29.3%)	29 (41.4%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0105: TEAEs: Overall Summary by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
TEAE Leading to Death				
Number of subjects, n(%)	0	0	2 (7.7%)	1 (5.0%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0105: TEAEs: Overall Summary by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=58)	BAT (N=70)	p-value
TEAE Leading to Death			
Number of subjects, n(%)	2 (3.4%)	2 (2.9%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0108: TEAEs: Overall Summary by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
TEAE				
Number of subjects, n(%)	56 (94.9%)	52 (96.3%)	15 (93.8%)	28 (100.0%)
Unadjusted Relative Risk (95% CI)	0.99 (0.91, 1.07)		0.93 (0.79, 1.08)	
p-value [1]	0.72		0.34	
Unadjusted Odds Ratio (95% CI)	0.72 (0.12, 4.47)		0.18 (0.01, 4.72)	
p-value [1]	0.72		0.30	
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.09, 0.06)		-0.07 (-0.21, 0.07)	
Interaction test for Treatment*Myelofibrosis Disease Type [2]				
TEAE with Grade >=3				
Number of subjects, n(%)	27 (45.8%)	24 (44.4%)	10 (62.5%)	20 (71.4%)
Unadjusted Relative Risk (95% CI)	1.03 (0.69, 1.55)		0.88 (0.56, 1.37)	
p-value [1]	0.89		0.56	
Unadjusted Odds Ratio (95% CI)	1.05 (0.50, 2.21)		0.67 (0.18, 2.45)	
p-value [1]	0.89		0.54	
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.17, 0.20)		-0.09 (-0.38, 0.20)	
Interaction test for Treatment*Myelofibrosis Disease Type [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
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Table 3.0108: TEAEs: Overall Summary by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=11)	BAT (N=12)	p-value
TEAE			
Number of subjects, n(%)	10 (90.9%)	11 (91.7%)	
Unadjusted Relative Risk (95% CI)	0.99 (0.77, 1.28)		
p-value [1]	0.95		
Unadjusted Odds Ratio (95% CI)	0.91 (0.05, 16.54)		
p-value [1]	0.95		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.24, 0.22)		
Interaction test for Treatment*Myelofibrosis Disease Type [2]			0.79
TEAE with Grade >=3			
Number of subjects, n(%)	5 (45.5%)	8 (66.7%)	
Unadjusted Relative Risk (95% CI)	0.68 (0.32, 1.46)		
p-value [1]	0.32		
Unadjusted Odds Ratio (95% CI)	0.42 (0.08, 2.25)		
p-value [1]	0.31		
Unadjusted Absolute Risk Difference (95% CI)	-0.21 (-0.61, 0.19)		
Interaction test for Treatment*Myelofibrosis Disease Type [2]			0.61

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0108: TEAEs: Overall Summary by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
TEAE with Grade 3 or 4				
Number of subjects, n(%)	26 (44.1%)	24 (44.4%)	10 (62.5%)	20 (71.4%)
Unadjusted Relative Risk (95% CI)	0.99 (0.66, 1.50)		0.88 (0.56, 1.37)	
p-value [1]	0.97		0.56	
Unadjusted Odds Ratio (95% CI)	0.98 (0.47, 2.07)		0.67 (0.18, 2.45)	
p-value [1]	0.97		0.54	
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.19, 0.18)		-0.09 (-0.38, 0.20)	
Interaction test for Treatment*Myelofibrosis Disease Type [2]				
TEAE Related to Study Drug				
Number of subjects, n(%)	40 (67.8%)	32 (59.3%)	12 (75.0%)	17 (60.7%)
Unadjusted Relative Risk (95% CI)	1.14 (0.86, 1.52)		1.24 (0.82, 1.86)	
p-value [1]	0.35		0.31	
Unadjusted Odds Ratio (95% CI)	1.45 (0.67, 3.13)		1.94 (0.50, 7.58)	
p-value [1]	0.35		0.34	
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.09, 0.26)		0.14 (-0.14, 0.42)	
Interaction test for Treatment*Myelofibrosis Disease Type [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0108: TEAEs: Overall Summary by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=11)	BAT (N=12)	p-value
TEAE with Grade 3 or 4			
Number of subjects, n(%)	5 (45.5%)	8 (66.7%)	
Unadjusted Relative Risk (95% CI)	0.68 (0.32, 1.46)		
p-value [1]	0.32		
Unadjusted Odds Ratio (95% CI)	0.42 (0.08, 2.25)		
p-value [1]	0.31		
Unadjusted Absolute Risk Difference (95% CI)	-0.21 (-0.61, 0.19)		
Interaction test for Treatment*Myelofibrosis Disease Type [2]			0.68
TEAE Related to Study Drug			
Number of subjects, n(%)	6 (54.5%)	10 (83.3%)	
Unadjusted Relative Risk (95% CI)	0.65 (0.36, 1.19)		
p-value [1]	0.16		
Unadjusted Odds Ratio (95% CI)	0.24 (0.03, 1.65)		
p-value [1]	0.15		
Unadjusted Absolute Risk Difference (95% CI)	-0.29 (-0.65, 0.07)		
Interaction test for Treatment*Myelofibrosis Disease Type [2]			0.17

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0108: TEAEs: Overall Summary by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
TEAE Related to Study Drug with Grade >=3				
Number of subjects, n(%)	16 (27.1%)	16 (29.6%)	6 (37.5%)	11 (39.3%)
Unadjusted Relative Risk (95% CI)	0.92 (0.51, 1.65)		0.95 (0.44, 2.09)	
p-value [1]	0.77		0.91	
Unadjusted Odds Ratio (95% CI)	0.88 (0.39, 2.00)		0.93 (0.26, 3.28)	
p-value [1]	0.77		0.91	
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.19, 0.14)		-0.02 (-0.32, 0.28)	
Interaction test for Treatment*Myelofibrosis Disease Type [2]				
Serious TEAE				
Number of subjects, n(%)	19 (32.2%)	10 (18.5%)	2 (12.5%)	8 (28.6%)
Unadjusted Relative Risk (95% CI)	1.74 (0.89, 3.40)		0.44 (0.11, 1.81)	
p-value [1]	0.11		0.25	
Unadjusted Odds Ratio (95% CI)	2.09 (0.87, 5.03)		0.36 (0.07, 1.94)	
p-value [1]	0.100		0.23	
Unadjusted Absolute Risk Difference (95% CI)	0.14 (-0.02, 0.29)		-0.16 (-0.39, 0.07)	
Interaction test for Treatment*Myelofibrosis Disease Type [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0108: TEAEs: Overall Summary by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=11)	BAT (N=12)	p-value
TEAE Related to Study Drug with Grade >=3			
Number of subjects, n(%)	2 (18.2%)	4 (33.3%)	
Unadjusted Relative Risk (95% CI)	0.55 (0.12, 2.41)		
p-value [1]	0.42		
Unadjusted Odds Ratio (95% CI)	0.44 (0.06, 3.11)		
p-value [1]	0.41		
Unadjusted Absolute Risk Difference (95% CI)	-0.15 (-0.50, 0.20)		
Interaction test for Treatment*Myelofibrosis Disease Type [2]			0.78
Serious TEAE			
Number of subjects, n(%)	5 (45.5%)	5 (41.7%)	
Unadjusted Relative Risk (95% CI)	1.09 (0.43, 2.77)		
p-value [1]	0.85		
Unadjusted Odds Ratio (95% CI)	1.17 (0.22, 6.08)		
p-value [1]	0.85		
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.37, 0.44)		
Interaction test for Treatment*Myelofibrosis Disease Type [2]			0.15

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0108: TEAEs: Overall Summary by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
Serious TEAE Related to Study Drug				
Number of subjects, n(%)	7 (11.9%)	2 (3.7%)	1 (6.3%)	4 (14.3%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Myelofibrosis Disease Type [2]				
Non-Fatal SAEs				
Number of subjects, n(%)	17 (28.8%)	10 (18.5%)	2 (12.5%)	8 (28.6%)
Unadjusted Relative Risk (95% CI)	1.56 (0.78, 3.10)		0.44 (0.11, 1.81)	
p-value [1]	0.21		0.25	
Unadjusted Odds Ratio (95% CI)	1.78 (0.73, 4.33)		0.36 (0.07, 1.94)	
p-value [1]	0.20		0.23	
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.05, 0.26)		-0.16 (-0.39, 0.07)	
Interaction test for Treatment*Myelofibrosis Disease Type [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0108: TEAEs: Overall Summary by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=11)	BAT (N=12)	p-value
Serious TEAE Related to Study Drug			
Number of subjects, n(%)	2 (18.2%)	2 (16.7%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Myelofibrosis Disease Type [2]			NA
Non-Fatal SAEs			
Number of subjects, n(%)	5 (45.5%)	5 (41.7%)	
Unadjusted Relative Risk (95% CI)	1.09 (0.43, 2.77)		
p-value [1]	0.85		
Unadjusted Odds Ratio (95% CI)	1.17 (0.22, 6.08)		
p-value [1]	0.85		
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.37, 0.44)		
Interaction test for Treatment*Myelofibrosis Disease Type [2]			0.21

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0108: TEAEs: Overall Summary by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
TEAE Leading to Premature Discontinuation of Study Drug of MMB\MMB Matched Placebo				
Number of subjects, n(%)	12 (20.3%)	1 (1.9%)	2 (12.5%)	2 (7.1%)
Unadjusted Relative Risk (95% CI)	10.98 (1.48, 81.67)		1.75 (0.27, 11.26)	
p-value [1]	0.019		0.56	
Unadjusted Odds Ratio (95% CI)	13.53 (1.69, 108.04)		1.86 (0.24, 14.64)	
p-value [1]	0.014		0.56	
Unadjusted Absolute Risk Difference (95% CI)	0.18 (0.08, 0.29)		0.05 (-0.13, 0.24)	
Interaction test for Treatment*Myelofibrosis Disease Type [2]				
TEAE Leading to Premature Discontinuation of Study Drug of RUX\RUX Matched Placebo				
Number of subjects, n(%)	12 (20.3%)	1 (1.9%)	2 (12.5%)	2 (7.1%)
Unadjusted Relative Risk (95% CI)	10.98 (1.48, 81.67)		1.75 (0.27, 11.26)	
p-value [1]	0.019		0.56	
Unadjusted Odds Ratio (95% CI)	13.53 (1.69, 108.04)		1.86 (0.24, 14.64)	
p-value [1]	0.014		0.56	
Unadjusted Absolute Risk Difference (95% CI)	0.18 (0.08, 0.29)		0.05 (-0.13, 0.24)	
Interaction test for Treatment*Myelofibrosis Disease Type [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0108: TEAEs: Overall Summary by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=11)	BAT (N=12)	p-value
TEAE Leading to Premature Discontinuation of Study Drug of MMB\MMB Matched Placebo			
Number of subjects, n(%)	3 (27.3%)	2 (16.7%)	
Unadjusted Relative Risk (95% CI)	1.64 (0.33, 8.03)		
p-value [1]	0.54		
Unadjusted Odds Ratio (95% CI)	1.88 (0.25, 14.08)		
p-value [1]	0.54		
Unadjusted Absolute Risk Difference (95% CI)	0.11 (-0.23, 0.44)		
Interaction test for Treatment*Myelofibrosis Disease Type [2]			0.24
TEAE Leading to Premature Discontinuation of Study Drug of RUX\RUX Matched Placebo			
Number of subjects, n(%)	3 (27.3%)	2 (16.7%)	
Unadjusted Relative Risk (95% CI)	1.64 (0.33, 8.03)		
p-value [1]	0.54		
Unadjusted Odds Ratio (95% CI)	1.88 (0.25, 14.08)		
p-value [1]	0.54		
Unadjusted Absolute Risk Difference (95% CI)	0.11 (-0.23, 0.44)		
Interaction test for Treatment*Myelofibrosis Disease Type [2]			0.24

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0108: TEAEs: Overall Summary by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
TEAE Leading to Dose Reduction or Temporary Interruption of Study Drug of MMB\MMB Matched Placebo				
Number of subjects, n(%)	14 (23.7%)	6 (11.1%)	4 (25.0%)	6 (21.4%)
Unadjusted Relative Risk (95% CI)	2.14 (0.88, 5.16)		1.17 (0.39, 3.53)	
p-value [1]	0.092		0.78	
Unadjusted Odds Ratio (95% CI)	2.49 (0.88, 7.04)		1.22 (0.29, 5.20)	
p-value [1]	0.085		0.79	
Unadjusted Absolute Risk Difference (95% CI)	0.13 (-0.01, 0.26)		0.04 (-0.23, 0.30)	
Interaction test for Treatment*Myelofibrosis Disease Type [2]				
TEAE Leading to Dose Reduction or Temporary Interruption of Study Drug of RUX\RUX Matched Placebo				
Number of subjects, n(%)	17 (28.8%)	19 (35.2%)	7 (43.8%)	11 (39.3%)
Unadjusted Relative Risk (95% CI)	0.82 (0.48, 1.41)		1.11 (0.54, 2.29)	
p-value [1]	0.47		0.77	
Unadjusted Odds Ratio (95% CI)	0.75 (0.34, 1.65)		1.20 (0.35, 4.18)	
p-value [1]	0.47		0.77	
Unadjusted Absolute Risk Difference (95% CI)	-0.06 (-0.24, 0.11)		0.04 (-0.26, 0.35)	
Interaction test for Treatment*Myelofibrosis Disease Type [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0108: TEAEs: Overall Summary by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=11)	BAT (N=12)	p-value
TEAE Leading to Dose Reduction or Temporary Interruption of Study Drug of MMB\MMB Matched Placebo			
Number of subjects, n(%)	1 (9.1%)	3 (25.0%)	
Unadjusted Relative Risk (95% CI)	0.36 (0.04, 3.00)		
p-value [1]	0.35		
Unadjusted Odds Ratio (95% CI)	0.30 (0.03, 3.43)		
p-value [1]	0.33		
Unadjusted Absolute Risk Difference (95% CI)	-0.16 (-0.46, 0.14)		
Interaction test for Treatment*Myelofibrosis Disease Type [2]			0.26
TEAE Leading to Dose Reduction or Temporary Interruption of Study Drug of RUX\RUX Matched Placebo			
Number of subjects, n(%)	2 (18.2%)	4 (33.3%)	
Unadjusted Relative Risk (95% CI)	0.55 (0.12, 2.41)		
p-value [1]	0.42		
Unadjusted Odds Ratio (95% CI)	0.44 (0.06, 3.11)		
p-value [1]	0.41		
Unadjusted Absolute Risk Difference (95% CI)	-0.15 (-0.50, 0.20)		
Interaction test for Treatment*Myelofibrosis Disease Type [2]			0.64

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0108: TEAEs: Overall Summary by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
TEAE Leading to Death				
Number of subjects, n(%)	2 (3.4%)	0	0	2 (7.1%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Myelofibrosis Disease Type [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0108: TEAEs: Overall Summary by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=11)	BAT (N=12)	p-value
TEAE Leading to Death			
Number of subjects, n(%)	2 (18.2%)	1 (8.3%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Myelofibrosis Disease Type [2]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

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Table 3.0103: TEAEs: Overall Summary by Gender
Double-Blind Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
TEAE					
Number of subjects, n(%)	48 (96.0%)	54 (96.4%)	33 (91.7%)	37 (97.4%)	
Unadjusted Relative Risk (95% CI)	1.00 (0.92, 1.07)		0.94 (0.84, 1.05)		
p-value [1]	0.91		0.29		
Unadjusted Odds Ratio (95% CI)	0.89 (0.12, 6.56)		0.30 (0.03, 3.00)		
p-value [1]	0.91		0.30		
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.08, 0.07)		-0.06 (-0.16, 0.05)		
Interaction test for Treatment*Gender [2]					0.41
TEAE with Grade >=3					
Number of subjects, n(%)	27 (54.0%)	32 (57.1%)	15 (41.7%)	20 (52.6%)	
Unadjusted Relative Risk (95% CI)	0.95 (0.67, 1.33)		0.79 (0.48, 1.29)		
p-value [1]	0.75		0.35		
Unadjusted Odds Ratio (95% CI)	0.88 (0.41, 1.90)		0.64 (0.26, 1.61)		
p-value [1]	0.75		0.35		
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.22, 0.16)		-0.11 (-0.34, 0.12)		
Interaction test for Treatment*Gender [2]					0.56

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test. [2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Modified Poisson regression model did not converge for some categories so these values are presented as NE.

Data Extracted: CRF data: 01JUL2019

Table 3.0103: TEAEs: Overall Summary by Gender
Double-Blind Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
TEAE with Grade 3 or 4					
Number of subjects, n(%)	27 (54.0%)	32 (57.1%)	14 (38.9%)	20 (52.6%)	
Unadjusted Relative Risk (95% CI)	0.95 (0.67, 1.33)		0.74 (0.44, 1.23)		
p-value [1]	0.75		0.24		
Unadjusted Odds Ratio (95% CI)	0.88 (0.41, 1.90)		0.57 (0.23, 1.44)		
p-value [1]	0.75		0.24		
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.22, 0.16)		-0.14 (-0.36, 0.09)		
Interaction test for Treatment*Gender [2]					0.43
TEAE Related to Study Drug					
Number of subjects, n(%)	34 (68.0%)	38 (67.9%)	24 (66.7%)	21 (55.3%)	
Unadjusted Relative Risk (95% CI)	1.00 (0.77, 1.30)		1.21 (0.84, 1.74)		
p-value [1]	0.99		0.32		
Unadjusted Odds Ratio (95% CI)	1.01 (0.44, 2.28)		1.62 (0.63, 4.16)		
p-value [1]	0.99		0.32		
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.18, 0.18)		0.11 (-0.11, 0.33)		
Interaction test for Treatment*Gender [2]					0.42

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test. [2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Modified Poisson regression model did not converge for some categories so these values are presented as NE.

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Table 3.0103: TEAEs: Overall Summary by Gender
Double-Blind Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
TEAE Related to Study Drug with Grade >=3					
Number of subjects, n(%)	12 (24.0%)	19 (33.9%)	12 (33.3%)	12 (31.6%)	
Unadjusted Relative Risk (95% CI)	0.71 (0.38, 1.31)		1.06 (0.55, 2.04)		
p-value [1]	0.27		0.87		
Unadjusted Odds Ratio (95% CI)	0.61 (0.26, 1.44)		1.08 (0.41, 2.87)		
p-value [1]	0.26		0.87		
Unadjusted Absolute Risk Difference (95% CI)	-0.10 (-0.27, 0.07)		0.02 (-0.20, 0.23)		
Interaction test for Treatment*Gender [2]					0.38
Serious TEAE					
Number of subjects, n(%)	20 (40.0%)	18 (32.1%)	6 (16.7%)	5 (13.2%)	
Unadjusted Relative Risk (95% CI)	1.24 (0.75, 2.07)		1.27 (0.42, 3.79)		
p-value [1]	0.40		0.67		
Unadjusted Odds Ratio (95% CI)	1.41 (0.63, 3.12)		1.32 (0.36, 4.77)		
p-value [1]	0.40		0.67		
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.10, 0.26)		0.04 (-0.13, 0.20)		
Interaction test for Treatment*Gender [2]					0.98

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test. [2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Modified Poisson regression model did not converge for some categories so these values are presented as NE.

Data Extracted: CRF data: 01JUL2019

Table 3.0103: TEAEs: Overall Summary by Gender
Double-Blind Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Serious TEAE Related to Study Drug					
Number of subjects, n(%)	8 (16.0%)	7 (12.5%)	2 (5.6%)	1 (2.6%)	
Unadjusted Relative Risk (95% CI)	1.28 (0.50, 3.28)		2.11 (0.20, 22.29)		
p-value [1]	0.61		0.53		
Unadjusted Odds Ratio (95% CI)	1.33 (0.45, 3.99)		2.18 (0.19, 25.10)		
p-value [1]	0.61		0.53		
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.10, 0.17)		0.03 (-0.06, 0.12)		
Interaction test for Treatment*Gender [2]					0.69
Non-Fatal SAEs					
Number of subjects, n(%)	20 (40.0%)	18 (32.1%)	4 (11.1%)	5 (13.2%)	
Unadjusted Relative Risk (95% CI)	1.24 (0.75, 2.07)		0.84 (0.25, 2.90)		
p-value [1]	0.40		0.79		
Unadjusted Odds Ratio (95% CI)	1.41 (0.63, 3.12)		0.83 (0.20, 3.35)		
p-value [1]	0.40		0.79		
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.10, 0.26)		-0.02 (-0.17, 0.13)		
Interaction test for Treatment*Gender [2]					0.57

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test. [2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Modified Poisson regression model did not converge for some categories so these values are presented as NE.

Data Extracted: CRF data: 01JUL2019

Table 3.0103: TEAEs: Overall Summary by Gender
Double-Blind Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
TEAE Leading to Premature Discontinuation of Study Drug of MMB\MMB Matched Placebo					
Number of subjects, n(%)	7 (14.0%)	5 (8.9%)	10 (27.8%)	0	
Unadjusted Relative Risk (95% CI)	1.57 (0.53, 4.63)		22.14 (1.34, 364.44)		
p-value [1]	0.42		0.030		
Unadjusted Odds Ratio (95% CI)	1.66 (0.49, 5.61)		30.51 (1.71, 543.45)		
p-value [1]	0.41		0.020		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.07, 0.17)		0.27 (0.12, 0.42)		
Interaction test for Treatment*Gender [2]					NE
TEAE Leading to Premature Discontinuation of Study Drug of RUX\RUX Matched Placebo					
Number of subjects, n(%)	7 (14.0%)	5 (8.9%)	10 (27.8%)	0	
Unadjusted Relative Risk (95% CI)	1.57 (0.53, 4.63)		22.14 (1.34, 364.44)		
p-value [1]	0.42		0.030		
Unadjusted Odds Ratio (95% CI)	1.66 (0.49, 5.61)		30.51 (1.71, 543.45)		
p-value [1]	0.41		0.020		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.07, 0.17)		0.27 (0.12, 0.42)		
Interaction test for Treatment*Gender [2]					NE

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test. [2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Modified Poisson regression model did not converge for some categories so these values are presented as NE.

Data Extracted: CRF data: 01JUL2019

Table 3.0103: TEAEs: Overall Summary by Gender
Double-Blind Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
TEAE Leading to Dose Reduction or Temporary Interruption of Study Drug of MMB\MMB Matched Placebo					
Number of subjects, n(%)	12 (24.0%)	10 (17.9%)	7 (19.4%)	5 (13.2%)	
Unadjusted Relative Risk (95% CI)	1.34 (0.64, 2.84)		1.48 (0.52, 4.24)		
p-value [1]	0.44		0.47		
Unadjusted Odds Ratio (95% CI)	1.45 (0.57, 3.73)		1.59 (0.46, 5.57)		
p-value [1]	0.44		0.47		
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.09, 0.22)		0.06 (-0.11, 0.23)		
Interaction test for Treatment*Gender [2]					0.89
TEAE Leading to Dose Reduction or Temporary Interruption of Study Drug of RUX\RUX Matched Placebo					
Number of subjects, n(%)	16 (32.0%)	21 (37.5%)	10 (27.8%)	13 (34.2%)	
Unadjusted Relative Risk (95% CI)	0.85 (0.50, 1.45)		0.81 (0.41, 1.61)		
p-value [1]	0.56		0.55		
Unadjusted Odds Ratio (95% CI)	0.78 (0.35, 1.75)		0.74 (0.27, 1.99)		
p-value [1]	0.55		0.55		
Unadjusted Absolute Risk Difference (95% CI)	-0.06 (-0.24, 0.13)		-0.06 (-0.27, 0.15)		
Interaction test for Treatment*Gender [2]					0.91

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test. [2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Modified Poisson regression model did not converge for some categories so these values are presented as NE.

Data Extracted: CRF data: 01JUL2019

Table 3.0103: TEAEs: Overall Summary by Gender
Double-Blind Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
TEAE Leading to Death					
Number of subjects, n(%)	1 (2.0%)	3 (5.4%)	3 (8.3%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Gender [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test. [2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Modified Poisson regression model did not converge for some categories so these values are presented as NE.

Data Extracted: CRF data: 01JUL2019

Table 3.0110: TEAEs: Overall Summary by Baseline Spleen Volume
Double-Blind Phase
SAF-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
TEAE					
Number of subjects, n(%)	43 (91.5%)	43 (100.0%)	38 (97.4%)	48 (94.1%)	
Unadjusted Relative Risk (95% CI)	0.92 (0.83, 1.01)		1.04 (0.95, 1.13)		
p-value [1]	0.077		0.43		
Unadjusted Odds Ratio (95% CI)	0.11 (0.01, 2.13)		2.38 (0.24, 23.76)		
p-value [1]	0.14		0.46		
Unadjusted Absolute Risk Difference (95% CI)	-0.08 (-0.17, 0.01)		0.03 (-0.05, 0.11)		
Interaction test for Treatment*Baseline Spleen Volume Group [2]					0.045
TEAE with Grade >=3					
Number of subjects, n(%)	21 (44.7%)	22 (51.2%)	21 (53.8%)	30 (58.8%)	
Unadjusted Relative Risk (95% CI)	0.87 (0.57, 1.34)		0.92 (0.63, 1.33)		
p-value [1]	0.54		0.64		
Unadjusted Odds Ratio (95% CI)	0.77 (0.34, 1.77)		0.82 (0.35, 1.89)		
p-value [1]	0.54		0.64		
Unadjusted Absolute Risk Difference (95% CI)	-0.06 (-0.27, 0.14)		-0.05 (-0.26, 0.16)		
Interaction test for Treatment*Baseline Spleen Volume Group [2]					0.87

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test. [2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Modified Poisson regression model did not converge for some categories so these values are presented as NE.

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Table 3.0110: TEAEs: Overall Summary by Baseline Spleen Volume
Double-Blind Phase
SAF-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
TEAE with Grade 3 or 4					
Number of subjects, n(%)	20 (42.6%)	22 (51.2%)	21 (53.8%)	30 (58.8%)	
Unadjusted Relative Risk (95% CI)	0.83 (0.53, 1.29)		0.92 (0.63, 1.33)		
p-value [1]	0.41		0.64		
Unadjusted Odds Ratio (95% CI)	0.71 (0.31, 1.62)		0.82 (0.35, 1.89)		
p-value [1]	0.41		0.64		
Unadjusted Absolute Risk Difference (95% CI)	-0.09 (-0.29, 0.12)		-0.05 (-0.26, 0.16)		
Interaction test for Treatment*Baseline Spleen Volume Group [2]					0.74
TEAE Related to Study Drug					
Number of subjects, n(%)	29 (61.7%)	27 (62.8%)	29 (74.4%)	32 (62.7%)	
Unadjusted Relative Risk (95% CI)	0.98 (0.71, 1.36)		1.19 (0.90, 1.57)		
p-value [1]	0.92		0.24		
Unadjusted Odds Ratio (95% CI)	0.95 (0.41, 2.24)		1.72 (0.69, 4.30)		
p-value [1]	0.92		0.24		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.21, 0.19)		0.12 (-0.07, 0.31)		
Interaction test for Treatment*Baseline Spleen Volume Group [2]					0.39

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test. [2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Modified Poisson regression model did not converge for some categories so these values are presented as NE.

Data Extracted: CRF data: 01JUL2019

Table 3.0110: TEAEs: Overall Summary by Baseline Spleen Volume
Double-Blind Phase
SAF-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
TEAE Related to Study Drug with Grade >=3					
Number of subjects, n(%)	12 (25.5%)	12 (27.9%)	12 (30.8%)	19 (37.3%)	
Unadjusted Relative Risk (95% CI)	0.91 (0.46, 1.81)		0.83 (0.46, 1.49)		
p-value [1]	0.80		0.53		
Unadjusted Odds Ratio (95% CI)	0.89 (0.35, 2.26)		0.75 (0.31, 1.82)		
p-value [1]	0.80		0.52		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.21, 0.16)		-0.06 (-0.26, 0.13)		
Interaction test for Treatment*Baseline Spleen Volume Group [2]					0.82
Serious TEAE					
Number of subjects, n(%)	14 (29.8%)	12 (27.9%)	12 (30.8%)	11 (21.6%)	
Unadjusted Relative Risk (95% CI)	1.07 (0.56, 2.05)		1.43 (0.71, 2.88)		
p-value [1]	0.84		0.32		
Unadjusted Odds Ratio (95% CI)	1.10 (0.44, 2.73)		1.62 (0.62, 4.19)		
p-value [1]	0.84		0.32		
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.17, 0.21)		0.09 (-0.09, 0.28)		
Interaction test for Treatment*Baseline Spleen Volume Group [2]					0.55

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test. [2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Modified Poisson regression model did not converge for some categories so these values are presented as NE.

Data Extracted: CRF data: 01JUL2019

Table 3.0110: TEAEs: Overall Summary by Baseline Spleen Volume
Double-Blind Phase
SAF-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Serious TEAE Related to Study Drug					
Number of subjects, n(%)	5 (10.6%)	4 (9.3%)	5 (12.8%)	4 (7.8%)	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Baseline Spleen Volume Group [2]					NA
Non-Fatal SAEs					
Number of subjects, n(%)	13 (27.7%)	12 (27.9%)	11 (28.2%)	11 (21.6%)	
Unadjusted Relative Risk (95% CI)	0.99 (0.51, 1.93)		1.31 (0.63, 2.70)		
p-value [1]	0.98		0.47		
Unadjusted Odds Ratio (95% CI)	0.99 (0.39, 2.49)		1.43 (0.54, 3.75)		
p-value [1]	0.98		0.47		
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.19, 0.18)		0.07 (-0.11, 0.25)		
Interaction test for Treatment*Baseline Spleen Volume Group [2]					0.58

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test. [2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Modified Poisson regression model did not converge for some categories so these values are presented as NE.

Data Extracted: CRF data: 01JUL2019
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Table 3.0110: TEAEs: Overall Summary by Baseline Spleen Volume
Double-Blind Phase
SAF-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
TEAE Leading to Premature Discontinuation of Study Drug of MMB\MMB Matched Placebo					
Number of subjects, n(%)	9 (19.1%)	0	8 (20.5%)	5 (9.8%)	
Unadjusted Relative Risk (95% CI)	17.42 (1.04, 290.53)		2.09 (0.74, 5.90)		
p-value [1]	0.047		0.16		
Unadjusted Odds Ratio (95% CI)	21.47 (1.21, 381.19)		2.37 (0.71, 7.94)		
p-value [1]	0.037		0.16		
Unadjusted Absolute Risk Difference (95% CI)	0.19 (0.07, 0.30)		0.11 (-0.04, 0.26)		
Interaction test for Treatment*Baseline Spleen Volume Group [2]					NE
TEAE Leading to Premature Discontinuation of Study Drug of RUX\RUX Matched Placebo					
Number of subjects, n(%)	9 (19.1%)	0	8 (20.5%)	5 (9.8%)	
Unadjusted Relative Risk (95% CI)	17.42 (1.04, 290.53)		2.09 (0.74, 5.90)		
p-value [1]	0.047		0.16		
Unadjusted Odds Ratio (95% CI)	21.47 (1.21, 381.19)		2.37 (0.71, 7.94)		
p-value [1]	0.037		0.16		
Unadjusted Absolute Risk Difference (95% CI)	0.19 (0.07, 0.30)		0.11 (-0.04, 0.26)		
Interaction test for Treatment*Baseline Spleen Volume Group [2]					NE

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test. [2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Modified Poisson regression model did not converge for some categories so these values are presented as NE.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-sub-gba.sas V.03.05 Output file: t-aesum-gba-svb.pdf 24AUG2023:12:46

Table 3.0110: TEAEs: Overall Summary by Baseline Spleen Volume
Double-Blind Phase
SAF-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
TEAE Leading to Dose Reduction or Temporary Interruption of Study Drug of MMB\MMB Matched Placebo					
Number of subjects, n(%)	10 (21.3%)	7 (16.3%)	9 (23.1%)	8 (15.7%)	
Unadjusted Relative Risk (95% CI)	1.31 (0.55, 3.13)		1.47 (0.62, 3.46)		
p-value [1]	0.55		0.38		
Unadjusted Odds Ratio (95% CI)	1.39 (0.48, 4.05)		1.61 (0.56, 4.66)		
p-value [1]	0.55		0.38		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.11, 0.21)		0.07 (-0.09, 0.24)		
Interaction test for Treatment*Baseline Spleen Volume Group [2]					0.85
TEAE Leading to Dose Reduction or Temporary Interruption of Study Drug of RUX\RUX Matched Placebo					
Number of subjects, n(%)	13 (27.7%)	18 (41.9%)	13 (33.3%)	16 (31.4%)	
Unadjusted Relative Risk (95% CI)	0.66 (0.37, 1.18)		1.06 (0.58, 1.94)		
p-value [1]	0.16		0.84		
Unadjusted Odds Ratio (95% CI)	0.53 (0.22, 1.28)		1.09 (0.45, 2.66)		
p-value [1]	0.16		0.84		
Unadjusted Absolute Risk Difference (95% CI)	-0.14 (-0.34, 0.05)		0.02 (-0.18, 0.21)		
Interaction test for Treatment*Baseline Spleen Volume Group [2]					0.27

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test. [2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Modified Poisson regression model did not converge for some categories so these values are presented as NE.

Data Extracted: CRF data: 01JUL2019

Table 3.0110: TEAEs: Overall Summary by Baseline Spleen Volume
Double-Blind Phase
SAF-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
TEAE Leading to Death					
Number of subjects, n(%)	2 (4.3%)	0	2 (5.1%)	3 (5.9%)	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Baseline Spleen Volume Group [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test. [2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Modified Poisson regression model did not converge for some categories so these values are presented as NE.

Data Extracted: CRF data: 01JUL2019

Table 3.0109: TEAEs: Overall Summary by Baseline TSS
Double-Blind Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
TEAE					
Number of subjects, n(%)	39 (88.6%)	54 (98.2%)	41 (100.0%)	36 (94.7%)	
Unadjusted Relative Risk (95% CI)	0.90 (0.81, 1.01)		1.06 (0.97, 1.15)		
p-value [1]	0.073		0.23		
Unadjusted Odds Ratio (95% CI)	0.14 (0.02, 1.29)		5.68 (0.26, 122.32)		
p-value [1]	0.083		0.27		
Unadjusted Absolute Risk Difference (95% CI)	-0.10 (-0.20, 0.00)		0.05 (-0.03, 0.14)		
Interaction test for Treatment*Baseline TSS Group [2]					0.021
TEAE with Grade >=3					
Number of subjects, n(%)	19 (43.2%)	27 (49.1%)	23 (56.1%)	24 (63.2%)	
Unadjusted Relative Risk (95% CI)	0.88 (0.57, 1.36)		0.89 (0.62, 1.28)		
p-value [1]	0.56		0.52		
Unadjusted Odds Ratio (95% CI)	0.79 (0.36, 1.75)		0.75 (0.30, 1.84)		
p-value [1]	0.56		0.52		
Unadjusted Absolute Risk Difference (95% CI)	-0.06 (-0.26, 0.14)		-0.07 (-0.29, 0.15)		
Interaction test for Treatment*Baseline TSS Group [2]					0.97

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
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Table 3.0109: TEAEs: Overall Summary by Baseline TSS
Double-Blind Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
TEAE with Grade 3 or 4					
Number of subjects, n(%)	19 (43.2%)	27 (49.1%)	22 (53.7%)	24 (63.2%)	
Unadjusted Relative Risk (95% CI)	0.88 (0.57, 1.36)		0.85 (0.58, 1.23)		
p-value [1]	0.56		0.39		
Unadjusted Odds Ratio (95% CI)	0.79 (0.36, 1.75)		0.68 (0.27, 1.66)		
p-value [1]	0.56		0.39		
Unadjusted Absolute Risk Difference (95% CI)	-0.06 (-0.26, 0.14)		-0.09 (-0.31, 0.12)		
Interaction test for Treatment*Baseline TSS Group [2]					0.91
TEAE Related to Study Drug					
Number of subjects, n(%)	32 (72.7%)	36 (65.5%)	26 (63.4%)	23 (60.5%)	
Unadjusted Relative Risk (95% CI)	1.11 (0.85, 1.45)		1.05 (0.74, 1.48)		
p-value [1]	0.43		0.79		
Unadjusted Odds Ratio (95% CI)	1.41 (0.59, 3.34)		1.13 (0.46, 2.81)		
p-value [1]	0.44		0.79		
Unadjusted Absolute Risk Difference (95% CI)	0.07 (-0.11, 0.25)		0.03 (-0.19, 0.24)		
Interaction test for Treatment*Baseline TSS Group [2]					0.79

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.0109: TEAEs: Overall Summary by Baseline TSS
Double-Blind Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
TEAE Related to Study Drug with Grade >=3					
Number of subjects, n(%)	12 (27.3%)	20 (36.4%)	12 (29.3%)	11 (28.9%)	
Unadjusted Relative Risk (95% CI)	0.75 (0.41, 1.36)		1.01 (0.51, 2.01)		
p-value [1]	0.34		0.97		
Unadjusted Odds Ratio (95% CI)	0.66 (0.28, 1.55)		1.02 (0.38, 2.68)		
p-value [1]	0.34		0.97		
Unadjusted Absolute Risk Difference (95% CI)	-0.09 (-0.27, 0.09)		0.00 (-0.20, 0.20)		
Interaction test for Treatment*Baseline TSS Group [2]					0.52
Serious TEAE					
Number of subjects, n(%)	11 (25.0%)	14 (25.5%)	15 (36.6%)	9 (23.7%)	
Unadjusted Relative Risk (95% CI)	0.98 (0.50, 1.94)		1.54 (0.77, 3.11)		
p-value [1]	0.96		0.22		
Unadjusted Odds Ratio (95% CI)	0.98 (0.39, 2.43)		1.86 (0.70, 4.96)		
p-value [1]	0.96		0.22		
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.18, 0.17)		0.13 (-0.07, 0.33)		
Interaction test for Treatment*Baseline TSS Group [2]					0.36

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
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Table 3.0109: TEAEs: Overall Summary by Baseline TSS
Double-Blind Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Serious TEAE Related to Study Drug					
Number of subjects, n(%)	7 (15.9%)	6 (10.9%)	3 (7.3%)	2 (5.3%)	
Unadjusted Relative Risk (95% CI)	1.46 (0.53, 4.03)		1.39 (0.25, 7.87)		
p-value [1]	0.47		0.71		
Unadjusted Odds Ratio (95% CI)	1.55 (0.48, 4.98)		1.42 (0.22, 9.01)		
p-value [1]	0.47		0.71		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.09, 0.19)		0.02 (-0.09, 0.13)		
Interaction test for Treatment*Baseline TSS Group [2]					0.96
Non-Fatal SAEs					
Number of subjects, n(%)	11 (25.0%)	14 (25.5%)	13 (31.7%)	9 (23.7%)	
Unadjusted Relative Risk (95% CI)	0.98 (0.50, 1.94)		1.34 (0.65, 2.77)		
p-value [1]	0.96		0.43		
Unadjusted Odds Ratio (95% CI)	0.98 (0.39, 2.43)		1.50 (0.55, 4.05)		
p-value [1]	0.96		0.43		
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.18, 0.17)		0.08 (-0.12, 0.28)		
Interaction test for Treatment*Baseline TSS Group [2]					0.54

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-sub-gba.sas V.03.05 Output file: t-aesum-gba-tss.pdf 24AUG2023:12:46

Table 3.0109: TEAEs: Overall Summary by Baseline TSS
Double-Blind Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
TEAE Leading to Premature Discontinuation of Study Drug of MMB\MMB Matched Placebo					
Number of subjects, n(%)	5 (11.4%)	2 (3.6%)	12 (29.3%)	3 (7.9%)	
Unadjusted Relative Risk (95% CI)	3.13 (0.64, 15.34)		3.71 (1.13, 12.13)		
p-value [1]	0.16		0.030		
Unadjusted Odds Ratio (95% CI)	3.40 (0.63, 18.43)		4.83 (1.24, 18.76)		
p-value [1]	0.16		0.023		
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.03, 0.18)		0.21 (0.05, 0.38)		
Interaction test for Treatment*Baseline TSS Group [2]					0.87
TEAE Leading to Premature Discontinuation of Study Drug of RUX\RUX Matched Placebo					
Number of subjects, n(%)	5 (11.4%)	2 (3.6%)	12 (29.3%)	3 (7.9%)	
Unadjusted Relative Risk (95% CI)	3.13 (0.64, 15.34)		3.71 (1.13, 12.13)		
p-value [1]	0.16		0.030		
Unadjusted Odds Ratio (95% CI)	3.40 (0.63, 18.43)		4.83 (1.24, 18.76)		
p-value [1]	0.16		0.023		
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.03, 0.18)		0.21 (0.05, 0.38)		
Interaction test for Treatment*Baseline TSS Group [2]					0.87

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.0109: TEAEs: Overall Summary by Baseline TSS
Double-Blind Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
TEAE Leading to Dose Reduction or Temporary Interruption of Study Drug of MMB\MMB Matched Placebo					
Number of subjects, n(%)	10 (22.7%)	7 (12.7%)	9 (22.0%)	8 (21.1%)	
Unadjusted Relative Risk (95% CI)	1.79 (0.74, 4.31)		1.04 (0.45, 2.42)		
p-value [1]	0.20		0.92		
Unadjusted Odds Ratio (95% CI)	2.02 (0.70, 5.83)		1.05 (0.36, 3.09)		
p-value [1]	0.20		0.92		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.05, 0.25)		0.01 (-0.17, 0.19)		
Interaction test for Treatment*Baseline TSS Group [2]					0.39
TEAE Leading to Dose Reduction or Temporary Interruption of Study Drug of RUX\RUX Matched Placebo					
Number of subjects, n(%)	13 (29.5%)	24 (43.6%)	13 (31.7%)	10 (26.3%)	
Unadjusted Relative Risk (95% CI)	0.68 (0.39, 1.17)		1.20 (0.60, 2.42)		
p-value [1]	0.16		0.60		
Unadjusted Odds Ratio (95% CI)	0.54 (0.23, 1.25)		1.30 (0.49, 3.45)		
p-value [1]	0.15		0.60		
Unadjusted Absolute Risk Difference (95% CI)	-0.14 (-0.33, 0.05)		0.05 (-0.15, 0.25)		
Interaction test for Treatment*Baseline TSS Group [2]					0.20

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.0109: TEAEs: Overall Summary by Baseline TSS
Double-Blind Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
TEAE Leading to Death					
Number of subjects, n(%)	0	2 (3.6%)	4 (9.8%)	1 (2.6%)	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Baseline TSS Group [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Related to study drug under DB phase refers to related to either of MMB\MMB matched placebo, or RUX\RUX matched placebo.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
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Table 3.1802: TEAEs with Grade 2 or less by Age
Double-Blind Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Number of subjects, n(%)	21 (87.5%)	33 (91.7%)	56 (90.3%)	57 (98.3%)	
Unadjusted Relative Risk (95% CI)	0.95 (0.80, 1.14)		0.92 (0.84, 1.00)		
p-value [1]	0.61		0.061		
Unadjusted Odds Ratio (95% CI)	0.64 (0.12, 3.45)		0.16 (0.02, 1.40)		
p-value [1]	0.60		0.099		
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.20, 0.12)		-0.08 (-0.16, 0.00)		
Interaction test for Treatment*Age Group [2]					0.71

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-gle2-sub-gba.sas V.03.05 Output file: t-aesum-gle2-gba-age.pdf 24AUG2023:12:47

Table 3.1804: TEAEs with Grade 2 or less by Region
Double-Blind Phase
SAF-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Number of subjects, n(%)	51 (96.2%)	51 (100.0%)	26 (78.8%)	39 (90.7%)	
Unadjusted Relative Risk (95% CI)	0.96 (0.90, 1.03)		0.87 (0.71, 1.06)		
p-value [1]	0.25		0.17		
Unadjusted Odds Ratio (95% CI)	0.20 (0.01, 4.27)		0.38 (0.10, 1.43)		
p-value [1]	0.30		0.15		
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.10, 0.03)		-0.12 (-0.28, 0.05)		
Interaction test for Treatment*Region [2]					0.33

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-gle2-sub-gba.sas V.03.05 Output file: t-aesum-gle2-gba-geo.pdf 24AUG2023:12:47

Table 3.1807: TEAEs with Grade 2 or less by Baseline Hemoglobin Level
Double-Blind Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Number of subjects, n(%)	25 (89.3%)	20 (95.2%)	52 (89.7%)	70 (95.9%)	
Unadjusted Relative Risk (95% CI)	0.94 (0.80, 1.10)		0.93 (0.85, 1.03)		
p-value [1]	0.43		0.19		
Unadjusted Odds Ratio (95% CI)	0.42 (0.04, 4.32)		0.37 (0.09, 1.55)		
p-value [1]	0.46		0.18		
Unadjusted Absolute Risk Difference (95% CI)	-0.06 (-0.21, 0.09)		-0.06 (-0.15, 0.03)		
Interaction test for Treatment*Baseline Hemoglobin Level Group [2]					0.98

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.1806: TEAEs with Grade 2 or less by Baseline IPSS Two-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Number of subjects, n(%)	25 (89.3%)	24 (100.0%)	52 (89.7%)	66 (94.3%)	
Unadjusted Relative Risk (95% CI)	0.90 (0.78, 1.04)		0.95 (0.86, 1.06)		
p-value [1]	0.15		0.35		
Unadjusted Odds Ratio (95% CI)	0.15 (0.01, 3.03)		0.53 (0.14, 1.96)		
p-value [1]	0.22		0.34		
Unadjusted Absolute Risk Difference (95% CI)	-0.10 (-0.23, 0.03)		-0.05 (-0.14, 0.05)		
Interaction test for Treatment*Baseline IPSS 2-Level Risk [2]					0.45

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-gle2-sub-gba.sas V.03.05 Output file: t-aesum-gle2-gba-ipss2.pdf 24AUG2023:12:48

Table 3.1805: TEAEs with Grade 2 or less by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Number of subjects, n(%)	2 (100.0%)	4 (100.0%)	23 (88.5%)	20 (100.0%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.1805: TEAEs with Grade 2 or less by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=58)	RUX (N=70)	p-value
Number of subjects, n(%)	52 (89.7%)	66 (94.3%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-gle2-sub-gba.sas V.03.05 Output file: t-aesum-gle2-gba-ipss3.pdf 24AUG2023:12:47

Table 3.1808: TEAEs with Grade 2 or less by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
Number of subjects, n(%)	53 (89.8%)	52 (96.3%)	14 (87.5%)	27 (96.4%)
Unadjusted Relative Risk (95% CI)	0.93 (0.84, 1.03)		0.91 (0.74, 1.11)	
p-value [1]	0.18		0.34	
Unadjusted Odds Ratio (95% CI)	0.34 (0.07, 1.76)		0.26 (0.02, 3.11)	
p-value [1]	0.20		0.29	
Unadjusted Absolute Risk Difference (95% CI)	-0.06 (-0.16, 0.03)		-0.09 (-0.27, 0.09)	
Interaction test for Treatment*Myelofibrosis Disease Type [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-gle2-sub-gba.sas V.03.05 Output file: t-aesum-gle2-gba-mf.pdf 24AUG2023:12:48

Table 3.1808: TEAEs with Grade 2 or less by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=11)	RUX (N=12)	p-value
Number of subjects, n(%)	10 (90.9%)	11 (91.7%)	
Unadjusted Relative Risk (95% CI)	0.99 (0.77, 1.28)		
p-value [1]	0.95		
Unadjusted Odds Ratio (95% CI)	0.91 (0.05, 16.54)		
p-value [1]	0.95		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.24, 0.22)		
Interaction test for Treatment*Myelofibrosis Disease Type [2]			0.86

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-gle2-sub-gba.sas V.03.05 Output file: t-aesum-gle2-gba-mf.pdf 24AUG2023:12:48

Table 3.1803: TEAEs with Grade 2 or less by Gender
Double-Blind Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Number of subjects, n(%)	46 (92.0%)	54 (96.4%)	31 (86.1%)	36 (94.7%)	
Unadjusted Relative Risk (95% CI)	0.95 (0.87, 1.05)		0.91 (0.78, 1.06)		
p-value [1]	0.34		0.22		
Unadjusted Odds Ratio (95% CI)	0.43 (0.07, 2.43)		0.34 (0.06, 1.90)		
p-value [1]	0.34		0.22		
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.13, 0.05)		-0.09 (-0.22, 0.05)		
Interaction test for Treatment*Gender [2]					0.59

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-gle2-sub-gba.sas V.03.05 Output file: t-aesum-gle2-gba-sex.pdf 24AUG2023:12:47

Table 3.1810: TEAEs with Grade 2 or less by Baseline Spleen Volume
Double-Blind Phase
SAF-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Number of subjects, n(%)	40 (85.1%)	42 (97.7%)	37 (94.9%)	48 (94.1%)	
Unadjusted Relative Risk (95% CI)	0.87 (0.77, 0.99)		1.01 (0.91, 1.11)		
p-value [1]	0.035		0.88		
Unadjusted Odds Ratio (95% CI)	0.14 (0.02, 1.16)		1.16 (0.18, 7.28)		
p-value [1]	0.068		0.88		
Unadjusted Absolute Risk Difference (95% CI)	-0.13 (-0.24, -0.01)		0.01 (-0.09, 0.10)		
Interaction test for Treatment*Baseline Spleen Volume Group [2]					0.077

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-gle2-sub-gba.sas V.03.05 Output file: t-aesum-gle2-gba-svb.pdf 24AUG2023:12:48

Table 3.1809: TEAEs with Grade 2 or less by Baseline TSS
Double-Blind Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Number of subjects, n(%)	38 (86.4%)	54 (98.2%)	38 (92.7%)	35 (92.1%)	
Unadjusted Relative Risk (95% CI)	0.88 (0.78, 0.99)		1.01 (0.89, 1.14)		
p-value [1]	0.041		0.92		
Unadjusted Odds Ratio (95% CI)	0.12 (0.01, 1.01)		1.09 (0.21, 5.74)		
p-value [1]	0.052		0.92		
Unadjusted Absolute Risk Difference (95% CI)	-0.12 (-0.23, -0.01)		0.01 (-0.11, 0.12)		
Interaction test for Treatment*Baseline TSS Group [2]					0.13

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-gle2-sub-gba.sas V.03.05 Output file: t-aesum-gle2-gba-tss.pdf 24AUG2023:12:48

Table 3.0202: TEAEs by SOC and PT by Age
Double-Blind Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Blood and lymphatic system disorders					
Any Event	11 (45.8%)	23 (63.9%)	24 (38.7%)	35 (60.3%)	
Unadjusted Relative Risk (95% CI)	0.72 (0.44, 1.18)		0.64 (0.44, 0.93)		
p-value [1]	0.19		0.021		
Unadjusted Odds Ratio (95% CI)	0.48 (0.17, 1.37)		0.42 (0.20, 0.86)		
p-value [1]	0.17		0.019		
Unadjusted Absolute Risk Difference (95% CI)	-0.18 (-0.43, 0.07)		-0.22 (-0.39, -0.04)		
Interaction test for Treatment*Age Group [2]					0.73
Blood and lymphatic system disorders					
Anaemia	4 (16.7%)	15 (41.7%)	10 (16.1%)	21 (36.2%)	
Unadjusted Relative Risk (95% CI)	0.40 (0.15, 1.06)		0.45 (0.23, 0.86)		
p-value [1]	0.065		0.017		
Unadjusted Odds Ratio (95% CI)	0.28 (0.08, 0.99)		0.34 (0.14, 0.80)		
p-value [1]	0.048		0.014		
Unadjusted Absolute Risk Difference (95% CI)	-0.25 (-0.47, -0.03)		-0.20 (-0.35, -0.05)		
Interaction test for Treatment*Age Group [2]					0.86

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-sub-gba.sas V.03.05 Output file: t-ae-socpt-gba-age.pdf 24AUG2023:12:45

Table 3.0202: TEAEs by SOC and PT by Age
Double-Blind Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Gastrointestinal disorders					
Nausea	8 (33.3%)	1 (2.8%)	11 (17.7%)	2 (3.4%)	
Unadjusted Relative Risk (95% CI)	12.00 (1.60, 89.89)		5.15 (1.19, 22.23)		
p-value [1]	0.016		0.028		
Unadjusted Odds Ratio (95% CI)	17.50 (2.02, 151.96)		6.04 (1.28, 28.56)		
p-value [1]	0.009		0.023		
Unadjusted Absolute Risk Difference (95% CI)	0.31 (0.11, 0.50)		0.14 (0.04, 0.25)		
Interaction test for Treatment*Age Group [2]					0.50
Vascular disorders					
Hypotension	3 (12.5%)	0	9 (14.5%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Age Group [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-sub-gba.sas V.03.05 Output file: t-ae-socpt-gba-age.pdf 24AUG2023:12:45

Table 3.0204: TEAEs by SOC and PT by Region
Double-Blind Phase
SAF-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Blood and lymphatic system disorders					
Any Event	18 (34.0%)	31 (60.8%)	17 (51.5%)	27 (62.8%)	
Unadjusted Relative Risk (95% CI)	0.56 (0.36, 0.86)		0.82 (0.55, 1.23)		
p-value [1]	0.009		0.34		
Unadjusted Odds Ratio (95% CI)	0.33 (0.15, 0.74)		0.63 (0.25, 1.58)		
p-value [1]	0.007		0.32		
Unadjusted Absolute Risk Difference (95% CI)	-0.27 (-0.45, -0.08)		-0.11 (-0.34, 0.11)		
Interaction test for Treatment*Region [2]					0.21
Blood and lymphatic system disorders					
Anaemia	4 (7.5%)	14 (27.5%)	10 (30.3%)	22 (51.2%)	
Unadjusted Relative Risk (95% CI)	0.27 (0.10, 0.78)		0.59 (0.33, 1.07)		
p-value [1]	0.015		0.084		
Unadjusted Odds Ratio (95% CI)	0.22 (0.07, 0.71)		0.42 (0.16, 1.08)		
p-value [1]	0.012		0.071		
Unadjusted Absolute Risk Difference (95% CI)	-0.20 (-0.34, -0.06)		-0.21 (-0.43, 0.01)		
Interaction test for Treatment*Region [2]					0.18

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates. Modified Poisson regression model did not converge for some categories so these are presented as NE.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-sub-gba.sas V.03.05 Output file: t-ae-socpt-gba-geo.pdf 24AUG2023:12:45

Table 3.0204: TEAEs by SOC and PT by Region
Double-Blind Phase
SAF-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Gastrointestinal disorders					
Nausea	17 (32.1%)	3 (5.9%)	2 (6.1%)	0	
Unadjusted Relative Risk (95% CI)	5.45 (1.70, 17.49)		6.47 (0.32, 130.39)		
p-value [1]	0.004		0.22		
Unadjusted Odds Ratio (95% CI)	7.56 (2.06, 27.76)		6.90 (0.32, 148.87)		
p-value [1]	0.002		0.22		
Unadjusted Absolute Risk Difference (95% CI)	0.26 (0.12, 0.40)		0.06 (-0.03, 0.16)		
Interaction test for Treatment*Region [2]					NE
Vascular disorders					
Hypotension	10 (18.9%)	0	2 (6.1%)	0	
Unadjusted Relative Risk (95% CI)	20.22 (1.22, 336.36)		6.47 (0.32, 130.39)		
p-value [1]	0.036		0.22		
Unadjusted Odds Ratio (95% CI)	24.86 (1.42, 436.59)		6.90 (0.32, 148.87)		
p-value [1]	0.028		0.22		
Unadjusted Absolute Risk Difference (95% CI)	0.18 (0.08, 0.29)		0.06 (-0.03, 0.16)		
Interaction test for Treatment*Region [2]					NE

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates. Modified Poisson regression model did not converge for some categories so these are presented as NE.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-sub-gba.sas V.03.05 Output file: t-ae-socpt-gba-geo.pdf 24AUG2023:12:45

Table 3.0207: TEAEs by SOC and PT by Baseline Hemoglobin Level
Double-Blind Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Blood and lymphatic system disorders					
Any Event	10 (35.7%)	13 (61.9%)	25 (43.1%)	45 (61.6%)	
Unadjusted Relative Risk (95% CI)	0.58 (0.32, 1.05)		0.70 (0.49, 0.99)		
p-value [1]	0.072		0.043		
Unadjusted Odds Ratio (95% CI)	0.34 (0.11, 1.10)		0.47 (0.23, 0.95)		
p-value [1]	0.073		0.036		
Unadjusted Absolute Risk Difference (95% CI)	-0.26 (-0.54, 0.01)		-0.19 (-0.35, -0.02)		
Interaction test for Treatment*Baseline Hemoglobin Level Group [2]					0.58
Blood and lymphatic system disorders					
Anaemia	5 (17.9%)	7 (33.3%)	9 (15.5%)	29 (39.7%)	
Unadjusted Relative Risk (95% CI)	0.54 (0.20, 1.45)		0.39 (0.20, 0.76)		
p-value [1]	0.22		0.005		
Unadjusted Odds Ratio (95% CI)	0.43 (0.12, 1.64)		0.28 (0.12, 0.65)		
p-value [1]	0.22		0.003		
Unadjusted Absolute Risk Difference (95% CI)	-0.15 (-0.40, 0.09)		-0.24 (-0.39, -0.10)		
Interaction test for Treatment*Baseline Hemoglobin Level Group [2]					0.61

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates. Modified Poisson regression model did not converge for some categories so these are presented as NE.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-sub-gba.sas V.03.05 Output file: t-ae-socpt-gba-hgb.pdf 24AUG2023:12:46

Table 3.0207: TEAEs by SOC and PT by Baseline Hemoglobin Level
Double-Blind Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Gastrointestinal disorders					
Nausea	5 (17.9%)	0	14 (24.1%)	3 (4.1%)	
Unadjusted Relative Risk (95% CI)	8.34 (0.49, 143.05)		5.87 (1.77, 19.47)		
p-value [1]	0.14		0.004		
Unadjusted Odds Ratio (95% CI)	10.06 (0.52, 192.97)		7.42 (2.02, 27.32)		
p-value [1]	0.13		0.003		
Unadjusted Absolute Risk Difference (95% CI)	0.17 (0.01, 0.32)		0.20 (0.08, 0.32)		
Interaction test for Treatment*Baseline Hemoglobin Level Group [2]					NE
Vascular disorders					
Hypotension	3 (10.7%)	0	9 (15.5%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Baseline Hemoglobin Level Group [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates. Modified Poisson regression model did not converge for some categories so these are presented as NE.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-sub-gba.sas V.03.05 Output file: t-ae-socpt-gba-hgb.pdf 24AUG2023:12:46

Table 3.0206: TEAEs by SOC and PT by Baseline IPSS Two-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Blood and lymphatic system disorders					
Any Event	11 (39.3%)	14 (58.3%)	24 (41.4%)	44 (62.9%)	
Unadjusted Relative Risk (95% CI)	0.67 (0.38, 1.19)		0.66 (0.46, 0.94)		
p-value [1]	0.18		0.021		
Unadjusted Odds Ratio (95% CI)	0.46 (0.15, 1.40)		0.42 (0.20, 0.85)		
p-value [1]	0.17		0.016		
Unadjusted Absolute Risk Difference (95% CI)	-0.19 (-0.46, 0.08)		-0.21 (-0.38, -0.04)		
Interaction test for Treatment*Baseline IPSS 2-Level Risk [2]					0.95
Blood and lymphatic system disorders					
Anaemia	3 (10.7%)	7 (29.2%)	11 (19.0%)	29 (41.4%)	
Unadjusted Relative Risk (95% CI)	0.37 (0.11, 1.27)		0.46 (0.25, 0.83)		
p-value [1]	0.11		0.011		
Unadjusted Odds Ratio (95% CI)	0.29 (0.07, 1.29)		0.33 (0.15, 0.74)		
p-value [1]	0.10		0.007		
Unadjusted Absolute Risk Difference (95% CI)	-0.18 (-0.40, 0.03)		-0.22 (-0.38, -0.07)		
Interaction test for Treatment*Baseline IPSS 2-Level Risk [2]					0.75

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates. Modified Poisson regression model did not converge for some categories so these are presented as NE.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-sub-gba.sas V.03.05 Output file: t-ae-socpt-gba-ipss2.pdf 24AUG2023:12:46

Table 3.0206: TEAEs by SOC and PT by Baseline IPSS Two-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Gastrointestinal disorders					
Nausea	8 (28.6%)	0	11 (19.0%)	3 (4.3%)	
Unadjusted Relative Risk (95% CI)	14.66 (0.89, 241.39)		4.43 (1.30, 15.11)		
p-value [1]	0.060		0.018		
Unadjusted Odds Ratio (95% CI)	20.32 (1.10, 373.68)		5.23 (1.38, 19.76)		
p-value [1]	0.043		0.015		
Unadjusted Absolute Risk Difference (95% CI)	0.27 (0.10, 0.45)		0.15 (0.04, 0.26)		
Interaction test for Treatment*Baseline IPSS 2-Level Risk [2]					NE
Vascular disorders					
Hypotension	3 (10.7%)	0	9 (15.5%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Baseline IPSS 2-Level Risk [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates. Modified Poisson regression model did not converge for some categories so these are presented as NE.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-sub-gba.sas V.03.05 Output file: t-ae-socpt-gba-ipss2.pdf 24AUG2023:12:46

Table 3.0205: TEAEs by SOC and PT by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Blood and lymphatic system disorders				
Any Event	0	2 (50.0%)	11 (42.3%)	12 (60.0%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]				
Blood and lymphatic system disorders				
Anaemia	0	2 (50.0%)	3 (11.5%)	5 (25.0%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-sub-gba.sas V.03.05 Output file: t-ae-socpt-gba-ipss3.pdf 24AUG2023:12:46

Table 3.0205: TEAEs by SOC and PT by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=58)	RUX (N=70)	p-value
Blood and lymphatic system disorders			
Any Event	24 (41.4%)	44 (62.9%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]			NA
Blood and lymphatic system disorders			
Anaemia	11 (19.0%)	29 (41.4%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-sub-gba.sas V.03.05 Output file: t-ae-socpt-gba-ipss3.pdf 24AUG2023:12:46

Table 3.0205: TEAEs by SOC and PT by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Gastrointestinal disorders				
Nausea	1 (50.0%)	0	7 (26.9%)	0
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]				
Vascular disorders				
Hypotension	1 (50.0%)	0	2 (7.7%)	0
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-sub-gba.sas V.03.05 Output file: t-ae-socpt-gba-ipss3.pdf 24AUG2023:12:46

Table 3.0205: TEAEs by SOC and PT by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=58)	RUX (N=70)	p-value
Gastrointestinal disorders			
Nausea	11 (19.0%)	3 (4.3%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]			NA
Vascular disorders			
Hypotension	9 (15.5%)	0	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-sub-gba.sas V.03.05 Output file: t-ae-socpt-gba-ipss3.pdf 24AUG2023:12:46

Table 3.0208: TEAEs by SOC and PT by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
Blood and lymphatic system disorders				
Any Event	23 (39.0%)	31 (57.4%)	9 (56.3%)	19 (67.9%)
Unadjusted Relative Risk (95% CI)	0.68 (0.46, 1.01)		0.83 (0.50, 1.37)	
p-value [1]	0.054		0.46	
Unadjusted Odds Ratio (95% CI)	0.47 (0.22, 1.00)		0.61 (0.17, 2.16)	
p-value [1]	0.052		0.44	
Unadjusted Absolute Risk Difference (95% CI)	-0.18 (-0.37, 0.00)		-0.12 (-0.41, 0.18)	
Interaction test for Treatment*Myelofibrosis Disease Type [2]				
Blood and lymphatic system disorders				
Anaemia	10 (16.9%)	18 (33.3%)	4 (25.0%)	13 (46.4%)
Unadjusted Relative Risk (95% CI)	0.51 (0.26, 1.00)		0.54 (0.21, 1.37)	
p-value [1]	0.051		0.20	
Unadjusted Odds Ratio (95% CI)	0.41 (0.17, 0.99)		0.38 (0.10, 1.49)	
p-value [1]	0.047		0.17	
Unadjusted Absolute Risk Difference (95% CI)	-0.16 (-0.32, -0.01)		-0.21 (-0.50, 0.07)	
Interaction test for Treatment*Myelofibrosis Disease Type [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates. Modified Poisson regression model did not converge for some categories so these are presented as NE.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-sub-gba.sas V.03.05 Output file: t-ae-socpt-gba-mf.pdf 24AUG2023:12:46

Table 3.0208: TEAEs by SOC and PT by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=11)	RUX (N=12)	p-value
Blood and lymphatic system disorders			
Any Event	3 (27.3%)	8 (66.7%)	
Unadjusted Relative Risk (95% CI)	0.41 (0.14, 1.16)		
p-value [1]	0.094		
Unadjusted Odds Ratio (95% CI)	0.19 (0.03, 1.12)		
p-value [1]	0.067		
Unadjusted Absolute Risk Difference (95% CI)	-0.39 (-0.77, -0.02)		
Interaction test for Treatment*Myelofibrosis Disease Type [2]			0.43
Blood and lymphatic system disorders			
Anaemia	0	5 (41.7%)	
Unadjusted Relative Risk (95% CI)	0.10 (0.01, 1.60)		
p-value [1]	0.10		
Unadjusted Odds Ratio (95% CI)	0.06 (0.00, 1.24)		
p-value [1]	0.068		
Unadjusted Absolute Risk Difference (95% CI)	-0.38 (-0.67, -0.09)		
Interaction test for Treatment*Myelofibrosis Disease Type [2]			NE

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates. Modified Poisson regression model did not converge for some categories so these are presented as NE.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-sub-gba.sas V.03.05 Output file: t-ae-socpt-gba-mf.pdf 24AUG2023:12:46

Table 3.0208: TEAEs by SOC and PT by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
Gastrointestinal disorders				
Nausea	13 (22.0%)	0	5 (31.3%)	3 (10.7%)
Unadjusted Relative Risk (95% CI)	24.75 (1.51, 406.56)		2.92 (0.80, 10.63)	
p-value [1]	0.025		0.10	
Unadjusted Odds Ratio (95% CI)	31.65 (1.83, 546.92)		3.79 (0.77, 18.71)	
p-value [1]	0.018		0.10	
Unadjusted Absolute Risk Difference (95% CI)	0.22 (0.11, 0.32)		0.21 (-0.05, 0.46)	
Interaction test for Treatment*Myelofibrosis Disease Type [2]				
Vascular disorders				
Hypotension	9 (15.3%)	0	2 (12.5%)	0
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Myelofibrosis Disease Type [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates. Modified Poisson regression model did not converge for some categories so these are presented as NE.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-sub-gba.sas V.03.05 Output file: t-ae-socpt-gba-mf.pdf 24AUG2023:12:46

Table 3.0208: TEAEs by SOC and PT by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=11)	RUX (N=12)	p-value
Gastrointestinal disorders			
Nausea	1 (9.1%)	0	
Unadjusted Relative Risk (95% CI)	3.25 (0.15, 72.36)		
p-value [1]	0.46		
Unadjusted Odds Ratio (95% CI)	3.57 (0.13, 97.23)		
p-value [1]	0.45		
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.13, 0.30)		
Interaction test for Treatment*Myelofibrosis Disease Type [2]			NE
Vascular disorders			
Hypotension	1 (9.1%)	0	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Myelofibrosis Disease Type [2]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates. Modified Poisson regression model did not converge for some categories so these are presented as NE.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-sub-gba.sas V.03.05 Output file: t-ae-socpt-gba-mf.pdf 24AUG2023:12:46

Table 3.0203: TEAEs by SOC and PT by Gender
Double-Blind Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Blood and lymphatic system disorders					
Any Event	22 (44.0%)	36 (64.3%)	13 (36.1%)	22 (57.9%)	
Unadjusted Relative Risk (95% CI)	0.68 (0.47, 0.99)		0.62 (0.37, 1.04)		
p-value [1]	0.044		0.071		
Unadjusted Odds Ratio (95% CI)	0.44 (0.20, 0.95)		0.41 (0.16, 1.05)		
p-value [1]	0.038		0.063		
Unadjusted Absolute Risk Difference (95% CI)	-0.20 (-0.39, -0.02)		-0.22 (-0.44, 0.00)		
Interaction test for Treatment*Gender [2]					0.77
Blood and lymphatic system disorders					
Anaemia	7 (14.0%)	22 (39.3%)	7 (19.4%)	14 (36.8%)	
Unadjusted Relative Risk (95% CI)	0.36 (0.17, 0.76)		0.53 (0.24, 1.16)		
p-value [1]	0.008		0.11		
Unadjusted Odds Ratio (95% CI)	0.25 (0.10, 0.66)		0.41 (0.14, 1.19)		
p-value [1]	0.005		0.10		
Unadjusted Absolute Risk Difference (95% CI)	-0.25 (-0.41, -0.09)		-0.17 (-0.37, 0.03)		
Interaction test for Treatment*Gender [2]					0.49

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-sub-gba.sas V.03.05 Output file: t-ae-socpt-gba-sex.pdf 24AUG2023:12:45

Table 3.0203: TEAEs by SOC and PT by Gender
Double-Blind Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Gastrointestinal disorders					
Nausea	4 (8.0%)	2 (3.6%)	15 (41.7%)	1 (2.6%)	
Unadjusted Relative Risk (95% CI)	2.24 (0.43, 11.71)		15.83 (2.20, 113.80)		
p-value [1]	0.34		0.006		
Unadjusted Odds Ratio (95% CI)	2.35 (0.41, 13.41)		26.43 (3.26, 214.51)		
p-value [1]	0.34		0.002		
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.05, 0.13)		0.39 (0.22, 0.56)		
Interaction test for Treatment*Gender [2]					0.21
Vascular disorders					
Hypotension	6 (12.0%)	0	6 (16.7%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Gender [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-sub-gba.sas V.03.05 Output file: t-ae-socpt-gba-sex.pdf 24AUG2023:12:45

Table 3.0210: TEAEs by SOC and PT by Baseline Spleen Volume
Double-Blind Phase
SAF-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Blood and lymphatic system disorders					
Any Event	16 (34.0%)	28 (65.1%)	19 (48.7%)	30 (58.8%)	
Unadjusted Relative Risk (95% CI)	0.52 (0.33, 0.82)		0.83 (0.56, 1.23)		
p-value [1]	0.005		0.35		
Unadjusted Odds Ratio (95% CI)	0.28 (0.12, 0.66)		0.67 (0.29, 1.54)		
p-value [1]	0.004		0.34		
Unadjusted Absolute Risk Difference (95% CI)	-0.31 (-0.51, -0.11)		-0.10 (-0.31, 0.11)		
Interaction test for Treatment*Baseline Spleen Volume Group [2]					0.13
Blood and lymphatic system disorders					
Anaemia	7 (14.9%)	17 (39.5%)	7 (17.9%)	19 (37.3%)	
Unadjusted Relative Risk (95% CI)	0.38 (0.17, 0.82)		0.48 (0.23, 1.03)		
p-value [1]	0.014		0.060		
Unadjusted Odds Ratio (95% CI)	0.27 (0.10, 0.73)		0.37 (0.14, 1.00)		
p-value [1]	0.010		0.049		
Unadjusted Absolute Risk Difference (95% CI)	-0.25 (-0.42, -0.07)		-0.19 (-0.37, -0.01)		
Interaction test for Treatment*Baseline Spleen Volume Group [2]					0.66

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates. Modified Poisson regression model did not converge for some categories so these are presented as NE.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-sub-gba.sas V.03.05 Output file: t-ae-socpt-gba-svb.pdf 24AUG2023:12:46

Table 3.0210: TEAEs by SOC and PT by Baseline Spleen Volume
Double-Blind Phase
SAF-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Gastrointestinal disorders					
Nausea	13 (27.7%)	0	6 (15.4%)	3 (5.9%)	
Unadjusted Relative Risk (95% CI)	24.75 (1.52, 404.13)		2.62 (0.70, 9.81)		
p-value [1]	0.024		0.15		
Unadjusted Odds Ratio (95% CI)	34.04 (1.95, 593.19)		2.91 (0.68, 12.46)		
p-value [1]	0.016		0.15		
Unadjusted Absolute Risk Difference (95% CI)	0.27 (0.14, 0.40)		0.10 (-0.04, 0.23)		
Interaction test for Treatment*Baseline Spleen Volume Group [2]					NE
Vascular disorders					
Hypotension	5 (10.6%)	0	7 (17.9%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Baseline Spleen Volume Group [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates. Modified Poisson regression model did not converge for some categories so these are presented as NE.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-sub-gba.sas V.03.05 Output file: t-ae-socpt-gba-svb.pdf 24AUG2023:12:46

Table 3.0209: TEAEs by SOC and PT by Baseline TSS
Double-Blind Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Blood and lymphatic system disorders					
Any Event	15 (34.1%)	38 (69.1%)	20 (48.8%)	20 (52.6%)	
Unadjusted Relative Risk (95% CI)	0.49 (0.32, 0.77)		0.93 (0.60, 1.43)		
p-value [1]	0.002		0.73		
Unadjusted Odds Ratio (95% CI)	0.23 (0.10, 0.54)		0.86 (0.35, 2.07)		
p-value [1]	<0.001		0.73		
Unadjusted Absolute Risk Difference (95% CI)	-0.35 (-0.54, -0.16)		-0.04 (-0.26, 0.18)		
Interaction test for Treatment*Baseline TSS Group [2]					0.045
Blood and lymphatic system disorders					
Anaemia	5 (11.4%)	24 (43.6%)	9 (22.0%)	12 (31.6%)	
Unadjusted Relative Risk (95% CI)	0.26 (0.11, 0.63)		0.70 (0.33, 1.46)		
p-value [1]	0.003		0.34		
Unadjusted Odds Ratio (95% CI)	0.17 (0.06, 0.48)		0.61 (0.22, 1.67)		
p-value [1]	0.001		0.34		
Unadjusted Absolute Risk Difference (95% CI)	-0.32 (-0.48, -0.16)		-0.10 (-0.29, 0.10)		
Interaction test for Treatment*Baseline TSS Group [2]					0.089

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-sub-gba.sas V.03.05 Output file: t-ae-socpt-gba-tss.pdf 24AUG2023:12:46

Table 3.0209: TEAEs by SOC and PT by Baseline TSS
Double-Blind Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Gastrointestinal disorders					
Nausea	7 (15.9%)	2 (3.6%)	12 (29.3%)	1 (2.6%)	
Unadjusted Relative Risk (95% CI)	4.38 (0.96, 20.02)		11.12 (1.52, 81.50)		
p-value [1]	0.057		0.018		
Unadjusted Odds Ratio (95% CI)	5.01 (0.99, 25.50)		15.31 (1.88, 124.67)		
p-value [1]	0.052		0.011		
Unadjusted Absolute Risk Difference (95% CI)	0.12 (0.00, 0.24)		0.27 (0.12, 0.41)		
Interaction test for Treatment*Baseline TSS Group [2]					0.46
Vascular disorders					
Hypotension	6 (13.6%)	0	6 (14.6%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Baseline TSS Group [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.0302: TEAEs with Grade 3 or more by SOC and PT by Age
Double-Blind Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Blood and lymphatic system disorders					
Anaemia	3 (12.5%)	12 (33.3%)	7 (11.3%)	14 (24.1%)	
Unadjusted Relative Risk (95% CI)	0.38 (0.12, 1.19)		0.47 (0.20, 1.08)		
p-value [1]	0.096		0.074		
Unadjusted Odds Ratio (95% CI)	0.29 (0.07, 1.15)		0.40 (0.15, 1.08)		
p-value [1]	0.078		0.070		
Unadjusted Absolute Risk Difference (95% CI)	-0.21 (-0.41, -0.01)		-0.13 (-0.26, 0.01)		
Interaction test for Treatment*Age Group [2]					0.76

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-gge3-sub-gba.sas V.03.05 Output file: t-ae-socpt-gge3-gba-age.pdf 24AUG2023:12:47

Table 3.0304: TEAEs with Grade 3 or more by SOC and PT by Region
Double-Blind Phase
SAF-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Blood and lymphatic system disorders					
Anaemia	4 (7.5%)	9 (17.6%)	6 (18.2%)	17 (39.5%)	
Unadjusted Relative Risk (95% CI)	0.43 (0.14, 1.30)		0.46 (0.20, 1.04)		
p-value [1]	0.13		0.061		
Unadjusted Odds Ratio (95% CI)	0.38 (0.11, 1.33)		0.34 (0.12, 1.00)		
p-value [1]	0.13		0.049		
Unadjusted Absolute Risk Difference (95% CI)	-0.10 (-0.23, 0.03)		-0.21 (-0.41, -0.02)		
Interaction test for Treatment*Region [2]					0.92

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-gge3-sub-gba.sas V.03.05 Output file: t-ae-socpt-gge3-gba-geo.pdf 24AUG2023:12:47

Table 3.0307: TEAEs with Grade 3 or more by SOC and PT by Baseline Hemoglobin Level
Double-Blind Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Blood and lymphatic system disorders					
Anaemia	5 (17.9%)	5 (23.8%)	5 (8.6%)	21 (28.8%)	
Unadjusted Relative Risk (95% CI)	0.75 (0.25, 2.26)		0.30 (0.12, 0.75)		
p-value [1]	0.61		0.010		
Unadjusted Odds Ratio (95% CI)	0.70 (0.17, 2.80)		0.23 (0.08, 0.67)		
p-value [1]	0.61		0.007		
Unadjusted Absolute Risk Difference (95% CI)	-0.06 (-0.29, 0.17)		-0.20 (-0.33, -0.07)		
Interaction test for Treatment*Baseline Hemoglobin Level Group [2]					0.22

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-gge3-sub-gba.sas V.03.05 Output file: t-ae-socpt-gge3-gba-hgb.pdf 24AUG2023:12:47

Table 3.0306: TEAEs with Grade 3 or more by SOC and PT by Baseline IPSS Two-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Blood and lymphatic system disorders					
Anaemia	2 (7.1%)	5 (20.8%)	8 (13.8%)	21 (30.0%)	
Unadjusted Relative Risk (95% CI)	0.34 (0.07, 1.61)		0.46 (0.22, 0.96)		
p-value [1]	0.17		0.039		
Unadjusted Odds Ratio (95% CI)	0.29 (0.05, 1.67)		0.37 (0.15, 0.92)		
p-value [1]	0.17		0.033		
Unadjusted Absolute Risk Difference (95% CI)	-0.14 (-0.33, 0.05)		-0.16 (-0.30, -0.02)		
Interaction test for Treatment*Baseline IPSS 2-Level Risk [2]					0.73

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-gge3-sub-gba.sas V.03.05 Output file: t-ae-socpt-gge3-gba-ipss2.pdf 24AUG2023:12:47

Table 3.0305: TEAEs with Grade 3 or more by SOC and PT by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Blood and lymphatic system disorders				
Anaemia	0	0	2 (7.7%)	5 (25.0%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-gge3-sub-gba.sas V.03.05 Output file: t-ae-socpt-gge3-gba-ipss3.pdf 24AUG2023:12:47

Table 3.0305: TEAEs with Grade 3 or more by SOC and PT by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=58)	RUX (N=70)	p-value
Blood and lymphatic system disorders			
Anaemia	8 (13.8%)	21 (30.0%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-gge3-sub-gba.sas V.03.05 Output file: t-ae-socpt-gge3-gba-ipss3.pdf 24AUG2023:12:47

Table 3.0308: TEAEs with Grade 3 or more by SOC and PT by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
Blood and lymphatic system disorders				
Anaemia	7 (11.9%)	12 (22.2%)	3 (18.8%)	10 (35.7%)
Unadjusted Relative Risk (95% CI)	0.53 (0.23, 1.26)		0.53 (0.17, 1.63)	
p-value [1]	0.15		0.27	
Unadjusted Odds Ratio (95% CI)	0.47 (0.17, 1.30)		0.42 (0.10, 1.81)	
p-value [1]	0.15		0.24	
Unadjusted Absolute Risk Difference (95% CI)	-0.10 (-0.24, 0.03)		-0.17 (-0.43, 0.09)	
Interaction test for Treatment*Myelofibrosis Disease Type [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates. Modified Poisson regression model did not converge so values are presented as NE.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-gge3-sub-gba.sas V.03.05 Output file: t-ae-socpt-gge3-gba-mf.pdf 24AUG2023:12:47

Table 3.0308: TEAEs with Grade 3 or more by SOC and PT by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=11)	RUX (N=12)	p-value
Blood and lymphatic system disorders			
Anaemia	0	4 (33.3%)	
Unadjusted Relative Risk (95% CI)	0.12 (0.01, 2.01)		
p-value [1]	0.14		
Unadjusted Odds Ratio (95% CI)	0.08 (0.00, 1.74)		
p-value [1]	0.11		
Unadjusted Absolute Risk Difference (95% CI)	-0.30 (-0.59, -0.02)		
Interaction test for Treatment*Myelofibrosis Disease Type [2]			NE

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates. Modified Poisson regression model did not converge so values are presented as NE.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-gge3-sub-gba.sas V.03.05 Output file: t-ae-socpt-gge3-gba-mf.pdf 24AUG2023:12:47

Table 3.0303: TEAEs with Grade 3 or more by SOC and PT by Gender
Double-Blind Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Blood and lymphatic system disorders					
Anaemia	4 (8.0%)	17 (30.4%)	6 (16.7%)	9 (23.7%)	
Unadjusted Relative Risk (95% CI)	0.26 (0.10, 0.73)		0.70 (0.28, 1.78)		
p-value [1]	0.010		0.46		
Unadjusted Odds Ratio (95% CI)	0.20 (0.06, 0.64)		0.64 (0.20, 2.04)		
p-value [1]	0.007		0.45		
Unadjusted Absolute Risk Difference (95% CI)	-0.22 (-0.37, -0.08)		-0.07 (-0.25, 0.11)		
Interaction test for Treatment*Gender [2]					0.17

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-gge3-sub-gba.sas V.03.05 Output file: t-ae-socpt-gge3-gba-sex.pdf 24AUG2023:12:47

Table 3.0310: TEAEs with Grade 3 or more by SOC and PT by Baseline Spleen Volume
Double-Blind Phase
SAF-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Blood and lymphatic system disorders					
Anaemia	4 (8.5%)	13 (30.2%)	6 (15.4%)	13 (25.5%)	
Unadjusted Relative Risk (95% CI)	0.28 (0.10, 0.80)		0.60 (0.25, 1.44)		
p-value [1]	0.017		0.26		
Unadjusted Odds Ratio (95% CI)	0.21 (0.06, 0.72)		0.53 (0.18, 1.56)		
p-value [1]	0.013		0.25		
Unadjusted Absolute Risk Difference (95% CI)	-0.22 (-0.38, -0.06)		-0.10 (-0.27, 0.06)		
Interaction test for Treatment*Baseline Spleen Volume Group [2]					0.27

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-gge3-sub-gba.sas V.03.05 Output file: t-ae-socpt-gge3-gba-svb.pdf 24AUG2023:12:48

Table 3.0309: TEAEs with Grade 3 or more by SOC and PT by Baseline TSS
Double-Blind Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Blood and lymphatic system disorders					
Anaemia	4 (9.1%)	17 (30.9%)	6 (14.6%)	9 (23.7%)	
Unadjusted Relative Risk (95% CI)	0.29 (0.11, 0.81)		0.62 (0.24, 1.57)		
p-value [1]	0.018		0.31		
Unadjusted Odds Ratio (95% CI)	0.22 (0.07, 0.72)		0.55 (0.18, 1.73)		
p-value [1]	0.013		0.31		
Unadjusted Absolute Risk Difference (95% CI)	-0.22 (-0.37, -0.07)		-0.09 (-0.26, 0.08)		
Interaction test for Treatment*Baseline TSS Group [2]					0.29

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-gge3-sub-gba.sas V.03.05 Output file: t-ae-socpt-gge3-gba-tss.pdf 24AUG2023:12:47

Table 3.1702: TEAEs with Grade 2 or less by SOC and PT by Age
Double-Blind Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Blood and lymphatic system disorders					
Any Event	9 (37.5%)	14 (38.9%)	17 (27.4%)	31 (53.4%)	
Unadjusted Relative Risk (95% CI)	0.96 (0.50, 1.86)		0.51 (0.32, 0.82)		
p-value [1]	0.91		0.005		
Unadjusted Odds Ratio (95% CI)	0.94 (0.33, 2.73)		0.33 (0.15, 0.70)		
p-value [1]	0.91		0.004		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.26, 0.24)		-0.26 (-0.43, -0.09)		
Interaction test for Treatment*Age Group [2]					0.15
Blood and lymphatic system disorders					
Anaemia	2 (8.3%)	8 (22.2%)	6 (9.7%)	13 (22.4%)	
Unadjusted Relative Risk (95% CI)	0.38 (0.09, 1.62)		0.43 (0.18, 1.06)		
p-value [1]	0.19		0.067		
Unadjusted Odds Ratio (95% CI)	0.32 (0.06, 1.65)		0.37 (0.13, 1.05)		
p-value [1]	0.17		0.063		
Unadjusted Absolute Risk Difference (95% CI)	-0.14 (-0.31, 0.04)		-0.13 (-0.26, 0.00)		
Interaction test for Treatment*Age Group [2]					0.87

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-gle2-sub-gba.sas V.03.05 Output file: t-ae-socpt-gle2-gba-age.pdf 24AUG2023:12:46

Table 3.1702: TEAEs with Grade 2 or less by SOC and PT by Age
Double-Blind Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Vascular disorders					
Any Event	6 (25.0%)	2 (5.6%)	10 (16.1%)	3 (5.2%)	
Unadjusted Relative Risk (95% CI)	4.50 (0.99, 20.47)		3.12 (0.90, 10.77)		
p-value [1]	0.052		0.072		
Unadjusted Odds Ratio (95% CI)	5.67 (1.04, 31.00)		3.53 (0.92, 13.53)		
p-value [1]	0.045		0.066		
Unadjusted Absolute Risk Difference (95% CI)	0.19 (0.01, 0.38)		0.11 (0.00, 0.22)		
Interaction test for Treatment*Age Group [2]					0.71
Vascular disorders					
Hypotension	3 (12.5%)	0	7 (11.3%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Age Group [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-gle2-sub-gba.sas V.03.05 Output file: t-ae-socpt-gle2-gba-age.pdf 24AUG2023:12:46

Table 3.1702: TEAEs with Grade 2 or less by SOC and PT by Age
Double-Blind Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Gastrointestinal disorders					
Nausea	8 (33.3%)	1 (2.8%)	11 (17.7%)	2 (3.4%)	
Unadjusted Relative Risk (95% CI)	12.00 (1.60, 89.89)		5.15 (1.19, 22.23)		
p-value [1]	0.016		0.028		
Unadjusted Odds Ratio (95% CI)	17.50 (2.02, 151.96)		6.04 (1.28, 28.56)		
p-value [1]	0.009		0.023		
Unadjusted Absolute Risk Difference (95% CI)	0.31 (0.11, 0.50)		0.14 (0.04, 0.25)		
Interaction test for Treatment*Age Group [2]					0.50

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-gle2-sub-gba.sas V.03.05 Output file: t-ae-socpt-gle2-gba-age.pdf 24AUG2023:12:46

Table 3.1704: TEAEs with Grade 2 or less by SOC and PT by Region
Double-Blind Phase
SAF-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Blood and lymphatic system disorders					
Any Event	14 (26.4%)	25 (49.0%)	12 (36.4%)	20 (46.5%)	
Unadjusted Relative Risk (95% CI)	0.54 (0.32, 0.91)		0.78 (0.45, 1.36)		
p-value [1]	0.022		0.38		
Unadjusted Odds Ratio (95% CI)	0.37 (0.16, 0.85)		0.66 (0.26, 1.66)		
p-value [1]	0.019		0.38		
Unadjusted Absolute Risk Difference (95% CI)	-0.23 (-0.41, -0.04)		-0.10 (-0.32, 0.12)		
Interaction test for Treatment*Region [2]					0.35
Blood and lymphatic system disorders					
Anaemia	2 (3.8%)	10 (19.6%)	6 (18.2%)	11 (25.6%)	
Unadjusted Relative Risk (95% CI)	0.19 (0.04, 0.84)		0.71 (0.29, 1.72)		
p-value [1]	0.028		0.45		
Unadjusted Odds Ratio (95% CI)	0.16 (0.03, 0.78)		0.65 (0.21, 1.98)		
p-value [1]	0.023		0.44		
Unadjusted Absolute Risk Difference (95% CI)	-0.16 (-0.28, -0.04)		-0.07 (-0.26, 0.11)		
Interaction test for Treatment*Region [2]					0.11

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates. Modified Poisson regression model did not converge for some categories so these are presented as NE.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-gle2-sub-gba.sas V.03.05 Output file: t-ae-socpt-gle2-gba-geo.pdf 24AUG2023:12:46

Table 3.1704: TEAEs with Grade 2 or less by SOC and PT by Region
Double-Blind Phase
SAF-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Vascular disorders					
Any Event	12 (22.6%)	3 (5.9%)	4 (12.1%)	2 (4.7%)	
Unadjusted Relative Risk (95% CI)	3.85 (1.15, 12.85)		2.61 (0.51, 13.38)		
p-value [1]	0.028		0.25		
Unadjusted Odds Ratio (95% CI)	4.68 (1.24, 17.74)		2.83 (0.49, 16.48)		
p-value [1]	0.023		0.25		
Unadjusted Absolute Risk Difference (95% CI)	0.17 (0.04, 0.30)		0.07 (-0.05, 0.20)		
Interaction test for Treatment*Region [2]					0.71
Vascular disorders					
Hypotension	8 (15.1%)	0	2 (6.1%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Region [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates. Modified Poisson regression model did not converge for some categories so these are presented as NE.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-gle2-sub-gba.sas V.03.05 Output file: t-ae-socpt-gle2-gba-geo.pdf 24AUG2023:12:46

Table 3.1704: TEAEs with Grade 2 or less by SOC and PT by Region
Double-Blind Phase
SAF-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Gastrointestinal disorders					
Nausea	17 (32.1%)	3 (5.9%)	2 (6.1%)	0	
Unadjusted Relative Risk (95% CI)	5.45 (1.70, 17.49)		6.47 (0.32, 130.39)		
p-value [1]	0.004		0.22		
Unadjusted Odds Ratio (95% CI)	7.56 (2.06, 27.76)		6.90 (0.32, 148.87)		
p-value [1]	0.002		0.22		
Unadjusted Absolute Risk Difference (95% CI)	0.26 (0.12, 0.40)		0.06 (-0.03, 0.16)		
Interaction test for Treatment*Region [2]					NE

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates. Modified Poisson regression model did not converge for some categories so these are presented as NE.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-gle2-sub-gba.sas V.03.05 Output file: t-ae-socpt-gle2-gba-geo.pdf 24AUG2023:12:46

Table 3.1707: TEAEs with Grade 2 or less by SOC and PT by Baseline Hemoglobin Level
Double-Blind Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Blood and lymphatic system disorders					
Any Event	6 (21.4%)	8 (38.1%)	20 (34.5%)	37 (50.7%)	
Unadjusted Relative Risk (95% CI)	0.56 (0.23, 1.38)		0.68 (0.45, 1.04)		
p-value [1]	0.21		0.073		
Unadjusted Odds Ratio (95% CI)	0.44 (0.13, 1.56)		0.51 (0.25, 1.04)		
p-value [1]	0.21		0.065		
Unadjusted Absolute Risk Difference (95% CI)	-0.17 (-0.42, 0.09)		-0.16 (-0.33, 0.01)		
Interaction test for Treatment*Baseline Hemoglobin Level Group [2]					0.70
Blood and lymphatic system disorders					
Anaemia	2 (7.1%)	3 (14.3%)	6 (10.3%)	18 (24.7%)	
Unadjusted Relative Risk (95% CI)	0.50 (0.09, 2.73)		0.42 (0.18, 0.99)		
p-value [1]	0.42		0.047		
Unadjusted Odds Ratio (95% CI)	0.46 (0.07, 3.05)		0.35 (0.13, 0.96)		
p-value [1]	0.42		0.041		
Unadjusted Absolute Risk Difference (95% CI)	-0.07 (-0.25, 0.11)		-0.14 (-0.27, -0.02)		
Interaction test for Treatment*Baseline Hemoglobin Level Group [2]					0.86

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates. Modified Poisson regression model did not converge for some categories so these are presented as NE.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-gle2-sub-gba.sas V.03.05 Output file: t-ae-socpt-gle2-gba-hgb.pdf 24AUG2023:12:47

Table 3.1707: TEAEs with Grade 2 or less by SOC and PT by Baseline Hemoglobin Level
Double-Blind Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Vascular disorders					
Any Event	3 (10.7%)	2 (9.5%)	13 (22.4%)	3 (4.1%)	
Unadjusted Relative Risk (95% CI)	1.13 (0.21, 6.14)		5.45 (1.63, 18.24)		
p-value [1]	0.89		0.006		
Unadjusted Odds Ratio (95% CI)	1.14 (0.17, 7.52)		6.74 (1.82, 24.98)		
p-value [1]	0.89		0.004		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.16, 0.18)		0.18 (0.07, 0.30)		
Interaction test for Treatment*Baseline Hemoglobin Level Group [2]					0.25
Vascular disorders					
Hypotension	2 (7.1%)	0	8 (13.8%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Baseline Hemoglobin Level Group [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates. Modified Poisson regression model did not converge for some categories so these are presented as NE.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-gle2-sub-gba.sas V.03.05 Output file: t-ae-socpt-gle2-gba-hgb.pdf 24AUG2023:12:47

Table 3.1707: TEAEs with Grade 2 or less by SOC and PT by Baseline Hemoglobin Level
Double-Blind Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Gastrointestinal disorders					
Nausea	5 (17.9%)	0	14 (24.1%)	3 (4.1%)	
Unadjusted Relative Risk (95% CI)	8.34 (0.49, 143.05)		5.87 (1.77, 19.47)		
p-value [1]	0.14		0.004		
Unadjusted Odds Ratio (95% CI)	10.06 (0.52, 192.97)		7.42 (2.02, 27.32)		
p-value [1]	0.13		0.003		
Unadjusted Absolute Risk Difference (95% CI)	0.17 (0.01, 0.32)		0.20 (0.08, 0.32)		
Interaction test for Treatment*Baseline Hemoglobin Level Group [2]					NE

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates. Modified Poisson regression model did not converge for some categories so these are presented as NE.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-gle2-sub-gba.sas V.03.05 Output file: t-ae-socpt-gle2-gba-hgb.pdf 24AUG2023:12:47

Table 3.1706: TEAEs with Grade 2 or less by SOC and PT by Baseline IPSS Two-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Blood and lymphatic system disorders					
Any Event	9 (32.1%)	9 (37.5%)	17 (29.3%)	36 (51.4%)	
Unadjusted Relative Risk (95% CI)	0.86 (0.41, 1.81)		0.57 (0.36, 0.90)		
p-value [1]	0.69		0.017		
Unadjusted Odds Ratio (95% CI)	0.79 (0.25, 2.48)		0.39 (0.19, 0.82)		
p-value [1]	0.69		0.012		
Unadjusted Absolute Risk Difference (95% CI)	-0.05 (-0.31, 0.21)		-0.22 (-0.39, -0.06)		
Interaction test for Treatment*Baseline IPSS 2-Level Risk [2]					0.37
Blood and lymphatic system disorders					
Anaemia	1 (3.6%)	5 (20.8%)	7 (12.1%)	16 (22.9%)	
Unadjusted Relative Risk (95% CI)	0.17 (0.02, 1.37)		0.53 (0.23, 1.20)		
p-value [1]	0.096		0.13		
Unadjusted Odds Ratio (95% CI)	0.14 (0.02, 1.30)		0.46 (0.18, 1.22)		
p-value [1]	0.084		0.12		
Unadjusted Absolute Risk Difference (95% CI)	-0.17 (-0.35, 0.00)		-0.11 (-0.24, 0.02)		
Interaction test for Treatment*Baseline IPSS 2-Level Risk [2]					0.25

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates. Modified Poisson regression model did not converge for some categories so these are presented as NE.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-gle2-sub-gba.sas V.03.05 Output file: t-ae-socpt-gle2-gba-ipss2.pdf 24AUG2023:12:46

Table 3.1706: TEAEs with Grade 2 or less by SOC and PT by Baseline IPSS Two-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Vascular disorders					
Any Event	5 (17.9%)	1 (4.2%)	11 (19.0%)	4 (5.7%)	
Unadjusted Relative Risk (95% CI)	4.29 (0.54, 34.19)		3.32 (1.12, 9.87)		
p-value [1]	0.17		0.031		
Unadjusted Odds Ratio (95% CI)	5.00 (0.54, 46.20)		3.86 (1.16, 12.87)		
p-value [1]	0.16		0.028		
Unadjusted Absolute Risk Difference (95% CI)	0.14 (-0.03, 0.30)		0.13 (0.02, 0.25)		
Interaction test for Treatment*Baseline IPSS 2-Level Risk [2]					0.82
Vascular disorders					
Hypotension	2 (7.1%)	0	8 (13.8%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Baseline IPSS 2-Level Risk [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates. Modified Poisson regression model did not converge for some categories so these are presented as NE.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-gle2-sub-gba.sas V.03.05 Output file: t-ae-socpt-gle2-gba-ipss2.pdf 24AUG2023:12:46

Table 3.1706: TEAEs with Grade 2 or less by SOC and PT by Baseline IPSS Two-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Gastrointestinal disorders					
Nausea	8 (28.6%)	0	11 (19.0%)	3 (4.3%)	
Unadjusted Relative Risk (95% CI)	14.66 (0.89, 241.39)		4.43 (1.30, 15.11)		
p-value [1]	0.060		0.018		
Unadjusted Odds Ratio (95% CI)	20.32 (1.10, 373.68)		5.23 (1.38, 19.76)		
p-value [1]	0.043		0.015		
Unadjusted Absolute Risk Difference (95% CI)	0.27 (0.10, 0.45)		0.15 (0.04, 0.26)		
Interaction test for Treatment*Baseline IPSS 2-Level Risk [2]					NE

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates. Modified Poisson regression model did not converge for some categories so these are presented as NE.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-gle2-sub-gba.sas V.03.05 Output file: t-ae-socpt-gle2-gba-ipss2.pdf 24AUG2023:12:46

Table 3.1705: TEAEs with Grade 2 or less by SOC and PT by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Blood and lymphatic system disorders				
Any Event	0	2 (50.0%)	9 (34.6%)	7 (35.0%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]				
Blood and lymphatic system disorders				
Anaemia	0	2 (50.0%)	1 (3.8%)	3 (15.0%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-gle2-sub-gba.sas V.03.05 Output file: t-ae-socpt-gle2-gba-ipss3.pdf 24AUG2023:12:46

Table 3.1705: TEAEs with Grade 2 or less by SOC and PT by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=58)	RUX (N=70)	p-value
Blood and lymphatic system disorders			
Any Event	17 (29.3%)	36 (51.4%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]			NA
Blood and lymphatic system disorders			
Anaemia	7 (12.1%)	16 (22.9%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-gle2-sub-gba.sas V.03.05 Output file: t-ae-socpt-gle2-gba-ipss3.pdf 24AUG2023:12:46

Table 3.1705: TEAEs with Grade 2 or less by SOC and PT by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Vascular disorders				
Any Event	1 (50.0%)	1 (25.0%)	4 (15.4%)	0
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]				
Vascular disorders				
Hypotension	0	0	2 (7.7%)	0
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-gle2-sub-gba.sas V.03.05 Output file: t-ae-socpt-gle2-gba-ipss3.pdf 24AUG2023:12:46

Table 3.1705: TEAEs with Grade 2 or less by SOC and PT by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=58)	RUX (N=70)	p-value
Vascular disorders			
Any Event	11 (19.0%)	4 (5.7%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]			NA
Vascular disorders			
Hypotension	8 (13.8%)	0	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-gle2-sub-gba.sas V.03.05 Output file: t-ae-socpt-gle2-gba-ipss3.pdf 24AUG2023:12:46

Table 3.1705: TEAEs with Grade 2 or less by SOC and PT by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Gastrointestinal disorders				
Nausea	1 (50.0%)	0	7 (26.9%)	0
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-gle2-sub-gba.sas V.03.05 Output file: t-ae-socpt-gle2-gba-ipss3.pdf 24AUG2023:12:46

Table 3.1705: TEAEs with Grade 2 or less by SOC and PT by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=58)	RUX (N=70)	p-value
Gastrointestinal disorders			
Nausea	11 (19.0%)	3 (4.3%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-gle2-sub-gba.sas V.03.05 Output file: t-ae-socpt-gle2-gba-ipss3.pdf 24AUG2023:12:46

Table 3.1708: TEAEs with Grade 2 or less by SOC and PT by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
Blood and lymphatic system disorders				
Any Event	16 (27.1%)	25 (46.3%)	7 (43.8%)	14 (50.0%)
Unadjusted Relative Risk (95% CI)	0.59 (0.35, 0.97)		0.88 (0.45, 1.71)	
p-value [1]	0.039		0.70	
Unadjusted Odds Ratio (95% CI)	0.43 (0.20, 0.95)		0.78 (0.23, 2.67)	
p-value [1]	0.036		0.69	
Unadjusted Absolute Risk Difference (95% CI)	-0.19 (-0.37, -0.02)		-0.06 (-0.37, 0.24)	
Interaction test for Treatment*Myelofibrosis Disease Type [2]				
Blood and lymphatic system disorders				
Anaemia	6 (10.2%)	10 (18.5%)	2 (12.5%)	8 (28.6%)
Unadjusted Relative Risk (95% CI)	0.55 (0.21, 1.41)		0.44 (0.11, 1.81)	
p-value [1]	0.21		0.25	
Unadjusted Odds Ratio (95% CI)	0.50 (0.17, 1.48)		0.36 (0.07, 1.94)	
p-value [1]	0.21		0.23	
Unadjusted Absolute Risk Difference (95% CI)	-0.08 (-0.21, 0.05)		-0.16 (-0.39, 0.07)	
Interaction test for Treatment*Myelofibrosis Disease Type [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates. Modified Poisson regression model did not converge for some categories so these are presented as NE.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-gle2-sub-gba.sas V.03.05 Output file: t-ae-socpt-gle2-gba-mf.pdf 24AUG2023:12:47

Table 3.1708: TEAEs with Grade 2 or less by SOC and PT by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=11)	RUX (N=12)	p-value
Blood and lymphatic system disorders			
Any Event	3 (27.3%)	6 (50.0%)	
Unadjusted Relative Risk (95% CI)	0.55 (0.18, 1.67)		
p-value [1]	0.29		
Unadjusted Odds Ratio (95% CI)	0.38 (0.07, 2.14)		
p-value [1]	0.27		
Unadjusted Absolute Risk Difference (95% CI)	-0.23 (-0.61, 0.16)		
Interaction test for Treatment*Myelofibrosis Disease Type [2]			0.63
Blood and lymphatic system disorders			
Anaemia	0	3 (25.0%)	
Unadjusted Relative Risk (95% CI)	0.15 (0.01, 2.70)		
p-value [1]	0.20		
Unadjusted Odds Ratio (95% CI)	0.12 (0.01, 2.58)		
p-value [1]	0.17		
Unadjusted Absolute Risk Difference (95% CI)	-0.23 (-0.49, 0.04)		
Interaction test for Treatment*Myelofibrosis Disease Type [2]			NE

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates. Modified Poisson regression model did not converge for some categories so these are presented as NE.
Data Extracted: CRF data: 01JUL2019

Table 3.1708: TEAEs with Grade 2 or less by SOC and PT by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
Vascular disorders				
Any Event	13 (22.0%)	4 (7.4%)	2 (12.5%)	1 (3.6%)
Unadjusted Relative Risk (95% CI)	2.97 (1.03, 8.57)		3.50 (0.34, 35.64)	
p-value [1]	0.043		0.29	
Unadjusted Odds Ratio (95% CI)	3.53 (1.07, 11.61)		3.86 (0.32, 46.33)	
p-value [1]	0.038		0.29	
Unadjusted Absolute Risk Difference (95% CI)	0.15 (0.02, 0.27)		0.09 (-0.09, 0.27)	
Interaction test for Treatment*Myelofibrosis Disease Type [2]				
Vascular disorders				
Hypotension	8 (13.6%)	0	1 (6.3%)	0
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Myelofibrosis Disease Type [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates. Modified Poisson regression model did not converge for some categories so these are presented as NE.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-gle2-sub-gba.sas V.03.05 Output file: t-ae-socpt-gle2-gba-mf.pdf 24AUG2023:12:47

Table 3.1708: TEAEs with Grade 2 or less by SOC and PT by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=11)	RUX (N=12)	p-value
Vascular disorders			
Any Event	1 (9.1%)	0	
Unadjusted Relative Risk (95% CI)	3.25 (0.15, 72.36)		
p-value [1]	0.46		
Unadjusted Odds Ratio (95% CI)	3.57 (0.13, 97.23)		
p-value [1]	0.45		
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.13, 0.30)		
Interaction test for Treatment*Myelofibrosis Disease Type [2]			NE
Vascular disorders			
Hypotension	1 (9.1%)	0	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Myelofibrosis Disease Type [2]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates. Modified Poisson regression model did not converge for some categories so these are presented as NE.
Data Extracted: CRF data: 01JUL2019

Table 3.1708: TEAEs with Grade 2 or less by SOC and PT by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
Gastrointestinal disorders				
Nausea	13 (22.0%)	0	5 (31.3%)	3 (10.7%)
Unadjusted Relative Risk (95% CI)	24.75 (1.51, 406.56)		2.92 (0.80, 10.63)	
p-value [1]	0.025		0.10	
Unadjusted Odds Ratio (95% CI)	31.65 (1.83, 546.92)		3.79 (0.77, 18.71)	
p-value [1]	0.018		0.10	
Unadjusted Absolute Risk Difference (95% CI)	0.22 (0.11, 0.32)		0.21 (-0.05, 0.46)	
Interaction test for Treatment*Myelofibrosis Disease Type [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates. Modified Poisson regression model did not converge for some categories so these are presented as NE.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-gle2-sub-gba.sas V.03.05 Output file: t-ae-socpt-gle2-gba-mf.pdf 24AUG2023:12:47

Table 3.1708: TEAEs with Grade 2 or less by SOC and PT by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=11)	RUX (N=12)	p-value
Gastrointestinal disorders			
Nausea	1 (9.1%)	0	
Unadjusted Relative Risk (95% CI)	3.25 (0.15, 72.36)		
p-value [1]	0.46		
Unadjusted Odds Ratio (95% CI)	3.57 (0.13, 97.23)		
p-value [1]	0.45		
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.13, 0.30)		
Interaction test for Treatment*Myelofibrosis Disease Type [2]			NE

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates. Modified Poisson regression model did not converge for some categories so these are presented as NE.
Data Extracted: CRF data: 01JUL2019

Table 3.1703: TEAEs with Grade 2 or less by SOC and PT by Gender
Double-Blind Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Blood and lymphatic system disorders					
Any Event	16 (32.0%)	30 (53.6%)	10 (27.8%)	15 (39.5%)	
Unadjusted Relative Risk (95% CI)	0.60 (0.37, 0.96)		0.70 (0.36, 1.36)		
p-value [1]	0.032		0.29		
Unadjusted Odds Ratio (95% CI)	0.41 (0.18, 0.90)		0.59 (0.22, 1.57)		
p-value [1]	0.027		0.29		
Unadjusted Absolute Risk Difference (95% CI)	-0.22 (-0.40, -0.03)		-0.12 (-0.33, 0.10)		
Interaction test for Treatment*Gender [2]					0.69
Blood and lymphatic system disorders					
Anaemia	4 (8.0%)	14 (25.0%)	4 (11.1%)	7 (18.4%)	
Unadjusted Relative Risk (95% CI)	0.32 (0.11, 0.91)		0.60 (0.19, 1.89)		
p-value [1]	0.032		0.39		
Unadjusted Odds Ratio (95% CI)	0.26 (0.08, 0.86)		0.55 (0.15, 2.08)		
p-value [1]	0.027		0.38		
Unadjusted Absolute Risk Difference (95% CI)	-0.17 (-0.31, -0.03)		-0.07 (-0.23, 0.09)		
Interaction test for Treatment*Gender [2]					0.43

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-gle2-sub-gba.sas V.03.05 Output file: t-ae-socpt-gle2-gba-sex.pdf 24AUG2023:12:46

Table 3.1703: TEAEs with Grade 2 or less by SOC and PT by Gender
Double-Blind Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Vascular disorders					
Any Event	8 (16.0%)	3 (5.4%)	8 (22.2%)	2 (5.3%)	
Unadjusted Relative Risk (95% CI)	2.99 (0.84, 10.65)		4.22 (0.96, 18.57)		
p-value [1]	0.092		0.057		
Unadjusted Odds Ratio (95% CI)	3.37 (0.84, 13.47)		5.14 (1.01, 26.15)		
p-value [1]	0.086		0.048		
Unadjusted Absolute Risk Difference (95% CI)	0.11 (-0.01, 0.22)		0.17 (0.02, 0.32)		
Interaction test for Treatment*Gender [2]					0.73
Vascular disorders					
Hypotension	5 (10.0%)	0	5 (13.9%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Gender [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 01JUL2019

Table 3.1703: TEAEs with Grade 2 or less by SOC and PT by Gender
Double-Blind Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Gastrointestinal disorders					
Nausea	4 (8.0%)	2 (3.6%)	15 (41.7%)	1 (2.6%)	
Unadjusted Relative Risk (95% CI)	2.24 (0.43, 11.71)		15.83 (2.20, 113.80)		
p-value [1]	0.34		0.006		
Unadjusted Odds Ratio (95% CI)	2.35 (0.41, 13.41)		26.43 (3.26, 214.51)		
p-value [1]	0.34		0.002		
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.05, 0.13)		0.39 (0.22, 0.56)		
Interaction test for Treatment*Gender [2]					0.21

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-gle2-sub-gba.sas V.03.05 Output file: t-ae-socpt-gle2-gba-sex.pdf 24AUG2023:12:46

Table 3.1710: TEAEs with Grade 2 or less by SOC and PT by Baseline Spleen Volume
Double-Blind Phase
SAF-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Blood and lymphatic system disorders					
Any Event	12 (25.5%)	23 (53.5%)	14 (35.9%)	22 (43.1%)	
Unadjusted Relative Risk (95% CI)	0.48 (0.27, 0.84)		0.83 (0.49, 1.41)		
p-value [1]	0.010		0.49		
Unadjusted Odds Ratio (95% CI)	0.30 (0.12, 0.72)		0.74 (0.31, 1.74)		
p-value [1]	0.008		0.49		
Unadjusted Absolute Risk Difference (95% CI)	-0.28 (-0.47, -0.09)		-0.07 (-0.28, 0.13)		
Interaction test for Treatment*Baseline Spleen Volume Group [2]					0.16
Blood and lymphatic system disorders					
Anaemia	4 (8.5%)	10 (23.3%)	4 (10.3%)	11 (21.6%)	
Unadjusted Relative Risk (95% CI)	0.37 (0.12, 1.08)		0.48 (0.16, 1.38)		
p-value [1]	0.069		0.17		
Unadjusted Odds Ratio (95% CI)	0.31 (0.09, 1.07)		0.42 (0.12, 1.42)		
p-value [1]	0.063		0.16		
Unadjusted Absolute Risk Difference (95% CI)	-0.15 (-0.30, 0.00)		-0.11 (-0.26, 0.03)		
Interaction test for Treatment*Baseline Spleen Volume Group [2]					0.74

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates. Modified Poisson regression model did not converge for some categories so these are presented as NE.
Data Extracted: CRF data: 01JUL2019

Table 3.1710: TEAEs with Grade 2 or less by SOC and PT by Baseline Spleen Volume
Double-Blind Phase
SAF-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Vascular disorders					
Any Event	8 (17.0%)	3 (7.0%)	8 (20.5%)	2 (3.9%)	
Unadjusted Relative Risk (95% CI)	2.44 (0.69, 8.61)		5.23 (1.18, 23.26)		
p-value [1]	0.17		0.030		
Unadjusted Odds Ratio (95% CI)	2.74 (0.68, 11.07)		6.32 (1.26, 31.74)		
p-value [1]	0.16		0.025		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.03, 0.23)		0.17 (0.03, 0.30)		
Interaction test for Treatment*Baseline Spleen Volume Group [2]					0.45
Vascular disorders					
Hypotension	4 (8.5%)	0	6 (15.4%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Baseline Spleen Volume Group [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates. Modified Poisson regression model did not converge for some categories so these are presented as NE.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-gle2-sub-gba.sas V.03.05 Output file: t-ae-socpt-gle2-gba-svb.pdf 24AUG2023:12:47

Table 3.1710: TEAEs with Grade 2 or less by SOC and PT by Baseline Spleen Volume
Double-Blind Phase
SAF-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Gastrointestinal disorders					
Nausea	13 (27.7%)	0	6 (15.4%)	3 (5.9%)	
Unadjusted Relative Risk (95% CI)	24.75 (1.52, 404.13)		2.62 (0.70, 9.81)		
p-value [1]	0.024		0.15		
Unadjusted Odds Ratio (95% CI)	34.04 (1.95, 593.19)		2.91 (0.68, 12.46)		
p-value [1]	0.016		0.15		
Unadjusted Absolute Risk Difference (95% CI)	0.27 (0.14, 0.40)		0.10 (-0.04, 0.23)		
Interaction test for Treatment*Baseline Spleen Volume Group [2]					NE

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates. Modified Poisson regression model did not converge for some categories so these are presented as NE.
Data Extracted: CRF data: 01JUL2019

Table 3.1709: TEAEs with Grade 2 or less by SOC and PT by Baseline TSS
Double-Blind Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Blood and lymphatic system disorders					
Any Event	11 (25.0%)	32 (58.2%)	15 (36.6%)	13 (34.2%)	
Unadjusted Relative Risk (95% CI)	0.43 (0.25, 0.75)		1.07 (0.59, 1.94)		
p-value [1]	0.003		0.83		
Unadjusted Odds Ratio (95% CI)	0.24 (0.10, 0.57)		1.11 (0.44, 2.79)		
p-value [1]	0.001		0.83		
Unadjusted Absolute Risk Difference (95% CI)	-0.33 (-0.51, -0.15)		0.02 (-0.19, 0.23)		
Interaction test for Treatment*Baseline TSS Group [2]					0.027
Blood and lymphatic system disorders					
Anaemia	2 (4.5%)	15 (27.3%)	6 (14.6%)	6 (15.8%)	
Unadjusted Relative Risk (95% CI)	0.17 (0.04, 0.69)		0.93 (0.33, 2.63)		
p-value [1]	0.013		0.89		
Unadjusted Odds Ratio (95% CI)	0.13 (0.03, 0.59)		0.91 (0.27, 3.12)		
p-value [1]	0.009		0.89		
Unadjusted Absolute Risk Difference (95% CI)	-0.23 (-0.36, -0.09)		-0.01 (-0.17, 0.15)		
Interaction test for Treatment*Baseline TSS Group [2]					0.045

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-gle2-sub-gba.sas V.03.05 Output file: t-ae-socpt-gle2-gba-tss.pdf 24AUG2023:12:47

Table 3.1709: TEAEs with Grade 2 or less by SOC and PT by Baseline TSS
Double-Blind Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Vascular disorders					
Any Event	8 (18.2%)	4 (7.3%)	8 (19.5%)	1 (2.6%)	
Unadjusted Relative Risk (95% CI)	2.50 (0.81, 7.76)		7.41 (0.97, 56.54)		
p-value [1]	0.11		0.053		
Unadjusted Odds Ratio (95% CI)	2.83 (0.79, 10.13)		8.97 (1.06, 75.57)		
p-value [1]	0.11		0.044		
Unadjusted Absolute Risk Difference (95% CI)	0.11 (-0.02, 0.24)		0.17 (0.04, 0.30)		
Interaction test for Treatment*Baseline TSS Group [2]					0.30
Vascular disorders					
Hypotension	5 (11.4%)	0	5 (12.2%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Baseline TSS Group [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-gle2-sub-gba.sas V.03.05 Output file: t-ae-socpt-gle2-gba-tss.pdf 24AUG2023:12:47

Table 3.1709: TEAEs with Grade 2 or less by SOC and PT by Baseline TSS
Double-Blind Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Gastrointestinal disorders					
Nausea	7 (15.9%)	2 (3.6%)	12 (29.3%)	1 (2.6%)	
Unadjusted Relative Risk (95% CI)	4.38 (0.96, 20.02)		11.12 (1.52, 81.50)		
p-value [1]	0.057		0.018		
Unadjusted Odds Ratio (95% CI)	5.01 (0.99, 25.50)		15.31 (1.88, 124.67)		
p-value [1]	0.052		0.011		
Unadjusted Absolute Risk Difference (95% CI)	0.12 (0.00, 0.24)		0.27 (0.12, 0.41)		
Interaction test for Treatment*Baseline TSS Group [2]					0.46

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-gle2-sub-gba.sas V.03.05 Output file: t-ae-socpt-gle2-gba-tss.pdf 24AUG2023:12:47

Table 3.1902: Serious TEAEs by SOC and PT by Age
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 01JUL2019

Table 3.1904: Serious TEAEs by SOC and PT by Region
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-ser-sub-gba.sas V.03.05 Output file: t-ae-socpt-ser-gba-geo.pdf 24AUG2023:12:47

Table 3.1907: Serious TEAEs by SOC and PT by Baseline Hemoglobin Level
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 01JUL2019

Table 3.1906: Serious TEAEs by SOC and PT by Baseline IPSS Two-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-ser-sub-gba.sas V.03.05 Output file: t-ae-socpt-ser-gba-ipss2.pdf 24AUG2023:12:47

Table 3.1905: Serious TEAEs by SOC and PT by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 01JUL2019
Source: t-ae-socpt-ser-sub-gba.sas V.03.05 Output file: t-ae-socpt-ser-gba-ipss3.pdf 24AUG2023:12:47

Table 3.1908: Serious TEAEs by SOC and PT by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 01JUL2019

Table 3.1903: Serious TEAEs by SOC and PT by Gender
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 01JUL2019

Table 3.1910: Serious TEAEs by SOC and PT by Baseline Spleen Volume
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 01JUL2019

Table 3.1909: Serious TEAEs by SOC and PT by Baseline TSS
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 01JUL2019

Table 3.2502: Any TE AESI by Age
Double-Blind Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Number of subjects, n(%)	21 (87.5%)	32 (88.9%)	58 (93.5%)	56 (96.6%)	
Unadjusted Relative Risk (95% CI)	0.98 (0.81, 1.19)		0.97 (0.89, 1.05)		
p-value [1]	0.87		0.45		
Unadjusted Odds Ratio (95% CI)	0.88 (0.18, 4.31)		0.52 (0.09, 2.94)		
p-value [1]	0.87		0.46		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.18, 0.15)		-0.03 (-0.11, 0.05)		
Interaction test for Treatment*Age Group [2]					0.88

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.2504: Any TE AESI by Region
Double-Blind Phase
SAF-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Number of subjects, n(%)	53 (100.0%)	50 (98.0%)	26 (78.8%)	38 (88.4%)	
Unadjusted Relative Risk (95% CI)	1.02 (0.97, 1.08)		0.89 (0.72, 1.10)		
p-value [1]	0.46		0.28		
Unadjusted Odds Ratio (95% CI)	3.18 (0.13, 79.84)		0.49 (0.14, 1.71)		
p-value [1]	0.48		0.26		
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.03, 0.07)		-0.10 (-0.27, 0.07)		
Interaction test for Treatment*Region [2]					0.20

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.2507: Any TE AESI by Baseline Hemoglobin Level
Double-Blind Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Number of subjects, n(%)	26 (92.9%)	19 (90.5%)	53 (91.4%)	69 (94.5%)	
Unadjusted Relative Risk (95% CI)	1.03 (0.86, 1.22)		0.97 (0.88, 1.06)		
p-value [1]	0.77		0.49		
Unadjusted Odds Ratio (95% CI)	1.37 (0.18, 10.60)		0.61 (0.16, 2.40)		
p-value [1]	0.76		0.48		
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.13, 0.18)		-0.03 (-0.12, 0.06)		
Interaction test for Treatment*Baseline Hemoglobin Level Group [2]					0.55

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-aesi-sub-gba.sas V.03.05 Output file: t-aesum-aesi-gba-hgb.pdf 29AUG2023: 8:55

Table 3.2506: Any TE AESI by Baseline IPSS Two-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Number of subjects, n(%)	25 (89.3%)	24 (100.0%)	54 (93.1%)	64 (91.4%)	
Unadjusted Relative Risk (95% CI)	0.90 (0.78, 1.04)		1.02 (0.92, 1.13)		
p-value [1]	0.15		0.72		
Unadjusted Odds Ratio (95% CI)	0.15 (0.01, 3.03)		1.27 (0.34, 4.72)		
p-value [1]	0.22		0.73		
Unadjusted Absolute Risk Difference (95% CI)	-0.10 (-0.23, 0.03)		0.02 (-0.08, 0.11)		
Interaction test for Treatment*Baseline IPSS 2-Level Risk [2]					0.11

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-aesi-sub-gba.sas V.03.05 Output file: t-aesum-aesi-gba-ipss2.pdf 29AUG2023: 8:55

Table 3.2505: Any TE AESI by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Number of subjects, n(%)	2 (100.0%)	4 (100.0%)	23 (88.5%)	20 (100.0%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-aesi-sub-gba.sas V.03.05 Output file: t-aesum-aesi-gba-ipss3.pdf 29AUG2023: 8:55

Table 3.2505: Any TE AESI by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=58)	RUX (N=70)	p-value
Number of subjects, n(%)	54 (93.1%)	64 (91.4%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-aesi-sub-gba.sas V.03.05 Output file: t-aesum-aesi-gba-ipss3.pdf 29AUG2023: 8:55

Table 3.2508: Any TE AESI by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
Number of subjects, n(%)	55 (93.2%)	50 (92.6%)	14 (87.5%)	27 (96.4%)
Unadjusted Relative Risk (95% CI)	1.01 (0.91, 1.12)		0.91 (0.74, 1.11)	
p-value [1]	0.90		0.34	
Unadjusted Odds Ratio (95% CI)	1.10 (0.26, 4.63)		0.26 (0.02, 3.11)	
p-value [1]	0.90		0.29	
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.09, 0.10)		-0.09 (-0.27, 0.09)	
Interaction test for Treatment*Myelofibrosis Disease Type [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.2508: Any TE AESI by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=11)	RUX (N=12)	p-value
Number of subjects, n(%)	10 (90.9%)	11 (91.7%)	
Unadjusted Relative Risk (95% CI)	0.99 (0.77, 1.28)		
p-value [1]	0.95		
Unadjusted Odds Ratio (95% CI)	0.91 (0.05, 16.54)		
p-value [1]	0.95		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.24, 0.22)		
Interaction test for Treatment*Myelofibrosis Disease Type [2]			0.65

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-aesi-sub-gba.sas V.03.05 Output file: t-aesum-aesi-gba-mf.pdf 29AUG2023: 8:55

Table 3.2503: Any TE AESI by Gender
Double-Blind Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Number of subjects, n(%)	46 (92.0%)	51 (91.1%)	33 (91.7%)	37 (97.4%)	
Unadjusted Relative Risk (95% CI)	1.01 (0.90, 1.13)		0.94 (0.84, 1.05)		
p-value [1]	0.86		0.29		
Unadjusted Odds Ratio (95% CI)	1.13 (0.29, 4.45)		0.30 (0.03, 3.00)		
p-value [1]	0.86		0.30		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.10, 0.12)		-0.06 (-0.16, 0.05)		
Interaction test for Treatment*Gender [2]					0.39

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.2510: Any TE AESI by Baseline Spleen Volume
Double-Blind Phase
SAF-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Number of subjects, n(%)	41 (87.2%)	42 (97.7%)	38 (97.4%)	46 (90.2%)	
Unadjusted Relative Risk (95% CI)	0.89 (0.79, 1.01)		1.08 (0.97, 1.20)		
p-value [1]	0.062		0.14		
Unadjusted Odds Ratio (95% CI)	0.16 (0.02, 1.41)		4.13 (0.46, 36.89)		
p-value [1]	0.099		0.20		
Unadjusted Absolute Risk Difference (95% CI)	-0.10 (-0.21, 0.00)		0.07 (-0.02, 0.17)		
Interaction test for Treatment*Baseline Spleen Volume Group [2]					0.017

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-aesi-sub-gba.sas V.03.05 Output file: t-aesum-aesi-gba-svb.pdf 29AUG2023: 8:55

Table 3.2509: Any TE AESI by Baseline TSS
Double-Blind Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Number of subjects, n(%)	38 (86.4%)	52 (94.5%)	40 (97.6%)	35 (92.1%)	
Unadjusted Relative Risk (95% CI)	0.91 (0.80, 1.04)		1.06 (0.95, 1.18)		
p-value [1]	0.18		0.28		
Unadjusted Odds Ratio (95% CI)	0.37 (0.09, 1.55)		3.43 (0.34, 34.48)		
p-value [1]	0.17		0.30		
Unadjusted Absolute Risk Difference (95% CI)	-0.08 (-0.20, 0.04)		0.05 (-0.04, 0.15)		
Interaction test for Treatment*Baseline TSS Group [2]					0.084

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.2702: Any TE AESI of Grade 3 or more by Age
Double-Blind Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Number of subjects, n(%)	5 (20.8%)	5 (13.9%)	28 (45.2%)	21 (36.2%)	
Unadjusted Relative Risk (95% CI)	1.50 (0.49, 4.63)		1.25 (0.80, 1.93)		
p-value [1]	0.48		0.32		
Unadjusted Odds Ratio (95% CI)	1.63 (0.42, 6.39)		1.45 (0.70, 3.02)		
p-value [1]	0.48		0.32		
Unadjusted Absolute Risk Difference (95% CI)	0.07 (-0.13, 0.27)		0.09 (-0.09, 0.26)		
Interaction test for Treatment*Age Group [2]					0.77

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-aesi-sub-gba.sas V.03.05 Output file: t-aesum-aesi-gge3-gba-age.pdf 29AUG2023: 8:56

Table 3.2704: Any TE AESI of Grade 3 or more by Region
Double-Blind Phase
SAF-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Number of subjects, n(%)	24 (45.3%)	17 (33.3%)	9 (27.3%)	9 (20.9%)	
Unadjusted Relative Risk (95% CI)	1.36 (0.83, 2.21)		1.30 (0.58, 2.91)		
p-value [1]	0.22		0.52		
Unadjusted Odds Ratio (95% CI)	1.66 (0.75, 3.66)		1.42 (0.49, 4.10)		
p-value [1]	0.21		0.52		
Unadjusted Absolute Risk Difference (95% CI)	0.12 (-0.07, 0.31)		0.06 (-0.13, 0.26)		
Interaction test for Treatment*Region [2]					0.93

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.2707: Any TE AESI of Grade 3 or more by Baseline Hemoglobin Level
Double-Blind Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Number of subjects, n(%)	15 (53.6%)	8 (38.1%)	18 (31.0%)	18 (24.7%)	
Unadjusted Relative Risk (95% CI)	1.41 (0.74, 2.68)		1.26 (0.72, 2.19)		
p-value [1]	0.30		0.42		
Unadjusted Odds Ratio (95% CI)	1.88 (0.59, 5.93)		1.38 (0.64, 2.97)		
p-value [1]	0.28		0.42		
Unadjusted Absolute Risk Difference (95% CI)	0.15 (-0.12, 0.43)		0.06 (-0.09, 0.22)		
Interaction test for Treatment*Baseline Hemoglobin Level Group [2]					0.80

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-aesi-sub-gba.sas V.03.05 Output file: t-aesum-aesi-gge3-gba-hgb.pdf 29AUG2023: 8:56

Table 3.2706: Any TE AESI of Grade 3 or more by Baseline IPSS Two-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Number of subjects, n(%)	7 (25.0%)	5 (20.8%)	26 (44.8%)	21 (30.0%)	
Unadjusted Relative Risk (95% CI)	1.20 (0.44, 3.29)		1.49 (0.95, 2.36)		
p-value [1]	0.72		0.086		
Unadjusted Odds Ratio (95% CI)	1.27 (0.34, 4.67)		1.90 (0.92, 3.92)		
p-value [1]	0.72		0.085		
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.19, 0.27)		0.15 (-0.02, 0.32)		
Interaction test for Treatment*Baseline IPSS 2-Level Risk [2]					0.70

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-aesi-sub-gba.sas V.03.05 Output file: t-aesum-aesi-gge3-gba-ipss2.pdf 29AUG2023: 8:56

Table 3.2705: Any TE AESI of Grade 3 or more by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Number of subjects, n(%)	1 (50.0%)	1 (25.0%)	6 (23.1%)	4 (20.0%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-aesi-sub-gba.sas V.03.05 Output file: t-aesum-aesi-gge3-gba-ipss3.pdf 29AUG2023: 8:56

Table 3.2705: Any TE AESI of Grade 3 or more by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=58)	RUX (N=70)	p-value
Number of subjects, n(%)	26 (44.8%)	21 (30.0%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-aesi-sub-gba.sas V.03.05 Output file: t-aesum-aesi-gge3-gba-ipss3.pdf 29AUG2023: 8:56

Table 3.2708: Any TE AESI of Grade 3 or more by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
Number of subjects, n(%)	22 (37.3%)	11 (20.4%)	6 (37.5%)	11 (39.3%)
Unadjusted Relative Risk (95% CI)	1.83 (0.98, 3.41)		0.95 (0.44, 2.09)	
p-value [1]	0.057		0.91	
Unadjusted Odds Ratio (95% CI)	2.32 (1.00, 5.42)		0.93 (0.26, 3.28)	
p-value [1]	0.051		0.91	
Unadjusted Absolute Risk Difference (95% CI)	0.17 (0.01, 0.33)		-0.02 (-0.32, 0.28)	
Interaction test for Treatment*Myelofibrosis Disease Type [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-aesi-sub-gba.sas V.03.05 Output file: t-aesum-aesi-gge3-gba-mf.pdf 29AUG2023: 8:56

Table 3.2708: Any TE AESI of Grade 3 or more by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=11)	RUX (N=12)	p-value
Number of subjects, n(%)	5 (45.5%)	4 (33.3%)	
Unadjusted Relative Risk (95% CI)	1.36 (0.49, 3.82)		
p-value [1]	0.55		
Unadjusted Odds Ratio (95% CI)	1.67 (0.31, 9.01)		
p-value [1]	0.55		
Unadjusted Absolute Risk Difference (95% CI)	0.12 (-0.28, 0.52)		
Interaction test for Treatment*Myelofibrosis Disease Type [2]			0.42

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-aesi-sub-gba.sas V.03.05 Output file: t-aesum-aesi-gge3-gba-mf.pdf 29AUG2023: 8:56

Table 3.2703: Any TE AESI of Grade 3 or more by Gender
Double-Blind Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Number of subjects, n(%)	23 (46.0%)	14 (25.0%)	10 (27.8%)	12 (31.6%)	
Unadjusted Relative Risk (95% CI)	1.84 (1.07, 3.17)		0.88 (0.43, 1.78)		
p-value [1]	0.028		0.72		
Unadjusted Odds Ratio (95% CI)	2.56 (1.12, 5.81)		0.83 (0.31, 2.27)		
p-value [1]	0.025		0.72		
Unadjusted Absolute Risk Difference (95% CI)	0.21 (0.03, 0.39)		-0.04 (-0.25, 0.17)		
Interaction test for Treatment*Gender [2]					0.11

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-aesi-sub-gba.sas V.03.05 Output file: t-aesum-aesi-gge3-gba-sex.pdf 29AUG2023: 8:56

Table 3.2710: Any TE AESI of Grade 3 or more by Baseline Spleen Volume
Double-Blind Phase
SAF-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Number of subjects, n(%)	14 (29.8%)	11 (25.6%)	19 (48.7%)	15 (29.4%)	
Unadjusted Relative Risk (95% CI)	1.16 (0.59, 2.28)		1.66 (0.97, 2.82)		
p-value [1]	0.66		0.064		
Unadjusted Odds Ratio (95% CI)	1.23 (0.49, 3.12)		2.28 (0.96, 5.44)		
p-value [1]	0.66		0.063		
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.14, 0.23)		0.19 (-0.01, 0.39)		
Interaction test for Treatment*Baseline Spleen Volume Group [2]					0.43

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-aesi-sub-gba.sas V.03.05 Output file: t-aesum-aesi-gge3-gba-svb.pdf 29AUG2023: 8:56

Table 3.2709: Any TE AESI of Grade 3 or more by Baseline TSS
Double-Blind Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Number of subjects, n(%)	13 (29.5%)	11 (20.0%)	20 (48.8%)	14 (36.8%)	
Unadjusted Relative Risk (95% CI)	1.48 (0.73, 2.97)		1.32 (0.79, 2.23)		
p-value [1]	0.27		0.29		
Unadjusted Odds Ratio (95% CI)	1.68 (0.67, 4.23)		1.63 (0.66, 4.01)		
p-value [1]	0.27		0.29		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.08, 0.27)		0.12 (-0.10, 0.34)		
Interaction test for Treatment*Baseline TSS Group [2]					0.81

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-aesi-sub-gba.sas V.03.05 Output file: t-aesum-aesi-gge3-gba-tss.pdf 29AUG2023: 8:56

Table 3.2602: Any TE AESI of Grade 2 or less by Age
Double-Blind Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Number of subjects, n(%)	21 (87.5%)	32 (88.9%)	55 (88.7%)	55 (94.8%)	
Unadjusted Relative Risk (95% CI)	0.98 (0.81, 1.19)		0.94 (0.84, 1.04)		
p-value [1]	0.87		0.22		
Unadjusted Odds Ratio (95% CI)	0.88 (0.18, 4.31)		0.43 (0.11, 1.74)		
p-value [1]	0.87		0.24		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.18, 0.15)		-0.06 (-0.16, 0.04)		
Interaction test for Treatment*Age Group [2]					0.65

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-aesi-sub-gba.sas V.03.05 Output file: t-aesum-aesi-gle2-gba-age.pdf 29AUG2023: 8:55

Table 3.2604: Any TE AESI of Grade 2 or less by Region
Double-Blind Phase
SAF-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Number of subjects, n(%)	51 (96.2%)	50 (98.0%)	25 (75.8%)	37 (86.0%)	
Unadjusted Relative Risk (95% CI)	0.98 (0.92, 1.05)		0.88 (0.70, 1.11)		
p-value [1]	0.58		0.27		
Unadjusted Odds Ratio (95% CI)	0.51 (0.04, 5.80)		0.51 (0.16, 1.64)		
p-value [1]	0.59		0.26		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.08, 0.05)		-0.10 (-0.28, 0.08)		
Interaction test for Treatment*Region [2]					0.36

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-aesi-sub-gba.sas V.03.05 Output file: t-aesum-aesi-gle2-gba-geo.pdf 29AUG2023: 8:55

Table 3.2607: Any TE AESI of Grade 2 or less by Baseline Hemoglobin Level
Double-Blind Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Number of subjects, n(%)	25 (89.3%)	19 (90.5%)	51 (87.9%)	68 (93.2%)	
Unadjusted Relative Risk (95% CI)	0.99 (0.82, 1.19)		0.94 (0.84, 1.06)		
p-value [1]	0.89		0.32		
Unadjusted Odds Ratio (95% CI)	0.88 (0.13, 5.78)		0.54 (0.16, 1.79)		
p-value [1]	0.89		0.31		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.18, 0.16)		-0.05 (-0.15, 0.05)		
Interaction test for Treatment*Baseline Hemoglobin Level Group [2]					0.69

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-aesi-sub-gba.sas V.03.05 Output file: t-aesum-aesi-gle2-gba-hgb.pdf 29AUG2023: 8:55

Table 3.2606: Any TE AESI of Grade 2 or less by Baseline IPSS Two-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Number of subjects, n(%)	25 (89.3%)	24 (100.0%)	51 (87.9%)	63 (90.0%)	
Unadjusted Relative Risk (95% CI)	0.90 (0.78, 1.04)		0.98 (0.86, 1.11)		
p-value [1]	0.15		0.71		
Unadjusted Odds Ratio (95% CI)	0.15 (0.01, 3.03)		0.81 (0.27, 2.46)		
p-value [1]	0.22		0.71		
Unadjusted Absolute Risk Difference (95% CI)	-0.10 (-0.23, 0.03)		-0.02 (-0.13, 0.09)		
Interaction test for Treatment*Baseline IPSS 2-Level Risk [2]					0.32

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-aesi-sub-gba.sas V.03.05 Output file: t-aesum-aesi-gle2-gba-ipss2.pdf 29AUG2023: 8:55

Table 3.2605: Any TE AESI of Grade 2 or less by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Number of subjects, n(%)	2 (100.0%)	4 (100.0%)	23 (88.5%)	20 (100.0%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-aesi-sub-gba.sas V.03.05 Output file: t-aesum-aesi-gle2-gba-ipss3.pdf 29AUG2023: 8:55

Table 3.2605: Any TE AESI of Grade 2 or less by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=58)	RUX (N=70)	p-value
Number of subjects, n(%)	51 (87.9%)	63 (90.0%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-aesi-sub-gba.sas V.03.05 Output file: t-aesum-aesi-gle2-gba-ipss3.pdf 29AUG2023: 8:55

Table 3.2608: Any TE AESI of Grade 2 or less by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
Number of subjects, n(%)	53 (89.8%)	50 (92.6%)	13 (81.3%)	26 (92.9%)
Unadjusted Relative Risk (95% CI)	0.97 (0.87, 1.09)		0.88 (0.68, 1.13)	
p-value [1]	0.60		0.31	
Unadjusted Odds Ratio (95% CI)	0.71 (0.19, 2.65)		0.33 (0.05, 2.25)	
p-value [1]	0.61		0.26	
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.13, 0.08)		-0.12 (-0.33, 0.10)	
Interaction test for Treatment*Myelofibrosis Disease Type [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-aesi-sub-gba.sas V.03.05 Output file: t-aesum-aesi-gle2-gba-mf.pdf 29AUG2023: 8:55

Table 3.2608: Any TE AESI of Grade 2 or less by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=11)	RUX (N=12)	p-value
Number of subjects, n(%)	10 (90.9%)	11 (91.7%)	
Unadjusted Relative Risk (95% CI)	0.99 (0.77, 1.28)		
p-value [1]	0.95		
Unadjusted Odds Ratio (95% CI)	0.91 (0.05, 16.54)		
p-value [1]	0.95		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.24, 0.22)		
Interaction test for Treatment*Myelofibrosis Disease Type [2]			0.73

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-aesi-sub-gba.sas V.03.05 Output file: t-aesum-aesi-gle2-gba-mf.pdf 29AUG2023: 8:55

Table 3.2603: Any TE AESI of Grade 2 or less by Gender
Double-Blind Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Number of subjects, n(%)	45 (90.0%)	51 (91.1%)	31 (86.1%)	36 (94.7%)	
Unadjusted Relative Risk (95% CI)	0.99 (0.87, 1.12)		0.91 (0.78, 1.06)		
p-value [1]	0.85		0.22		
Unadjusted Odds Ratio (95% CI)	0.88 (0.24, 3.25)		0.34 (0.06, 1.90)		
p-value [1]	0.85		0.22		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.12, 0.10)		-0.09 (-0.22, 0.05)		
Interaction test for Treatment*Gender [2]					0.40

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-aesi-sub-gba.sas V.03.05 Output file: t-aesum-aesi-gle2-gba-sex.pdf 29AUG2023: 8:55

Table 3.2610: Any TE AESI of Grade 2 or less by Baseline Spleen Volume
Double-Blind Phase
SAF-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Number of subjects, n(%)	39 (83.0%)	41 (95.3%)	37 (94.9%)	46 (90.2%)	
Unadjusted Relative Risk (95% CI)	0.87 (0.75, 1.01)		1.05 (0.94, 1.18)		
p-value [1]	0.061		0.39		
Unadjusted Odds Ratio (95% CI)	0.24 (0.05, 1.19)		2.01 (0.37, 10.96)		
p-value [1]	0.080		0.42		
Unadjusted Absolute Risk Difference (95% CI)	-0.12 (-0.25, 0.00)		0.05 (-0.06, 0.15)		
Interaction test for Treatment*Baseline Spleen Volume Group [2]					0.044

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-aesi-sub-gba.sas V.03.05 Output file: t-aesum-aesi-gle2-gba-svb.pdf 29AUG2023: 8:56

Table 3.2609: Any TE AESI of Grade 2 or less by Baseline TSS
Double-Blind Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Number of subjects, n(%)	38 (86.4%)	52 (94.5%)	37 (90.2%)	34 (89.5%)	
Unadjusted Relative Risk (95% CI)	0.91 (0.80, 1.04)		1.01 (0.87, 1.17)		
p-value [1]	0.18		0.91		
Unadjusted Odds Ratio (95% CI)	0.37 (0.09, 1.55)		1.09 (0.25, 4.70)		
p-value [1]	0.17		0.91		
Unadjusted Absolute Risk Difference (95% CI)	-0.08 (-0.20, 0.04)		0.01 (-0.13, 0.14)		
Interaction test for Treatment*Baseline TSS Group [2]					0.33

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-aesi-sub-gba.sas V.03.05 Output file: t-aesum-aesi-gle2-gba-tss.pdf 29AUG2023: 8:56

Table 3.2802: Any Serious TE AESI by Age
Double-Blind Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Number of subjects, n(%)	3 (12.5%)	3 (8.3%)	21 (33.9%)	16 (27.6%)	
Unadjusted Relative Risk (95% CI)	1.50 (0.33, 6.82)		1.23 (0.71, 2.11)		
p-value [1]	0.60		0.46		
Unadjusted Odds Ratio (95% CI)	1.57 (0.29, 8.53)		1.34 (0.62, 2.93)		
p-value [1]	0.60		0.46		
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.12, 0.20)		0.06 (-0.10, 0.23)		
Interaction test for Treatment*Age Group [2]					0.81

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-aesi-sub-gba.sas V.03.05 Output file: t-aesum-aesi-ser-gba-age.pdf 29AUG2023: 8:56

Table 3.2804: Any Serious TE AESI by Region
Double-Blind Phase
SAF-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Number of subjects, n(%)	18 (34.0%)	11 (21.6%)	6 (18.2%)	8 (18.6%)	
Unadjusted Relative Risk (95% CI)	1.57 (0.83, 3.00)		0.98 (0.38, 2.54)		
p-value [1]	0.17		0.96		
Unadjusted Odds Ratio (95% CI)	1.87 (0.78, 4.49)		0.97 (0.30, 3.14)		
p-value [1]	0.16		0.96		
Unadjusted Absolute Risk Difference (95% CI)	0.12 (-0.05, 0.29)		0.00 (-0.18, 0.17)		
Interaction test for Treatment*Region [2]					0.42

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.2807: Any Serious TE AESI by Baseline Hemoglobin Level
Double-Blind Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Number of subjects, n(%)	10 (35.7%)	5 (23.8%)	14 (24.1%)	14 (19.2%)	
Unadjusted Relative Risk (95% CI)	1.50 (0.60, 3.74)		1.26 (0.65, 2.42)		
p-value [1]	0.38		0.49		
Unadjusted Odds Ratio (95% CI)	1.78 (0.50, 6.31)		1.34 (0.58, 3.10)		
p-value [1]	0.37		0.49		
Unadjusted Absolute Risk Difference (95% CI)	0.12 (-0.14, 0.37)		0.05 (-0.09, 0.19)		
Interaction test for Treatment*Baseline Hemoglobin Level Group [2]					0.76

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-aesi-sub-gba.sas V.03.05 Output file: t-aesum-aesi-ser-gba-hgb.pdf 29AUG2023: 8:56

Table 3.2806: Any Serious TE AESI by Baseline IPSS Two-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Number of subjects, n(%)	8 (28.6%)	3 (12.5%)	16 (27.6%)	16 (22.9%)	
Unadjusted Relative Risk (95% CI)	2.29 (0.68, 7.66)		1.21 (0.66, 2.20)		
p-value [1]	0.18		0.54		
Unadjusted Odds Ratio (95% CI)	2.80 (0.65, 12.07)		1.29 (0.58, 2.87)		
p-value [1]	0.17		0.54		
Unadjusted Absolute Risk Difference (95% CI)	0.16 (-0.05, 0.37)		0.05 (-0.10, 0.20)		
Interaction test for Treatment*Baseline IPSS 2-Level Risk [2]					0.32

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.2805: Any Serious TE AESI by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Number of subjects, n(%)	0	1 (25.0%)	8 (30.8%)	2 (10.0%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.2805: Any Serious TE AESI by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=58)	RUX (N=70)	p-value
Number of subjects, n(%)	16 (27.6%)	16 (22.9%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-aesi-sub-gba.sas V.03.05 Output file: t-aesum-aesi-ser-gba-ipss3.pdf 29AUG2023: 8:56

Table 3.2808: Any Serious TE AESI by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
Number of subjects, n(%)	17 (28.8%)	9 (16.7%)	2 (12.5%)	7 (25.0%)
Unadjusted Relative Risk (95% CI)	1.73 (0.84, 3.55)		0.50 (0.12, 2.12)	
p-value [1]	0.14		0.35	
Unadjusted Odds Ratio (95% CI)	2.02 (0.81, 5.03)		0.43 (0.08, 2.37)	
p-value [1]	0.13		0.33	
Unadjusted Absolute Risk Difference (95% CI)	0.12 (-0.03, 0.27)		-0.13 (-0.35, 0.10)	
Interaction test for Treatment*Myelofibrosis Disease Type [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-aesi-sub-gba.sas V.03.05 Output file: t-aesum-aesi-ser-gba-mf.pdf 29AUG2023: 8:56

Table 3.2808: Any Serious TE AESI by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=11)	RUX (N=12)	p-value
Number of subjects, n(%)	5 (45.5%)	3 (25.0%)	
Unadjusted Relative Risk (95% CI)	1.82 (0.56, 5.88)		
p-value [1]	0.32		
Unadjusted Odds Ratio (95% CI)	2.50 (0.43, 14.61)		
p-value [1]	0.31		
Unadjusted Absolute Risk Difference (95% CI)	0.20 (-0.18, 0.59)		
Interaction test for Treatment*Myelofibrosis Disease Type [2]			0.23

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.2803: Any Serious TE AESI by Gender
Double-Blind Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Number of subjects, n(%)	18 (36.0%)	15 (26.8%)	6 (16.7%)	4 (10.5%)	
Unadjusted Relative Risk (95% CI)	1.34 (0.76, 2.37)		1.58 (0.49, 5.15)		
p-value [1]	0.31		0.45		
Unadjusted Odds Ratio (95% CI)	1.54 (0.67, 3.51)		1.70 (0.44, 6.60)		
p-value [1]	0.31		0.44		
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.08, 0.27)		0.06 (-0.09, 0.22)		
Interaction test for Treatment*Gender [2]					0.80

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.2810: Any Serious TE AESI by Baseline Spleen Volume
Double-Blind Phase
SAF-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Number of subjects, n(%)	13 (27.7%)	10 (23.3%)	11 (28.2%)	9 (17.6%)	
Unadjusted Relative Risk (95% CI)	1.19 (0.58, 2.43)		1.60 (0.74, 3.47)		
p-value [1]	0.63		0.24		
Unadjusted Odds Ratio (95% CI)	1.26 (0.49, 3.27)		1.83 (0.67, 5.00)		
p-value [1]	0.63		0.24		
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.14, 0.22)		0.11 (-0.07, 0.28)		
Interaction test for Treatment*Baseline Spleen Volume Group [2]					0.58

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.2809: Any Serious TE AESI by Baseline TSS
Double-Blind Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Number of subjects, n(%)	9 (20.5%)	12 (21.8%)	15 (36.6%)	7 (18.4%)	
Unadjusted Relative Risk (95% CI)	0.94 (0.43, 2.02)		1.99 (0.91, 4.34)		
p-value [1]	0.87		0.085		
Unadjusted Odds Ratio (95% CI)	0.92 (0.35, 2.44)		2.55 (0.91, 7.21)		
p-value [1]	0.87		0.076		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.18, 0.15)		0.18 (-0.01, 0.37)		
Interaction test for Treatment*Baseline TSS Group [2]					0.17

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest (Peripheral Neuropathy SMQ (Narrow Terms Only), Non-Hematological MST, Cataract MST or First Dose Effect). Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-aesi-sub-gba.sas V.03.05 Output file: t-aesum-aesi-ser-gba-tss.pdf 29AUG2023: 8:56

Table 3.3002: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) by Age
Double-Blind Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Number of subjects, n(%)	5 (20.8%)	1 (2.8%)	5 (8.1%)	4 (6.9%)	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Age Group [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-pn-sub-gba.sas V.03.05 Output file: t-aesum-pn-gba-age.pdf 29AUG2023: 8:55

Table 3.3004: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) by Region
Double-Blind Phase
SAF-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Number of subjects, n(%)	8 (15.1%)	3 (5.9%)	2 (6.1%)	2 (4.7%)	
Unadjusted Relative Risk (95% CI)	2.57 (0.72, 9.14)		1.30 (0.19, 8.77)		
p-value [1]	0.15		0.79		
Unadjusted Odds Ratio (95% CI)	2.84 (0.71, 11.40)		1.32 (0.18, 9.92)		
p-value [1]	0.14		0.79		
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.02, 0.21)		0.01 (-0.09, 0.12)		
Interaction test for Treatment*Region [2]					0.57

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.3007: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) by Baseline Hemoglobin Level
Double-Blind Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Number of subjects, n(%)	2 (7.1%)	0	8 (13.8%)	5 (6.8%)	
Unadjusted Relative Risk (95% CI)	3.79 (0.19, 75.08)		2.01 (0.70, 5.83)		
p-value [1]	0.38		0.20		
Unadjusted Odds Ratio (95% CI)	4.06 (0.18, 89.09)		2.18 (0.67, 7.05)		
p-value [1]	0.37		0.19		
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.06, 0.18)		0.07 (-0.04, 0.18)		
Interaction test for Treatment*Baseline Hemoglobin Level Group [2]					NE

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Modified Poisson regression model did not converge so these values are presented as NE.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-pn-sub-gba.sas V.03.05 Output file: t-aesum-pn-gba-hgb.pdf 29AUG2023: 8:56

Table 3.3006: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) by Baseline IPSS Two-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Number of subjects, n(%)	6 (21.4%)	2 (8.3%)	4 (6.9%)	3 (4.3%)	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Baseline IPSS 2-Level Risk [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-pn-sub-gba.sas V.03.05 Output file: t-aesum-pn-gba-ipss2.pdf 29AUG2023: 8:56

Table 3.3005: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Number of subjects, n(%)	0	0	6 (23.1%)	2 (10.0%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-pn-sub-gba.sas V.03.05 Output file: t-aesum-pn-gba-ipss3.pdf 29AUG2023: 8:55

Table 3.3005: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=58)	RUX (N=70)	p-value
Number of subjects, n(%)	4 (6.9%)	3 (4.3%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-pn-sub-gba.sas V.03.05 Output file: t-aesum-pn-gba-ipss3.pdf 29AUG2023: 8:55

Table 3.3008: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
Number of subjects, n(%)	8 (13.6%)	2 (3.7%)	1 (6.3%)	2 (7.1%)
Unadjusted Relative Risk (95% CI)	3.66 (0.81, 16.49)		0.88 (0.09, 8.91)	
p-value [1]	0.091		0.91	
Unadjusted Odds Ratio (95% CI)	4.08 (0.83, 20.14)		0.87 (0.07, 10.38)	
p-value [1]	0.084		0.91	
Unadjusted Absolute Risk Difference (95% CI)	0.10 (0.00, 0.20)		-0.01 (-0.16, 0.14)	
Interaction test for Treatment*Myelofibrosis Disease Type [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-pn-sub-gba.sas V.03.05 Output file: t-aesum-pn-gba-mf.pdf 29AUG2023: 8:56

Table 3.3008: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=11)	RUX (N=12)	p-value
Number of subjects, n(%)	1 (9.1%)	1 (8.3%)	
Unadjusted Relative Risk (95% CI)	1.09 (0.08, 15.42)		
p-value [1]	0.95		
Unadjusted Odds Ratio (95% CI)	1.10 (0.06, 20.01)		
p-value [1]	0.95		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.22, 0.24)		
Interaction test for Treatment*Myelofibrosis Disease Type [2]			0.51

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-pn-sub-gba.sas V.03.05 Output file: t-aesum-pn-gba-mf.pdf 29AUG2023: 8:56

Table 3.3003: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) by Gender
Double-Blind Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Number of subjects, n(%)	6 (12.0%)	2 (3.6%)	4 (11.1%)	3 (7.9%)	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Gender [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-pn-sub-gba.sas V.03.05 Output file: t-aesum-pn-gba-sex.pdf 29AUG2023: 8:55

Table 3.3010: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) by Baseline Spleen Volume
Double-Blind Phase
SAF-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Number of subjects, n(%)	6 (12.8%)	4 (9.3%)	4 (10.3%)	1 (2.0%)	
Unadjusted Relative Risk (95% CI)	1.37 (0.42, 4.54)		5.23 (0.61, 44.96)		
p-value [1]	0.60		0.13		
Unadjusted Odds Ratio (95% CI)	1.43 (0.37, 5.44)		5.71 (0.61, 53.33)		
p-value [1]	0.60		0.13		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.09, 0.16)		0.08 (-0.02, 0.19)		
Interaction test for Treatment*Baseline Spleen Volume Group [2]					0.25

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-pn-sub-gba.sas V.03.05 Output file: t-aesum-pn-gba-svb.pdf 29AUG2023: 8:56

Table 3.3009: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) by Baseline TSS
Double-Blind Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Number of subjects, n(%)	6 (13.6%)	3 (5.5%)	4 (9.8%)	2 (5.3%)	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Baseline TSS Group [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-pn-sub-gba.sas V.03.05 Output file: t-aesum-pn-gba-tss.pdf 29AUG2023: 8:56

Table 3.3202: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) of Grade 3 or more by Age
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.

Data Extracted: CRF data: 01JUL2019

Table 3.3204: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) of Grade 3 or more by Region
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.

Data Extracted: CRF data: 01JUL2019

Table 3.3207: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) of Grade 3 or more by Baseline Hemoglobin Level
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-pn-sub-gba.sas V.03.05 Output file: t-aesum-pn-gge3-gba-hgb.pdf 29AUG2023: 8:56

Table 3.3206: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) of Grade 3 or more by Baseline IPSS Two-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.

Data Extracted: CRF data: 01JUL2019

Table 3.3205: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) of Grade 3 or more by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.

Data Extracted: CRF data: 01JUL2019

Table 3.3208: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) of Grade 3 or more by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-pn-sub-gba.sas V.03.05 Output file: t-aesum-pn-gge3-gba-mf.pdf 29AUG2023: 8:56

Table 3.3203: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) of Grade 3 or more by Gender
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-pn-sub-gba.sas V.03.05 Output file: t-aesum-pn-gge3-gba-sex.pdf 29AUG2023: 8:56

Table 3.3210: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) of Grade 3 or more by Baseline Spleen Volume
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.

Data Extracted: CRF data: 01JUL2019

Table 3.3209: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) of Grade 3 or more by Baseline TSS
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-pn-sub-gba.sas V.03.05 Output file: t-aesum-pn-gge3-gba-tss.pdf 29AUG2023: 8:56

Table 3.3102: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) of Grade 2 or less by Age
Double-Blind Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Number of subjects, n(%)	5 (20.8%)	1 (2.8%)	5 (8.1%)	4 (6.9%)	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Age Group [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-pn-sub-gba.sas V.03.05 Output file: t-aesum-pn-gle2-gba-age.pdf 29AUG2023: 8:56

Table 3.3104: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) of Grade 2 or less by Region
Double-Blind Phase
SAF-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Number of subjects, n(%)	8 (15.1%)	3 (5.9%)	2 (6.1%)	2 (4.7%)	
Unadjusted Relative Risk (95% CI)	2.57 (0.72, 9.14)		1.30 (0.19, 8.77)		
p-value [1]	0.15		0.79		
Unadjusted Odds Ratio (95% CI)	2.84 (0.71, 11.40)		1.32 (0.18, 9.92)		
p-value [1]	0.14		0.79		
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.02, 0.21)		0.01 (-0.09, 0.12)		
Interaction test for Treatment*Region [2]					0.57

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.3107: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) of Grade 2 or less by Baseline Hemoglobin Level
Double-Blind Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Number of subjects, n(%)	2 (7.1%)	0	8 (13.8%)	5 (6.8%)	
Unadjusted Relative Risk (95% CI)	3.79 (0.19, 75.08)		2.01 (0.70, 5.83)		
p-value [1]	0.38		0.20		
Unadjusted Odds Ratio (95% CI)	4.06 (0.18, 89.09)		2.18 (0.67, 7.05)		
p-value [1]	0.37		0.19		
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.06, 0.18)		0.07 (-0.04, 0.18)		
Interaction test for Treatment*Baseline Hemoglobin Level Group [2]					NE

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Modified Poisson regression model did not converge so these values are presented as NE.

Data Extracted: CRF data: 01JUL2019

Table 3.3106: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) of Grade 2 or less by Baseline IPSS Two-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Number of subjects, n(%)	6 (21.4%)	2 (8.3%)	4 (6.9%)	3 (4.3%)	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Baseline IPSS 2-Level Risk [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.3105: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) of Grade 2 or less by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Number of subjects, n(%)	0	0	6 (23.1%)	2 (10.0%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.3105: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) of Grade 2 or less by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=58)	RUX (N=70)	p-value
Number of subjects, n(%)	4 (6.9%)	3 (4.3%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.3108: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) of Grade 2 or less by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
Number of subjects, n(%)	8 (13.6%)	2 (3.7%)	1 (6.3%)	2 (7.1%)
Unadjusted Relative Risk (95% CI)	3.66 (0.81, 16.49)		0.88 (0.09, 8.91)	
p-value [1]	0.091		0.91	
Unadjusted Odds Ratio (95% CI)	4.08 (0.83, 20.14)		0.87 (0.07, 10.38)	
p-value [1]	0.084		0.91	
Unadjusted Absolute Risk Difference (95% CI)	0.10 (0.00, 0.20)		-0.01 (-0.16, 0.14)	
Interaction test for Treatment*Myelofibrosis Disease Type [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-pn-sub-gba.sas V.03.05 Output file: t-aesum-pn-gle2-gba-mf.pdf 29AUG2023: 8:56

Table 3.3108: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) of Grade 2 or less by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=11)	RUX (N=12)	p-value
Number of subjects, n(%)	1 (9.1%)	1 (8.3%)	
Unadjusted Relative Risk (95% CI)	1.09 (0.08, 15.42)		
p-value [1]	0.95		
Unadjusted Odds Ratio (95% CI)	1.10 (0.06, 20.01)		
p-value [1]	0.95		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.22, 0.24)		
Interaction test for Treatment*Myelofibrosis Disease Type [2]			0.51

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.3103: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) of Grade 2 or less by Gender
Double-Blind Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Number of subjects, n(%)	6 (12.0%)	2 (3.6%)	4 (11.1%)	3 (7.9%)	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Gender [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.3110: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) of Grade 2 or less by Baseline Spleen Volume
Double-Blind Phase
SAF-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Number of subjects, n(%)	6 (12.8%)	4 (9.3%)	4 (10.3%)	1 (2.0%)	
Unadjusted Relative Risk (95% CI)	1.37 (0.42, 4.54)		5.23 (0.61, 44.96)		
p-value [1]	0.60		0.13		
Unadjusted Odds Ratio (95% CI)	1.43 (0.37, 5.44)		5.71 (0.61, 53.33)		
p-value [1]	0.60		0.13		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.09, 0.16)		0.08 (-0.02, 0.19)		
Interaction test for Treatment*Baseline Spleen Volume Group [2]					0.25

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-pn-sub-gba.sas V.03.05 Output file: t-aesum-pn-gle2-gba-svb.pdf 29AUG2023: 8:56

Table 3.3109: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) of Grade 2 or less by Baseline TSS
Double-Blind Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Number of subjects, n(%)	6 (13.6%)	3 (5.5%)	4 (9.8%)	2 (5.3%)	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Baseline TSS Group [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-pn-sub-gba.sas V.03.05 Output file: t-aesum-pn-gle2-gba-tss.pdf 29AUG2023: 8:56

Table 3.3302: Serious TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) by Age
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-pn-sub-gba.sas V.03.05 Output file: t-aesum-pn-ser-gba-age.pdf 29AUG2023: 8:57

Table 3.3304: Serious TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) by Region
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 01JUL2019

Table 3.3307: Serious TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) by Baseline Hemoglobin Level
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-pn-sub-gba.sas V.03.05 Output file: t-aesum-pn-ser-gba-hgb.pdf 29AUG2023: 8:57

Table 3.3306: Serious TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) by Baseline IPSS Two-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-pn-sub-gba.sas V.03.05 Output file: t-aesum-pn-ser-gba-ipss2.pdf 29AUG2023: 8:57

Table 3.3305: Serious TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-pn-sub-gba.sas V.03.05 Output file: t-aesum-pn-ser-gba-ipss3.pdf 29AUG2023: 8:57

Table 3.3308: Serious TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 01JUL2019

Table 3.3303: Serious TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) by Gender
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 01JUL2019

Table 3.3310: Serious TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) by Baseline Spleen Volume
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 01JUL2019

Table 3.3309: Serious TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) by Baseline TSS
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 01JUL2019

Table 3.3402: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) leading to discontinuation of MMB\MMB Matched Placebo by Age
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 01JUL2019

Table 3.3404: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) leading to discontinuation of MMB\MMB Matched Placebo by Region
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 01JUL2019

Table 3.3407: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) leading to discontinuation of MMB\MMB Matched Placebo
by Baseline Hemoglobin Level
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 01JUL2019

Table 3.3406: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) leading to discontinuation of MMB\MMB Matched Placebo
by Baseline IPSS Two-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-pn-sub-gba.sas V.03.05 Output file: t-aesum-pn-dctmb-gba-ipss2.pdf 29AUG2023: 8:57

Table 3.3405: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) leading to discontinuation of MMB\MMB Matched Placebo
by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 01JUL2019

Table 3.3408: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) leading to discontinuation of MMB\MMB Matched Placebo
by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 01JUL2019

Table 3.3403: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) leading to discontinuation of MMB\MMB Matched Placebo by Gender
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-pn-sub-gba.sas V.03.05 Output file: t-aesum-pn-dctmb-gba-sex.pdf 29AUG2023: 8:57

Table 3.3410: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) leading to discontinuation of MMB\MMB Matched Placebo by Baseline Spleen Volume
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 01JUL2019

Table 3.3409: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) leading to discontinuation of MMB\MMB Matched Placebo by Baseline TSS
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-pn-sub-gba.sas V.03.05 Output file: t-aesum-pn-dctmb-gba-tss.pdf 29AUG2023: 8:57

Table 3.4702: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) leading to discontinuation of RUX\RUX Matched Placebo by Age
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 01JUL2019

Table 3.4704: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) leading to discontinuation of RUX\RUX Matched Placebo by Region
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 01JUL2019

Table 3.4707: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) leading to discontinuation of RUX\RUX Matched Placebo
by Baseline Hemoglobin Level
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-pn-sub-gba.sas V.03.05 Output file: t-aesum-pn-dctrx-gba-hgb.pdf 29AUG2023: 8:58

Table 3.4706: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) leading to discontinuation of RUX\RUX Matched Placebo
by Baseline IPSS Two-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 01JUL2019

Table 3.4705: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) leading to discontinuation of RUX\RUX Matched Placebo
by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 01JUL2019

Table 3.4708: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) leading to discontinuation of RUX\RUX Matched Placebo
by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 01JUL2019

Table 3.4703: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) leading to discontinuation of RUX\RUX Matched Placebo by Gender
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 01JUL2019

Table 3.4710: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) leading to discontinuation of RUX\RUX Matched Placebo by Baseline Spleen Volume
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 01JUL2019

Table 3.4709: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) leading to discontinuation of RUX\RUX Matched Placebo by Baseline TSS
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-pn-sub-gba.sas V.03.05 Output file: t-aesum-pn-dctrx-gba-tss.pdf 29AUG2023: 8:58

Table 3.3502: TEAEs of Non-Hematological MST by Age
Double-Blind Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Number of subjects, n(%)	21 (87.5%)	32 (88.9%)	58 (93.5%)	56 (96.6%)	
Unadjusted Relative Risk (95% CI)	0.98 (0.81, 1.19)		0.97 (0.89, 1.05)		
p-value [1]	0.87		0.45		
Unadjusted Odds Ratio (95% CI)	0.88 (0.18, 4.31)		0.52 (0.09, 2.94)		
p-value [1]	0.87		0.46		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.18, 0.15)		-0.03 (-0.11, 0.05)		
Interaction test for Treatment*Age Group [2]					0.88

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-gba-age.pdf 29AUG2023: 8:55

Table 3.3504: TEAEs of Non-Hematological MST by Region
Double-Blind Phase
SAF-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Number of subjects, n(%)	53 (100.0%)	50 (98.0%)	26 (78.8%)	38 (88.4%)	
Unadjusted Relative Risk (95% CI)	1.02 (0.97, 1.08)		0.89 (0.72, 1.10)		
p-value [1]	0.46		0.28		
Unadjusted Odds Ratio (95% CI)	3.18 (0.13, 79.84)		0.49 (0.14, 1.71)		
p-value [1]	0.48		0.26		
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.03, 0.07)		-0.10 (-0.27, 0.07)		
Interaction test for Treatment*Region [2]					0.20

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-gba-geo.pdf 29AUG2023: 8:55

Table 3.3507: TEAEs of Non-Hematological MST by Baseline Hemoglobin Level
Double-Blind Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Number of subjects, n(%)	26 (92.9%)	19 (90.5%)	53 (91.4%)	69 (94.5%)	
Unadjusted Relative Risk (95% CI)	1.03 (0.86, 1.22)		0.97 (0.88, 1.06)		
p-value [1]	0.77		0.49		
Unadjusted Odds Ratio (95% CI)	1.37 (0.18, 10.60)		0.61 (0.16, 2.40)		
p-value [1]	0.76		0.48		
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.13, 0.18)		-0.03 (-0.12, 0.06)		
Interaction test for Treatment*Baseline Hemoglobin Level Group [2]					0.55

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-gba-hgb.pdf 29AUG2023: 8:55

Table 3.3506: TEAEs of Non-Hematological MST by Baseline IPSS Two-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Number of subjects, n(%)	25 (89.3%)	24 (100.0%)	54 (93.1%)	64 (91.4%)	
Unadjusted Relative Risk (95% CI)	0.90 (0.78, 1.04)		1.02 (0.92, 1.13)		
p-value [1]	0.15		0.72		
Unadjusted Odds Ratio (95% CI)	0.15 (0.01, 3.03)		1.27 (0.34, 4.72)		
p-value [1]	0.22		0.73		
Unadjusted Absolute Risk Difference (95% CI)	-0.10 (-0.23, 0.03)		0.02 (-0.08, 0.11)		
Interaction test for Treatment*Baseline IPSS 2-Level Risk [2]					0.11

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-gba-ipss2.pdf 29AUG2023: 8:55

Table 3.3505: TEAEs of Non-Hematological MST by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Number of subjects, n(%)	2 (100.0%)	4 (100.0%)	23 (88.5%)	20 (100.0%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-gba-ipss3.pdf 29AUG2023: 8:55

Table 3.3505: TEAEs of Non-Hematological MST by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=58)	RUX (N=70)	p-value
Number of subjects, n(%)	54 (93.1%)	64 (91.4%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-gba-ipss3.pdf 29AUG2023: 8:55

Table 3.3508: TEAEs of Non-Hematological MST by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
Number of subjects, n(%)	55 (93.2%)	50 (92.6%)	14 (87.5%)	27 (96.4%)
Unadjusted Relative Risk (95% CI)	1.01 (0.91, 1.12)		0.91 (0.74, 1.11)	
p-value [1]	0.90		0.34	
Unadjusted Odds Ratio (95% CI)	1.10 (0.26, 4.63)		0.26 (0.02, 3.11)	
p-value [1]	0.90		0.29	
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.09, 0.10)		-0.09 (-0.27, 0.09)	
Interaction test for Treatment*Myelofibrosis Disease Type [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-gba-mf.pdf 29AUG2023: 8:55

Table 3.3508: TEAEs of Non-Hematological MST by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=11)	RUX (N=12)	p-value
Number of subjects, n(%)	10 (90.9%)	11 (91.7%)	
Unadjusted Relative Risk (95% CI)	0.99 (0.77, 1.28)		
p-value [1]	0.95		
Unadjusted Odds Ratio (95% CI)	0.91 (0.05, 16.54)		
p-value [1]	0.95		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.24, 0.22)		
Interaction test for Treatment*Myelofibrosis Disease Type [2]			0.65

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-gba-mf.pdf 29AUG2023: 8:55

Table 3.3503: TEAEs of Non-Hematological MST by Gender
Double-Blind Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Number of subjects, n(%)	46 (92.0%)	51 (91.1%)	33 (91.7%)	37 (97.4%)	
Unadjusted Relative Risk (95% CI)	1.01 (0.90, 1.13)		0.94 (0.84, 1.05)		
p-value [1]	0.86		0.29		
Unadjusted Odds Ratio (95% CI)	1.13 (0.29, 4.45)		0.30 (0.03, 3.00)		
p-value [1]	0.86		0.30		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.10, 0.12)		-0.06 (-0.16, 0.05)		
Interaction test for Treatment*Gender [2]					0.39

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-gba-sex.pdf 29AUG2023: 8:55

Table 3.3510: TEAEs of Non-Hematological MST by Baseline Spleen Volume
Double-Blind Phase
SAF-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Number of subjects, n(%)	41 (87.2%)	42 (97.7%)	38 (97.4%)	46 (90.2%)	
Unadjusted Relative Risk (95% CI)	0.89 (0.79, 1.01)		1.08 (0.97, 1.20)		
p-value [1]	0.062		0.14		
Unadjusted Odds Ratio (95% CI)	0.16 (0.02, 1.41)		4.13 (0.46, 36.89)		
p-value [1]	0.099		0.20		
Unadjusted Absolute Risk Difference (95% CI)	-0.10 (-0.21, 0.00)		0.07 (-0.02, 0.17)		
Interaction test for Treatment*Baseline Spleen Volume Group [2]					0.017

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-gba-svb.pdf 29AUG2023: 8:55

Table 3.3509: TEAEs of Non-Hematological MST by Baseline TSS
Double-Blind Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Number of subjects, n(%)	38 (86.4%)	52 (94.5%)	40 (97.6%)	35 (92.1%)	
Unadjusted Relative Risk (95% CI)	0.91 (0.80, 1.04)		1.06 (0.95, 1.18)		
p-value [1]	0.18		0.28		
Unadjusted Odds Ratio (95% CI)	0.37 (0.09, 1.55)		3.43 (0.34, 34.48)		
p-value [1]	0.17		0.30		
Unadjusted Absolute Risk Difference (95% CI)	-0.08 (-0.20, 0.04)		0.05 (-0.04, 0.15)		
Interaction test for Treatment*Baseline TSS Group [2]					0.084

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-gba-tss.pdf 29AUG2023: 8:55

Table 3.3702: TEAEs of Non-Hematological MST of Grade 3 or more by Age
Double-Blind Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Number of subjects, n(%)	5 (20.8%)	5 (13.9%)	28 (45.2%)	21 (36.2%)	
Unadjusted Relative Risk (95% CI)	1.50 (0.49, 4.63)		1.25 (0.80, 1.93)		
p-value [1]	0.48		0.32		
Unadjusted Odds Ratio (95% CI)	1.63 (0.42, 6.39)		1.45 (0.70, 3.02)		
p-value [1]	0.48		0.32		
Unadjusted Absolute Risk Difference (95% CI)	0.07 (-0.13, 0.27)		0.09 (-0.09, 0.26)		
Interaction test for Treatment*Age Group [2]					0.77

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-gge3-gba-age.pdf 29AUG2023: 8:55

Table 3.3704: TEAEs of Non-Hematological MST of Grade 3 or more by Region
Double-Blind Phase
SAF-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Number of subjects, n(%)	24 (45.3%)	17 (33.3%)	9 (27.3%)	9 (20.9%)	
Unadjusted Relative Risk (95% CI)	1.36 (0.83, 2.21)		1.30 (0.58, 2.91)		
p-value [1]	0.22		0.52		
Unadjusted Odds Ratio (95% CI)	1.66 (0.75, 3.66)		1.42 (0.49, 4.10)		
p-value [1]	0.21		0.52		
Unadjusted Absolute Risk Difference (95% CI)	0.12 (-0.07, 0.31)		0.06 (-0.13, 0.26)		
Interaction test for Treatment*Region [2]					0.93

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-gge3-gba-geo.pdf 29AUG2023: 8:55

Table 3.3707: TEAEs of Non-Hematological MST of Grade 3 or more by Baseline Hemoglobin Level
Double-Blind Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Number of subjects, n(%)	15 (53.6%)	8 (38.1%)	18 (31.0%)	18 (24.7%)	
Unadjusted Relative Risk (95% CI)	1.41 (0.74, 2.68)		1.26 (0.72, 2.19)		
p-value [1]	0.30		0.42		
Unadjusted Odds Ratio (95% CI)	1.88 (0.59, 5.93)		1.38 (0.64, 2.97)		
p-value [1]	0.28		0.42		
Unadjusted Absolute Risk Difference (95% CI)	0.15 (-0.12, 0.43)		0.06 (-0.09, 0.22)		
Interaction test for Treatment*Baseline Hemoglobin Level Group [2]					0.80

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.3706: TEAEs of Non-Hematological MST of Grade 3 or more by Baseline IPSS Two-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Number of subjects, n(%)	7 (25.0%)	5 (20.8%)	26 (44.8%)	21 (30.0%)	
Unadjusted Relative Risk (95% CI)	1.20 (0.44, 3.29)		1.49 (0.95, 2.36)		
p-value [1]	0.72		0.086		
Unadjusted Odds Ratio (95% CI)	1.27 (0.34, 4.67)		1.90 (0.92, 3.92)		
p-value [1]	0.72		0.085		
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.19, 0.27)		0.15 (-0.02, 0.32)		
Interaction test for Treatment*Baseline IPSS 2-Level Risk [2]					0.70

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.3705: TEAEs of Non-Hematological MST of Grade 3 or more by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Number of subjects, n(%)	1 (50.0%)	1 (25.0%)	6 (23.1%)	4 (20.0%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.3705: TEAEs of Non-Hematological MST of Grade 3 or more by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=58)	RUX (N=70)	p-value
Number of subjects, n(%)	26 (44.8%)	21 (30.0%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.3708: TEAEs of Non-Hematological MST of Grade 3 or more by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
Number of subjects, n(%)	22 (37.3%)	11 (20.4%)	6 (37.5%)	11 (39.3%)
Unadjusted Relative Risk (95% CI)	1.83 (0.98, 3.41)		0.95 (0.44, 2.09)	
p-value [1]	0.057		0.91	
Unadjusted Odds Ratio (95% CI)	2.32 (1.00, 5.42)		0.93 (0.26, 3.28)	
p-value [1]	0.051		0.91	
Unadjusted Absolute Risk Difference (95% CI)	0.17 (0.01, 0.33)		-0.02 (-0.32, 0.28)	
Interaction test for Treatment*Myelofibrosis Disease Type [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-gge3-gba-mf.pdf 29AUG2023: 8:56

Table 3.3708: TEAEs of Non-Hematological MST of Grade 3 or more by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=11)	RUX (N=12)	p-value
Number of subjects, n(%)	5 (45.5%)	4 (33.3%)	
Unadjusted Relative Risk (95% CI)	1.36 (0.49, 3.82)		
p-value [1]	0.55		
Unadjusted Odds Ratio (95% CI)	1.67 (0.31, 9.01)		
p-value [1]	0.55		
Unadjusted Absolute Risk Difference (95% CI)	0.12 (-0.28, 0.52)		
Interaction test for Treatment*Myelofibrosis Disease Type [2]			0.42

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-gge3-gba-mf.pdf 29AUG2023: 8:56

Table 3.3703: TEAEs of Non-Hematological MST of Grade 3 or more by Gender
Double-Blind Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Number of subjects, n(%)	23 (46.0%)	14 (25.0%)	10 (27.8%)	12 (31.6%)	
Unadjusted Relative Risk (95% CI)	1.84 (1.07, 3.17)		0.88 (0.43, 1.78)		
p-value [1]	0.028		0.72		
Unadjusted Odds Ratio (95% CI)	2.56 (1.12, 5.81)		0.83 (0.31, 2.27)		
p-value [1]	0.025		0.72		
Unadjusted Absolute Risk Difference (95% CI)	0.21 (0.03, 0.39)		-0.04 (-0.25, 0.17)		
Interaction test for Treatment*Gender [2]					0.11

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-gge3-gba-sex.pdf 29AUG2023: 8:55

Table 3.3710: TEAEs of Non-Hematological MST of Grade 3 or more by Baseline Spleen Volume
Double-Blind Phase
SAF-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Number of subjects, n(%)	14 (29.8%)	11 (25.6%)	19 (48.7%)	15 (29.4%)	
Unadjusted Relative Risk (95% CI)	1.16 (0.59, 2.28)		1.66 (0.97, 2.82)		
p-value [1]	0.66		0.064		
Unadjusted Odds Ratio (95% CI)	1.23 (0.49, 3.12)		2.28 (0.96, 5.44)		
p-value [1]	0.66		0.063		
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.14, 0.23)		0.19 (-0.01, 0.39)		
Interaction test for Treatment*Baseline Spleen Volume Group [2]					0.43

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.3709: TEAEs of Non-Hematological MST of Grade 3 or more by Baseline TSS
Double-Blind Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Number of subjects, n(%)	13 (29.5%)	11 (20.0%)	20 (48.8%)	14 (36.8%)	
Unadjusted Relative Risk (95% CI)	1.48 (0.73, 2.97)		1.32 (0.79, 2.23)		
p-value [1]	0.27		0.29		
Unadjusted Odds Ratio (95% CI)	1.68 (0.67, 4.23)		1.63 (0.66, 4.01)		
p-value [1]	0.27		0.29		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.08, 0.27)		0.12 (-0.10, 0.34)		
Interaction test for Treatment*Baseline TSS Group [2]					0.81

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-gge3-gba-tss.pdf 29AUG2023: 8:56

Table 3.3602: TEAEs of Non-Hematological MST of Grade 2 or less by Age
Double-Blind Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Number of subjects, n(%)	21 (87.5%)	32 (88.9%)	55 (88.7%)	55 (94.8%)	
Unadjusted Relative Risk (95% CI)	0.98 (0.81, 1.19)		0.94 (0.84, 1.04)		
p-value [1]	0.87		0.22		
Unadjusted Odds Ratio (95% CI)	0.88 (0.18, 4.31)		0.43 (0.11, 1.74)		
p-value [1]	0.87		0.24		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.18, 0.15)		-0.06 (-0.16, 0.04)		
Interaction test for Treatment*Age Group [2]					0.65

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.3604: TEAEs of Non-Hematological MST of Grade 2 or less by Region
Double-Blind Phase
SAF-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Number of subjects, n(%)	51 (96.2%)	50 (98.0%)	25 (75.8%)	37 (86.0%)	
Unadjusted Relative Risk (95% CI)	0.98 (0.92, 1.05)		0.88 (0.70, 1.11)		
p-value [1]	0.58		0.27		
Unadjusted Odds Ratio (95% CI)	0.51 (0.04, 5.80)		0.51 (0.16, 1.64)		
p-value [1]	0.59		0.26		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.08, 0.05)		-0.10 (-0.28, 0.08)		
Interaction test for Treatment*Region [2]					0.36

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-gle2-gba-geo.pdf 29AUG2023: 8:55

Table 3.3607: TEAEs of Non-Hematological MST of Grade 2 or less by Baseline Hemoglobin Level
Double-Blind Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Number of subjects, n(%)	25 (89.3%)	19 (90.5%)	51 (87.9%)	68 (93.2%)	
Unadjusted Relative Risk (95% CI)	0.99 (0.82, 1.19)		0.94 (0.84, 1.06)		
p-value [1]	0.89		0.32		
Unadjusted Odds Ratio (95% CI)	0.88 (0.13, 5.78)		0.54 (0.16, 1.79)		
p-value [1]	0.89		0.31		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.18, 0.16)		-0.05 (-0.15, 0.05)		
Interaction test for Treatment*Baseline Hemoglobin Level Group [2]					0.69

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.3606: TEAEs of Non-Hematological MST of Grade 2 or less by Baseline IPSS Two-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Number of subjects, n(%)	25 (89.3%)	24 (100.0%)	51 (87.9%)	63 (90.0%)	
Unadjusted Relative Risk (95% CI)	0.90 (0.78, 1.04)		0.98 (0.86, 1.11)		
p-value [1]	0.15		0.71		
Unadjusted Odds Ratio (95% CI)	0.15 (0.01, 3.03)		0.81 (0.27, 2.46)		
p-value [1]	0.22		0.71		
Unadjusted Absolute Risk Difference (95% CI)	-0.10 (-0.23, 0.03)		-0.02 (-0.13, 0.09)		
Interaction test for Treatment*Baseline IPSS 2-Level Risk [2]					0.32

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.3605: TEAEs of Non-Hematological MST of Grade 2 or less by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Number of subjects, n(%)	2 (100.0%)	4 (100.0%)	23 (88.5%)	20 (100.0%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.3605: TEAEs of Non-Hematological MST of Grade 2 or less by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=58)	RUX (N=70)	p-value
Number of subjects, n(%)	51 (87.9%)	63 (90.0%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.3608: TEAEs of Non-Hematological MST of Grade 2 or less by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
Number of subjects, n(%)	53 (89.8%)	50 (92.6%)	13 (81.3%)	26 (92.9%)
Unadjusted Relative Risk (95% CI)	0.97 (0.87, 1.09)		0.88 (0.68, 1.13)	
p-value [1]	0.60		0.31	
Unadjusted Odds Ratio (95% CI)	0.71 (0.19, 2.65)		0.33 (0.05, 2.25)	
p-value [1]	0.61		0.26	
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.13, 0.08)		-0.12 (-0.33, 0.10)	
Interaction test for Treatment*Myelofibrosis Disease Type [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-gle2-gba-mf.pdf 29AUG2023: 8:55

Table 3.3608: TEAEs of Non-Hematological MST of Grade 2 or less by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=11)	RUX (N=12)	p-value
Number of subjects, n(%)	10 (90.9%)	11 (91.7%)	
Unadjusted Relative Risk (95% CI)	0.99 (0.77, 1.28)		
p-value [1]	0.95		
Unadjusted Odds Ratio (95% CI)	0.91 (0.05, 16.54)		
p-value [1]	0.95		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.24, 0.22)		
Interaction test for Treatment*Myelofibrosis Disease Type [2]			0.73

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-gle2-gba-mf.pdf 29AUG2023: 8:55

Table 3.3603: TEAEs of Non-Hematological MST of Grade 2 or less by Gender
Double-Blind Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Number of subjects, n(%)	45 (90.0%)	51 (91.1%)	31 (86.1%)	36 (94.7%)	
Unadjusted Relative Risk (95% CI)	0.99 (0.87, 1.12)		0.91 (0.78, 1.06)		
p-value [1]	0.85		0.22		
Unadjusted Odds Ratio (95% CI)	0.88 (0.24, 3.25)		0.34 (0.06, 1.90)		
p-value [1]	0.85		0.22		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.12, 0.10)		-0.09 (-0.22, 0.05)		
Interaction test for Treatment*Gender [2]					0.40

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-gle2-gba-sex.pdf 29AUG2023: 8:55

Table 3.3610: TEAEs of Non-Hematological MST of Grade 2 or less by Baseline Spleen Volume
Double-Blind Phase
SAF-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Number of subjects, n(%)	39 (83.0%)	41 (95.3%)	37 (94.9%)	46 (90.2%)	
Unadjusted Relative Risk (95% CI)	0.87 (0.75, 1.01)		1.05 (0.94, 1.18)		
p-value [1]	0.061		0.39		
Unadjusted Odds Ratio (95% CI)	0.24 (0.05, 1.19)		2.01 (0.37, 10.96)		
p-value [1]	0.080		0.42		
Unadjusted Absolute Risk Difference (95% CI)	-0.12 (-0.25, 0.00)		0.05 (-0.06, 0.15)		
Interaction test for Treatment*Baseline Spleen Volume Group [2]					0.044

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.3609: TEAEs of Non-Hematological MST of Grade 2 or less by Baseline TSS
Double-Blind Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Number of subjects, n(%)	38 (86.4%)	52 (94.5%)	37 (90.2%)	34 (89.5%)	
Unadjusted Relative Risk (95% CI)	0.91 (0.80, 1.04)		1.01 (0.87, 1.17)		
p-value [1]	0.18		0.91		
Unadjusted Odds Ratio (95% CI)	0.37 (0.09, 1.55)		1.09 (0.25, 4.70)		
p-value [1]	0.17		0.91		
Unadjusted Absolute Risk Difference (95% CI)	-0.08 (-0.20, 0.04)		0.01 (-0.13, 0.14)		
Interaction test for Treatment*Baseline TSS Group [2]					0.33

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-gle2-gba-tss.pdf 29AUG2023: 8:55

Table 3.3802: Serious TEAEs of Non-Hematological MST by Age
Double-Blind Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Number of subjects, n(%)	3 (12.5%)	3 (8.3%)	21 (33.9%)	16 (27.6%)	
Unadjusted Relative Risk (95% CI)	1.50 (0.33, 6.82)		1.23 (0.71, 2.11)		
p-value [1]	0.60		0.46		
Unadjusted Odds Ratio (95% CI)	1.57 (0.29, 8.53)		1.34 (0.62, 2.93)		
p-value [1]	0.60		0.46		
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.12, 0.20)		0.06 (-0.10, 0.23)		
Interaction test for Treatment*Age Group [2]					0.81

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-ser-gba-age.pdf 29AUG2023: 8:56

Table 3.3804: Serious TEAEs of Non-Hematological MST by Region
Double-Blind Phase
SAF-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Number of subjects, n(%)	18 (34.0%)	11 (21.6%)	6 (18.2%)	8 (18.6%)	
Unadjusted Relative Risk (95% CI)	1.57 (0.83, 3.00)		0.98 (0.38, 2.54)		
p-value [1]	0.17		0.96		
Unadjusted Odds Ratio (95% CI)	1.87 (0.78, 4.49)		0.97 (0.30, 3.14)		
p-value [1]	0.16		0.96		
Unadjusted Absolute Risk Difference (95% CI)	0.12 (-0.05, 0.29)		0.00 (-0.18, 0.17)		
Interaction test for Treatment*Region [2]					0.42

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-ser-gba-geo.pdf 29AUG2023: 8:56

Table 3.3807: Serious TEAEs of Non-Hematological MST by Baseline Hemoglobin Level
Double-Blind Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Number of subjects, n(%)	10 (35.7%)	5 (23.8%)	14 (24.1%)	14 (19.2%)	
Unadjusted Relative Risk (95% CI)	1.50 (0.60, 3.74)		1.26 (0.65, 2.42)		
p-value [1]	0.38		0.49		
Unadjusted Odds Ratio (95% CI)	1.78 (0.50, 6.31)		1.34 (0.58, 3.10)		
p-value [1]	0.37		0.49		
Unadjusted Absolute Risk Difference (95% CI)	0.12 (-0.14, 0.37)		0.05 (-0.09, 0.19)		
Interaction test for Treatment*Baseline Hemoglobin Level Group [2]					0.76

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-ser-gba-hgb.pdf 29AUG2023: 8:56

Table 3.3806: Serious TEAEs of Non-Hematological MST by Baseline IPSS Two-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Number of subjects, n(%)	8 (28.6%)	3 (12.5%)	16 (27.6%)	16 (22.9%)	
Unadjusted Relative Risk (95% CI)	2.29 (0.68, 7.66)		1.21 (0.66, 2.20)		
p-value [1]	0.18		0.54		
Unadjusted Odds Ratio (95% CI)	2.80 (0.65, 12.07)		1.29 (0.58, 2.87)		
p-value [1]	0.17		0.54		
Unadjusted Absolute Risk Difference (95% CI)	0.16 (-0.05, 0.37)		0.05 (-0.10, 0.20)		
Interaction test for Treatment*Baseline IPSS 2-Level Risk [2]					0.32

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.3805: Serious TEAEs of Non-Hematological MST by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Number of subjects, n(%)	0	1 (25.0%)	8 (30.8%)	2 (10.0%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-ser-gba-ipss3.pdf 29AUG2023: 8:56

Table 3.3805: Serious TEAEs of Non-Hematological MST by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=58)	RUX (N=70)	p-value
Number of subjects, n(%)	16 (27.6%)	16 (22.9%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.3808: Serious TEAEs of Non-Hematological MST by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
Number of subjects, n(%)	17 (28.8%)	9 (16.7%)	2 (12.5%)	7 (25.0%)
Unadjusted Relative Risk (95% CI)	1.73 (0.84, 3.55)		0.50 (0.12, 2.12)	
p-value [1]	0.14		0.35	
Unadjusted Odds Ratio (95% CI)	2.02 (0.81, 5.03)		0.43 (0.08, 2.37)	
p-value [1]	0.13		0.33	
Unadjusted Absolute Risk Difference (95% CI)	0.12 (-0.03, 0.27)		-0.13 (-0.35, 0.10)	
Interaction test for Treatment*Myelofibrosis Disease Type [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-ser-gba-mf.pdf 29AUG2023: 8:56

Table 3.3808: Serious TEAEs of Non-Hematological MST by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=11)	RUX (N=12)	p-value
Number of subjects, n(%)	5 (45.5%)	3 (25.0%)	
Unadjusted Relative Risk (95% CI)	1.82 (0.56, 5.88)		
p-value [1]	0.32		
Unadjusted Odds Ratio (95% CI)	2.50 (0.43, 14.61)		
p-value [1]	0.31		
Unadjusted Absolute Risk Difference (95% CI)	0.20 (-0.18, 0.59)		
Interaction test for Treatment*Myelofibrosis Disease Type [2]			0.23

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-ser-gba-mf.pdf 29AUG2023: 8:56

Table 3.3803: Serious TEAEs of Non-Hematological MST by Gender
Double-Blind Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Number of subjects, n(%)	18 (36.0%)	15 (26.8%)	6 (16.7%)	4 (10.5%)	
Unadjusted Relative Risk (95% CI)	1.34 (0.76, 2.37)		1.58 (0.49, 5.15)		
p-value [1]	0.31		0.45		
Unadjusted Odds Ratio (95% CI)	1.54 (0.67, 3.51)		1.70 (0.44, 6.60)		
p-value [1]	0.31		0.44		
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.08, 0.27)		0.06 (-0.09, 0.22)		
Interaction test for Treatment*Gender [2]					0.80

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-ser-gba-sex.pdf 29AUG2023: 8:56

Table 3.3810: Serious TEAEs of Non-Hematological MST by Baseline Spleen Volume
Double-Blind Phase
SAF-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Number of subjects, n(%)	13 (27.7%)	10 (23.3%)	11 (28.2%)	9 (17.6%)	
Unadjusted Relative Risk (95% CI)	1.19 (0.58, 2.43)		1.60 (0.74, 3.47)		
p-value [1]	0.63		0.24		
Unadjusted Odds Ratio (95% CI)	1.26 (0.49, 3.27)		1.83 (0.67, 5.00)		
p-value [1]	0.63		0.24		
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.14, 0.22)		0.11 (-0.07, 0.28)		
Interaction test for Treatment*Baseline Spleen Volume Group [2]					0.58

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-ser-gba-svb.pdf 29AUG2023: 8:56

Table 3.3809: Serious TEAEs of Non-Hematological MST by Baseline TSS
Double-Blind Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Number of subjects, n(%)	9 (20.5%)	12 (21.8%)	15 (36.6%)	7 (18.4%)	
Unadjusted Relative Risk (95% CI)	0.94 (0.43, 2.02)		1.99 (0.91, 4.34)		
p-value [1]	0.87		0.085		
Unadjusted Odds Ratio (95% CI)	0.92 (0.35, 2.44)		2.55 (0.91, 7.21)		
p-value [1]	0.87		0.076		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.18, 0.15)		0.18 (-0.01, 0.37)		
Interaction test for Treatment*Baseline TSS Group [2]					0.17

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-ser-gba-tss.pdf 29AUG2023: 8:56

Table 3.3902: TEAEs of Cataract MST by Age
Double-Blind Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Number of subjects, n(%)	1 (4.2%)	1 (2.8%)	2 (3.2%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Age Group [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.3904: TEAEs of Cataract MST by Region
Double-Blind Phase
SAF-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Number of subjects, n(%)	1 (1.9%)	0	2 (6.1%)	1 (2.3%)	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Region [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
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Table 3.3907: TEAEs of Cataract MST by Baseline Hemoglobin Level
Double-Blind Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Number of subjects, n(%)	2 (7.1%)	1 (4.8%)	1 (1.7%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Baseline Hemoglobin Level Group [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-cat-sub-gba.sas V.03.05 Output file: t-aesum-cat-gba-hgb.pdf 29AUG2023: 9:42

Table 3.3906: TEAEs of Cataract MST by Baseline IPSS Two-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Number of subjects, n(%)	1 (3.6%)	1 (4.2%)	2 (3.4%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Baseline IPSS 2-Level Risk [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-cat-sub-gba.sas V.03.05 Output file: t-aesum-cat-gba-ipss2.pdf 29AUG2023: 9:42

Table 3.3905: TEAEs of Cataract MST by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Number of subjects, n(%)	0	0	1 (3.8%)	1 (5.0%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-cat-sub-gba.sas V.03.05 Output file: t-aesum-cat-gba-ipss3.pdf 29AUG2023: 9:42

Table 3.3905: TEAEs of Cataract MST by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=58)	RUX (N=70)	p-value
Number of subjects, n(%)	2 (3.4%)	0	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-cat-sub-gba.sas V.03.05 Output file: t-aesum-cat-gba-ipss3.pdf 29AUG2023: 9:42

Table 3.3908: TEAEs of Cataract MST by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
Number of subjects, n(%)	2 (3.4%)	0	0	1 (3.6%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Myelofibrosis Disease Type [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-cat-sub-gba.sas V.03.05 Output file: t-aesum-cat-gba-mf.pdf 29AUG2023: 9:42

Table 3.3908: TEAEs of Cataract MST by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=11)	RUX (N=12)	p-value
Number of subjects, n(%)	1 (9.1%)	0	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Myelofibrosis Disease Type [2]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-cat-sub-gba.sas V.03.05 Output file: t-aesum-cat-gba-mf.pdf 29AUG2023: 9:42

Table 3.3903: TEAEs of Cataract MST by Gender
Double-Blind Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Number of subjects, n(%)	3 (6.0%)	1 (1.8%)	0	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Gender [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.3910: TEAEs of Cataract MST by Baseline Spleen Volume
Double-Blind Phase
SAF-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Number of subjects, n(%)	1 (2.1%)	0	2 (5.1%)	1 (2.0%)	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Baseline Spleen Volume Group [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-cat-sub-gba.sas V.03.05 Output file: t-aesum-cat-gba-svb.pdf 29AUG2023: 9:42

Table 3.3909: TEAEs of Cataract MST by Baseline TSS
Double-Blind Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Number of subjects, n(%)	2 (4.5%)	1 (1.8%)	1 (2.4%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Baseline TSS Group [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.4102: TEAEs of Cataract MST of Grade 3 or more by Age
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-cat-sub-gba.sas V.03.05 Output file: t-aesum-cat-gge3-gba-age.pdf 29AUG2023: 9:42

Table 3.4104: TEAEs of Cataract MST of Grade 3 or more by Region
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-cat-sub-gba.sas V.03.05 Output file: t-aesum-cat-gge3-gba-geo.pdf 29AUG2023: 9:43

Table 3.4107: TEAEs of Cataract MST of Grade 3 or more by Baseline Hemoglobin Level
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-cat-sub-gba.sas V.03.05 Output file: t-aesum-cat-gge3-gba-hgb.pdf 29AUG2023: 9:43

Table 3.4106: TEAEs of Cataract MST of Grade 3 or more by Baseline IPSS Two-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-cat-sub-gba.sas V.03.05 Output file: t-aesum-cat-gge3-gba-ipss2.pdf 29AUG2023: 9:43

Table 3.4105: TEAEs of Cataract MST of Grade 3 or more by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-cat-sub-gba.sas V.03.05 Output file: t-aesum-cat-gge3-gba-ipss3.pdf 29AUG2023: 9:43

Table 3.4108: TEAEs of Cataract MST of Grade 3 or more by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-cat-sub-gba.sas V.03.05 Output file: t-aesum-cat-gge3-gba-mf.pdf 29AUG2023: 9:43

Table 3.4103: TEAEs of Cataract MST of Grade 3 or more by Gender
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-cat-sub-gba.sas V.03.05 Output file: t-aesum-cat-gge3-gba-sex.pdf 29AUG2023: 9:42

Table 3.4110: TEAEs of Cataract MST of Grade 3 or more by Baseline Spleen Volume
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-cat-sub-gba.sas V.03.05 Output file: t-aesum-cat-gge3-gba-svb.pdf 29AUG2023: 9:43

Table 3.4109: TEAEs of Cataract MST of Grade 3 or more by Baseline TSS
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-cat-sub-gba.sas V.03.05 Output file: t-aesum-cat-gge3-gba-tss.pdf 29AUG2023: 9:43

Table 3.4002: TEAEs of Cataract MST of Grade 2 or less by Age
Double-Blind Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Number of subjects, n(%)	1 (4.2%)	1 (2.8%)	2 (3.2%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Age Group [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.4004: TEAEs of Cataract MST of Grade 2 or less by Region
Double-Blind Phase
SAF-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Number of subjects, n(%)	1 (1.9%)	0	2 (6.1%)	1 (2.3%)	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Region [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-cat-sub-gba.sas V.03.05 Output file: t-aesum-cat-gle2-gba-geo.pdf 29AUG2023: 9:42

Table 3.4007: TEAEs of Cataract MST of Grade 2 or less by Baseline Hemoglobin Level
Double-Blind Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Number of subjects, n(%)	2 (7.1%)	1 (4.8%)	1 (1.7%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Baseline Hemoglobin Level Group [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.4006: TEAEs of Cataract MST of Grade 2 or less by Baseline IPSS Two-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Number of subjects, n(%)	1 (3.6%)	1 (4.2%)	2 (3.4%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Baseline IPSS 2-Level Risk [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-cat-sub-gba.sas V.03.05 Output file: t-aesum-cat-gle2-gba-ipss2.pdf 29AUG2023: 9:42

Table 3.4005: TEAEs of Cataract MST of Grade 2 or less by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Number of subjects, n(%)	0	0	1 (3.8%)	1 (5.0%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.4005: TEAEs of Cataract MST of Grade 2 or less by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=58)	RUX (N=70)	p-value
Number of subjects, n(%)	2 (3.4%)	0	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-cat-sub-gba.sas V.03.05 Output file: t-aesum-cat-gle2-gba-ipss3.pdf 29AUG2023: 9:42

Table 3.4008: TEAEs of Cataract MST of Grade 2 or less by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
Number of subjects, n(%)	2 (3.4%)	0	0	1 (3.6%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Myelofibrosis Disease Type [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-cat-sub-gba.sas V.03.05 Output file: t-aesum-cat-gle2-gba-mf.pdf 29AUG2023: 9:42

Table 3.4008: TEAEs of Cataract MST of Grade 2 or less by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=11)	RUX (N=12)	p-value
Number of subjects, n(%)	1 (9.1%)	0	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Myelofibrosis Disease Type [2]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-cat-sub-gba.sas V.03.05 Output file: t-aesum-cat-gle2-gba-mf.pdf 29AUG2023: 9:42

Table 3.4003: TEAEs of Cataract MST of Grade 2 or less by Gender
Double-Blind Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Number of subjects, n(%)	3 (6.0%)	1 (1.8%)	0	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Gender [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.4010: TEAEs of Cataract MST of Grade 2 or less by Baseline Spleen Volume
Double-Blind Phase
SAF-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Number of subjects, n(%)	1 (2.1%)	0	2 (5.1%)	1 (2.0%)	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Baseline Spleen Volume Group [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.4009: TEAEs of Cataract MST of Grade 2 or less by Baseline TSS
Double-Blind Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Number of subjects, n(%)	2 (4.5%)	1 (1.8%)	1 (2.4%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Baseline TSS Group [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.4202: Serious TEAEs of Cataract MST by Age
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-cat-sub-gba.sas V.03.05 Output file: t-aesum-cat-ser-gba-age.pdf 29AUG2023: 9:43

Table 3.4204: Serious TEAEs of Cataract MST by Region
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-cat-sub-gba.sas V.03.05 Output file: t-aesum-cat-ser-gba-geo.pdf 29AUG2023: 9:43

Table 3.4207: Serious TEAEs of Cataract MST by Baseline Hemoglobin Level
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-cat-sub-gba.sas V.03.05 Output file: t-aesum-cat-ser-gba-hgb.pdf 29AUG2023: 9:43

Table 3.4206: Serious TEAEs of Cataract MST by Baseline IPSS Two-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Table 3.4205: Serious TEAEs of Cataract MST by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Table 3.4208: Serious TEAEs of Cataract MST by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Table 3.4203: Serious TEAEs of Cataract MST by Gender
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-cat-sub-gba.sas V.03.05 Output file: t-aesum-cat-ser-gba-sex.pdf 29AUG2023: 9:43

Table 3.4210: Serious TEAEs of Cataract MST by Baseline Spleen Volume
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-cat-sub-gba.sas V.03.05 Output file: t-aesum-cat-ser-gba-svb.pdf 29AUG2023: 9:43

Table 3.4209: Serious TEAEs of Cataract MST by Baseline TSS
Double-Blind Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-cat-sub-gba.sas V.03.05 Output file: t-aesum-cat-ser-gba-tss.pdf 29AUG2023: 9:43

Table 3.4302: TEAEs of First Dose Effect by Age
Double-Blind Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Number of subjects, n(%)	1 (4.2%)	0	4 (6.5%)	1 (1.7%)	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Age Group [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-fds-sub-gba.sas V.03.05 Output file: t-aesum-fds-gba-age.pdf 29AUG2023: 8:54

Table 3.4304: TEAEs of First Dose Effect by Region
Double-Blind Phase
SAF-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Number of subjects, n(%)	5 (9.4%)	0	0	1 (2.3%)	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Region [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-fds-sub-gba.sas V.03.05 Output file: t-aesum-fds-gba-geo.pdf 29AUG2023: 8:54

Table 3.4307: TEAEs of First Dose Effect by Baseline Hemoglobin Level
Double-Blind Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Number of subjects, n(%)	1 (3.6%)	0	4 (6.9%)	1 (1.4%)	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Baseline Hemoglobin Level Group [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-fds-sub-gba.sas V.03.05 Output file: t-aesum-fds-gba-hgb.pdf 29AUG2023: 8:54

Table 3.4306: TEAEs of First Dose Effect by Baseline IPSS Two-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Number of subjects, n(%)	2 (7.1%)	0	3 (5.2%)	1 (1.4%)	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Baseline IPSS 2-Level Risk [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-fds-sub-gba.sas V.03.05 Output file: t-aesum-fds-gba-ipss2.pdf 29AUG2023: 8:54

Table 3.4305: TEAEs of First Dose Effect by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Number of subjects, n(%)	1 (50.0%)	0	1 (3.8%)	0
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-fds-sub-gba.sas V.03.05 Output file: t-aesum-fds-gba-ipss3.pdf 29AUG2023: 8:54

Table 3.4305: TEAEs of First Dose Effect by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=58)	RUX (N=70)	p-value
Number of subjects, n(%)	3 (5.2%)	1 (1.4%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-fds-sub-gba.sas V.03.05 Output file: t-aesum-fds-gba-ipss3.pdf 29AUG2023: 8:54

Table 3.4308: TEAEs of First Dose Effect by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
Number of subjects, n(%)	4 (6.8%)	1 (1.9%)	1 (6.3%)	0
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Myelofibrosis Disease Type [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-fds-sub-gba.sas V.03.05 Output file: t-aesum-fds-gba-mf.pdf 29AUG2023: 8:54

Table 3.4308: TEAEs of First Dose Effect by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=11)	RUX (N=12)	p-value
Number of subjects, n(%)	0	0	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Myelofibrosis Disease Type [2]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-fds-sub-gba.sas V.03.05 Output file: t-aesum-fds-gba-mf.pdf 29AUG2023: 8:54

Table 3.4303: TEAEs of First Dose Effect by Gender
Double-Blind Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Number of subjects, n(%)	3 (6.0%)	0	2 (5.6%)	1 (2.6%)	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Gender [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.4310: TEAEs of First Dose Effect by Baseline Spleen Volume
Double-Blind Phase
SAF-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Number of subjects, n(%)	3 (6.4%)	1 (2.3%)	2 (5.1%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Baseline Spleen Volume Group [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-fds-sub-gba.sas V.03.05 Output file: t-aesum-fds-gba-svb.pdf 29AUG2023: 8:54

Table 3.4309: TEAEs of First Dose Effect by Baseline TSS
Double-Blind Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Number of subjects, n(%)	3 (6.8%)	0	2 (4.9%)	1 (2.6%)	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Baseline TSS Group [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-fds-sub-gba.sas V.03.05 Output file: t-aesum-fds-gba-tss.pdf 29AUG2023: 8:54

Table 3.4502: TEAEs of First Dose Effect of Grade 3 or more by Age
Double-Blind Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Number of subjects, n(%)	0	0	1 (1.6%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Age Group [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.4504: TEAEs of First Dose Effect of Grade 3 or more by Region
Double-Blind Phase
SAF-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Number of subjects, n(%)	1 (1.9%)	0	0	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Region [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.4507: TEAEs of First Dose Effect of Grade 3 or more by Baseline Hemoglobin Level
Double-Blind Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Number of subjects, n(%)	1 (3.6%)	0	0	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Baseline Hemoglobin Level Group [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.4506: TEAEs of First Dose Effect of Grade 3 or more by Baseline IPSS Two-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Number of subjects, n(%)	0	0	1 (1.7%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Baseline IPSS 2-Level Risk [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.4505: TEAEs of First Dose Effect of Grade 3 or more by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Number of subjects, n(%)	0	0	0	0
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.4505: TEAEs of First Dose Effect of Grade 3 or more by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=58)	RUX (N=70)	p-value
Number of subjects, n(%)	1 (1.7%)	0	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-fds-sub-gba.sas V.03.05 Output file: t-aesum-fds-gge3-gba-ipss3.pdf 29AUG2023: 8:55

Table 3.4508: TEAEs of First Dose Effect of Grade 3 or more by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
Number of subjects, n(%)	0	0	1 (6.3%)	0
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Myelofibrosis Disease Type [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.4508: TEAEs of First Dose Effect of Grade 3 or more by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=11)	RUX (N=12)	p-value
Number of subjects, n(%)	0	0	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Myelofibrosis Disease Type [2]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.4503: TEAEs of First Dose Effect of Grade 3 or more by Gender
Double-Blind Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Number of subjects, n(%)	1 (2.0%)	0	0	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Gender [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.4510: TEAEs of First Dose Effect of Grade 3 or more by Baseline Spleen Volume
Double-Blind Phase
SAF-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Number of subjects, n(%)	0	0	1 (2.6%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Baseline Spleen Volume Group [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.4509: TEAEs of First Dose Effect of Grade 3 or more by Baseline TSS
Double-Blind Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Number of subjects, n(%)	0	0	1 (2.4%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Baseline TSS Group [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.4402: TEAEs of First Dose Effect of Grade 2 or less by Age
Double-Blind Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Number of subjects, n(%)	1 (4.2%)	0	3 (4.8%)	1 (1.7%)	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Age Group [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.4404: TEAEs of First Dose Effect of Grade 2 or less by Region
Double-Blind Phase
SAF-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Number of subjects, n(%)	4 (7.5%)	0	0	1 (2.3%)	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Region [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.4407: TEAEs of First Dose Effect of Grade 2 or less by Baseline Hemoglobin Level
Double-Blind Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Number of subjects, n(%)	0	0	4 (6.9%)	1 (1.4%)	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Baseline Hemoglobin Level Group [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.4406: TEAEs of First Dose Effect of Grade 2 or less by Baseline IPSS Two-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Number of subjects, n(%)	2 (7.1%)	0	2 (3.4%)	1 (1.4%)	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Baseline IPSS 2-Level Risk [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-fds-sub-gba.sas V.03.05 Output file: t-aesum-fds-gle2-gba-ipss2.pdf 29AUG2023: 8:54

Table 3.4405: TEAEs of First Dose Effect of Grade 2 or less by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Number of subjects, n(%)	1 (50.0%)	0	1 (3.8%)	0
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.4405: TEAEs of First Dose Effect of Grade 2 or less by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=58)	RUX (N=70)	p-value
Number of subjects, n(%)	2 (3.4%)	1 (1.4%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.4408: TEAEs of First Dose Effect of Grade 2 or less by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
Number of subjects, n(%)	4 (6.8%)	1 (1.9%)	0	0
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Myelofibrosis Disease Type [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-fds-sub-gba.sas V.03.05 Output file: t-aesum-fds-gle2-gba-mf.pdf 29AUG2023: 8:55

Table 3.4408: TEAEs of First Dose Effect of Grade 2 or less by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=11)	RUX (N=12)	p-value
Number of subjects, n(%)	0	0	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Myelofibrosis Disease Type [2]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-fds-sub-gba.sas V.03.05 Output file: t-aesum-fds-gle2-gba-mf.pdf 29AUG2023: 8:55

Table 3.4403: TEAEs of First Dose Effect of Grade 2 or less by Gender
Double-Blind Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Number of subjects, n(%)	2 (4.0%)	0	2 (5.6%)	1 (2.6%)	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Gender [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.4410: TEAEs of First Dose Effect of Grade 2 or less by Baseline Spleen Volume
Double-Blind Phase
SAF-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Number of subjects, n(%)	3 (6.4%)	1 (2.3%)	1 (2.6%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Baseline Spleen Volume Group [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.4409: TEAEs of First Dose Effect of Grade 2 or less by Baseline TSS
Double-Blind Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Number of subjects, n(%)	3 (6.8%)	0	1 (2.4%)	1 (2.6%)	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Baseline TSS Group [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.4602: Serious TEAEs of First Dose Effect by Age
Double-Blind Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)	p-value
Number of subjects, n(%)	0	0	1 (1.6%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Age Group [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.4604: Serious TEAEs of First Dose Effect by Region
Double-Blind Phase
SAF-Anemic Analysis Set

	Western Countries		Eastern Countries		
	MMB (N=53)	RUX (N=51)	MMB (N=33)	RUX (N=43)	p-value
Number of subjects, n(%)	1 (1.9%)	0	0	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Region [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.4607: Serious TEAEs of First Dose Effect by Baseline Hemoglobin Level
Double-Blind Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)	p-value
Number of subjects, n(%)	1 (3.6%)	0	0	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Baseline Hemoglobin Level Group [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-fds-sub-gba.sas V.03.05 Output file: t-aesum-fds-ser-gba-hgb.pdf 29AUG2023: 8:55

Table 3.4606: Serious TEAEs of First Dose Effect by Baseline IPSS Two-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)	p-value
Number of subjects, n(%)	0	0	1 (1.7%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Baseline IPSS 2-Level Risk [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-fds-sub-gba.sas V.03.05 Output file: t-aesum-fds-ser-gba-ipss2.pdf 29AUG2023: 8:55

Table 3.4605: Serious TEAEs of First Dose Effect by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=2)	RUX (N=4)	MMB (N=26)	RUX (N=20)
Number of subjects, n(%)	0	0	0	0
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-fds-sub-gba.sas V.03.05 Output file: t-aesum-fds-ser-gba-ipss3.pdf 29AUG2023: 8:55

Table 3.4605: Serious TEAEs of First Dose Effect by Baseline IPSS Three-level Risk
Double-Blind Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=58)	RUX (N=70)	p-value
Number of subjects, n(%)	1 (1.7%)	0	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Baseline IPSS 3-Level Risk [2]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-fds-sub-gba.sas V.03.05 Output file: t-aesum-fds-ser-gba-ipss3.pdf 29AUG2023: 8:55

Table 3.4608: Serious TEAEs of First Dose Effect by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
Number of subjects, n(%)	0	0	1 (6.3%)	0
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Interaction test for Treatment*Myelofibrosis Disease Type [2]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.4608: Serious TEAEs of First Dose Effect by Baseline MF Disease Status
Double-Blind Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=11)	RUX (N=12)	p-value
Number of subjects, n(%)	0	0	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Interaction test for Treatment*Myelofibrosis Disease Type [2]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-fds-sub-gba.sas V.03.05 Output file: t-aesum-fds-ser-gba-mf.pdf 29AUG2023: 8:55

Table 3.4603: Serious TEAEs of First Dose Effect by Gender
Double-Blind Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)	p-value
Number of subjects, n(%)	1 (2.0%)	0	0	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Gender [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019

Table 3.4610: Serious TEAEs of First Dose Effect by Baseline Spleen Volume
Double-Blind Phase
SAF-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3		
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)	p-value
Number of subjects, n(%)	0	0	1 (2.6%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Baseline Spleen Volume Group [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-fds-sub-gba.sas V.03.05 Output file: t-aesum-fds-ser-gba-svb.pdf 29AUG2023: 8:55

Table 3.4609: Serious TEAEs of First Dose Effect by Baseline TSS
Double-Blind Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=44)	RUX (N=55)	MMB (N=41)	RUX (N=38)	p-value
Number of subjects, n(%)	0	0	1 (2.4%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Interaction test for Treatment*Baseline TSS Group [2]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 01JUL2019
Source: t-aesum-fds-sub-gba.sas V.03.05 Output file: t-aesum-fds-ser-gba-tss.pdf 29AUG2023: 8:55

Table 2.5902: Overall Survival Analysis by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Subjects with Event					
Death, n(%)	2 (8.3%)	1 (11.1%)	2 (4.8%)	4 (13.3%)	
Censor					
Subjects Censored, n(%)	22 (91.7%)	8 (88.9%)	40 (95.2%)	26 (86.7%)	
Kaplan-Meier Estimate of Overall Survival (Months)					
25-percentile (95% CI)	NE (2.60, NE)	NE (2.46, NE)	NE (NE, NE)	NE (5.36, NE)	
Median (95% CI)	NE (NE, NE)	NE (2.46, NE)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	1.48, 6.80	1.64, 5.68	0.92, 6.01	0.43, 6.54	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Death in the RT phase is death occurring on or after the 1st RT dose up to the earliest of the last RT dose + 30 days, or the 1st ET dose -1 day.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-os-sub.sas V.03.05 Output file: t-os-age.pdf 24AUG2023:16:43

Table 2.5906: Overall Survival Analysis by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Subjects with Event					
Death, n(%)	2 (4.1%)	4 (12.9%)	2 (11.8%)	1 (12.5%)	
Censor					
Subjects Censored, n(%)	47 (95.9%)	27 (87.1%)	15 (88.2%)	7 (87.5%)	
Kaplan-Meier Estimate of Overall Survival (Months)					
25-percentile (95% CI)	NE (NE, NE)	NE (2.46, NE)	NE (0.92, NE)	NE (5.36, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (5.36, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	1.48, 6.80	1.61, 6.54	0.92, 5.98	0.43, 5.95	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Death in the RT phase is death occurring on or after the 1st RT dose up to the earliest of the last RT dose + 30 days, or the 1st ET dose -1 day.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-os-sub.sas V.03.05 Output file: t-os-dipss2.pdf 24AUG2023:16:43

Table 2.5905: Overall Survival Analysis by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Subjects with Event				
Death, n(%)	1 (20.0%)	1 (14.3%)	1 (2.3%)	3 (12.5%)
Censor				
Subjects Censored, n(%)	4 (80.0%)	6 (85.7%)	43 (97.7%)	21 (87.5%)
Kaplan-Meier Estimate of Overall Survival (Months)				
25-percentile (95% CI)	NE (2.60, NE)	5.68 (NE, NE)	NE (NE, NE)	NE (1.61, NE)
Median (95% CI)	NE (2.60, NE)	5.68 (NE, NE)	NE (NE, NE)	NE (NE, NE)
75-percentile (95% CI)	NE (2.60, NE)	5.68 (NE, NE)	NE (NE, NE)	NE (NE, NE)
Min, Max	2.60, 5.45	1.64, 5.68	1.48, 6.80	1.61, 6.54
Stratified Log-Rank Test p-value	NA		NA	
Adjusted Hazard Ratio (95% CI)	NA		NA	
Unstratified Log-Rank Test p-value	NA		NA	
Unadjusted Hazard Ratio (95% CI)	NA		NA	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Death in the RT phase is death occurring on or after the 1st RT dose up to the earliest of the last RT dose + 30 days, or the 1st ET dose -1 day.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-os-sub.sas V.03.05 Output file: t-os-dipss3.pdf 24AUG2023:16:43

Table 2.5905: Overall Survival Analysis by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=17)	High Risk BAT (N=8)	p-value
Subjects with Event			
Death, n(%)	2 (11.8%)	1 (12.5%)	
Censor			
Subjects Censored, n(%)	15 (88.2%)	7 (87.5%)	
Kaplan-Meier Estimate of Overall Survival (Months)			
25-percentile (95% CI)	NE (0.92, NE)	NE (5.36, NE)	
Median (95% CI)	NE (NE, NE)	NE (5.36, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	
Min, Max	0.92, 5.98	0.43, 5.95	
Stratified Log-Rank Test p-value	NA		
Adjusted Hazard Ratio (95% CI)	NA		
Unstratified Log-Rank Test p-value	NA		
Unadjusted Hazard Ratio (95% CI)	NA		
P-value for interaction test			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Death in the RT phase is death occurring on or after the 1st RT dose up to the earliest of the last RT dose + 30 days, or the 1st ET dose -1 day.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.5904: Overall Survival Analysis by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Subjects with Event					
Death, n(%)	1 (3.4%)	0	3 (8.1%)	5 (15.6%)	
Censor					
Subjects Censored, n(%)	28 (96.6%)	7 (100.0%)	34 (91.9%)	27 (84.4%)	
Kaplan-Meier Estimate of Overall Survival (Months)					
25-percentile (95% CI)	NE (3.81, NE)	NE (NE, NE)	NE (NE, NE)	NE (2.46, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	1.48, 5.98	0.43, 5.78	0.92, 6.80	1.61, 6.54	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Death in the RT phase is death occurring on or after the 1st RT dose up to the earliest of the last RT dose + 30 days, or the 1st ET dose -1 day.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-os-sub.sas V.03.05 Output file: t-os-geo.pdf 24AUG2023:16:43

Table 2.5907: Overall Survival Analysis by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Subjects with Event					
Death, n(%)	4 (14.8%)	1 (16.7%)	0	4 (12.1%)	
Censor					
Subjects Censored, n(%)	23 (85.2%)	5 (83.3%)	39 (100.0%)	29 (87.9%)	
Kaplan-Meier Estimate of Overall Survival (Months)					
25-percentile (95% CI)	NE (2.60, NE)	NE (1.77, NE)	NE (NE, NE)	NE (5.36, NE)	
Median (95% CI)	NE (NE, NE)	NE (1.77, NE)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (1.77, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	0.92, 5.98	1.64, 5.82	1.48, 6.80	0.43, 6.54	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Death in the RT phase is death occurring on or after the 1st RT dose up to the earliest of the last RT dose + 30 days, or the 1st ET dose -1 day.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-os-sub.sas V.03.05 Output file: t-os-hgb.pdf 24AUG2023:16:43

Table 2.5908: Overall Survival Analysis by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-ET Myelofibrosis		Post-PV Myelofibrosis	
	MMB (N=13)	BAT (N=8)	MMB (N=8)	BAT (N=8)
Subjects with Event				
Death, n(%)	2 (15.4%)	1 (12.5%)	0	1 (12.5%)
Censor				
Subjects Censored, n(%)	11 (84.6%)	7 (87.5%)	8 (100.0%)	7 (87.5%)
Kaplan-Meier Estimate of Overall Survival (Months)				
25-percentile (95% CI)	NE (0.92, NE)	NE (5.36, NE)	NE (NE, NE)	NE (1.77, NE)
Median (95% CI)	NE (3.58, NE)	NE (5.36, NE)	NE (NE, NE)	NE (1.77, NE)
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Min, Max	0.92, 5.75	0.43, 5.72	3.75, 5.75	1.77, 6.14
Stratified Log-Rank Test p-value	NA		NA	
Adjusted Hazard Ratio (95% CI)	NA		NA	
Unstratified Log-Rank Test p-value	NA		NA	
Unadjusted Hazard Ratio (95% CI)	NA		NA	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Death in the RT phase is death occurring on or after the 1st RT dose up to the earliest of the last RT dose + 30 days, or the 1st ET dose -1 day.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-os-sub.sas V.03.05 Output file: t-os-mf.pdf 24AUG2023:16:43

Table 2.5908: Overall Survival Analysis by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	Primary Myelofibrosis MMB (N=45)	Primary Myelofibrosis BAT (N=23)	p-value
Subjects with Event			
Death, n(%)	2 (4.4%)	3 (13.0%)	
Censor			
Subjects Censored, n(%)	43 (95.6%)	20 (87.0%)	
Kaplan-Meier Estimate of Overall Survival (Months)			
25-percentile (95% CI)	NE (NE, NE)	NE (1.61, NE)	
Median (95% CI)	NE (NE, NE)	NE (5.68, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	
Min, Max	1.48, 6.80	1.61, 6.54	
Stratified Log-Rank Test p-value	NA		
Adjusted Hazard Ratio (95% CI)	NA		
Unstratified Log-Rank Test p-value	NA		
Unadjusted Hazard Ratio (95% CI)	NA		
P-value for interaction test			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Death in the RT phase is death occurring on or after the 1st RT dose up to the earliest of the last RT dose + 30 days, or the 1st ET dose -1 day.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-os-sub.sas V.03.05 Output file: t-os-mf.pdf 24AUG2023:16:43

Table 2.5903: Overall Survival Analysis by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Subjects with Event					
Death, n(%)	3 (5.8%)	4 (22.2%)	1 (7.1%)	1 (4.8%)	
Censor					
Subjects Censored, n(%)	49 (94.2%)	14 (77.8%)	13 (92.9%)	20 (95.2%)	
Kaplan-Meier Estimate of Overall Survival (Months)					
25-percentile (95% CI)	NE (NE, NE)	5.68 (1.61, NE)	NE (3.58, NE)	NE (1.77, NE)	
Median (95% CI)	NE (NE, NE)	NE (5.68, NE)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	0.92, 6.80	0.43, 6.54	1.84, 6.47	1.77, 6.14	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Death in the RT phase is death occurring on or after the 1st RT dose up to the earliest of the last RT dose + 30 days, or the 1st ET dose -1 day.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-os-sub.sas V.03.05 Output file: t-os-sex.pdf 24AUG2023:16:43

Table 2.5910: Overall Survival Analysis by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Subjects with Event					
Death, n(%)	0	2 (8.3%)	4 (10.5%)	3 (20.0%)	
Censor					
Subjects Censored, n(%)	28 (100.0%)	22 (91.7%)	34 (89.5%)	12 (80.0%)	
Kaplan-Meier Estimate of Overall Survival (Months)					
25-percentile (95% CI)	NE (NE, NE)	NE (1.61, NE)	NE (3.81, NE)	5.68 (1.77, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (5.68, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	1.84, 5.75	0.43, 6.54	0.92, 6.80	1.64, 6.14	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Death in the RT phase is death occurring on or after the 1st RT dose up to the earliest of the last RT dose + 30 days, or the 1st ET dose -1 day.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-os-sub.sas V.03.05 Output file: t-os-svb.pdf 24AUG2023:16:43

Table 2.5909: Overall Survival Analysis by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Subjects with Event					
Death, n(%)	2 (4.8%)	2 (10.0%)	2 (8.3%)	3 (15.8%)	
Censor					
Subjects Censored, n(%)	40 (95.2%)	18 (90.0%)	22 (91.7%)	16 (84.2%)	
Kaplan-Meier Estimate of Overall Survival (Months)					
25-percentile (95% CI)	NE (NE, NE)	NE (1.61, NE)	NE (0.92, NE)	NE (1.77, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	1.48, 6.80	0.43, 6.54	0.92, 6.47	1.64, 5.75	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Death in the RT phase is death occurring on or after the 1st RT dose up to the earliest of the last RT dose + 30 days, or the 1st ET dose -1 day.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment and baseline TD (yes,no).
Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no)
and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.6102: Analysis of Time to Leukemic Transformation by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Subjects with Event					
Leukemic Transformation, n(%)	1 (4.2%)	0	1 (2.4%)	1 (3.3%)	
Censor					
Subjects Censored, n(%)	23 (95.8%)	9 (100.0%)	41 (97.6%)	29 (96.7%)	
Kaplan-Meier Estimate of Time to Leukemic Transformation (Months)					
25-percentile (95% CI)	NE (4.70, NE)	NE (NE, NE)	NE (NE, NE)	NE (5.55, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	1.48, 7.00	1.64, 5.68	0.92, 6.11	0.43, 6.14	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.6106: Analysis of Time to Leukemic Transformation by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Subjects with Event					
Leukemic Transformation, n(%)	1 (2.0%)	1 (3.2%)	1 (5.9%)	0	
Censor					
Subjects Censored, n(%)	48 (98.0%)	30 (96.8%)	16 (94.1%)	8 (100.0%)	
Kaplan-Meier Estimate of Time to Leukemic Transformation (Months)					
25-percentile (95% CI)	NE (NE, NE)	NE (5.55, NE)	NE (2.89, NE)	NE (NE, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	1.48, 7.00	1.61, 6.14	0.92, 6.11	0.43, 5.95	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-lt-sub.sas V.03.05 Output file: t-tte-lt-dipss2.pdf 24AUG2023:16:46

Table 2.6105: Analysis of Time to Leukemic Transformation by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Subjects with Event				
Leukemic Transformation, n(%)	0	0	1 (2.3%)	1 (4.2%)
Censor				
Subjects Censored, n(%)	5 (100.0%)	7 (100.0%)	43 (97.7%)	23 (95.8%)
Kaplan-Meier Estimate of Time to Leukemic Transformation (Months)				
25-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (5.55, NE)
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Min, Max	2.63, 5.45	1.64, 5.68	1.48, 7.00	1.61, 6.14
Stratified Log-Rank Test p-value	NA		NA	
Adjusted Hazard Ratio (95% CI)	NA		NA	
Unstratified Log-Rank Test p-value	NA		NA	
Unadjusted Hazard Ratio (95% CI)	NA		NA	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-lt-sub.sas V.03.05 Output file: t-tte-lt-dipss3.pdf 24AUG2023:16:46

Table 2.6105: Analysis of Time to Leukemic Transformation by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=17)	High Risk BAT (N=8)	p-value
Subjects with Event			
Leukemic Transformation, n(%)	1 (5.9%)	0	
Censor			
Subjects Censored, n(%)	16 (94.1%)	8 (100.0%)	
Kaplan-Meier Estimate of Time to Leukemic Transformation (Months)			
25-percentile (95% CI)	NE (2.89, NE)	NE (NE, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	
Min, Max	0.92, 6.11	0.43, 5.95	
Stratified Log-Rank Test p-value	NA		
Adjusted Hazard Ratio (95% CI)	NA		
Unstratified Log-Rank Test p-value	NA		
Unadjusted Hazard Ratio (95% CI)	NA		
P-value for interaction test			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-lt-sub.sas V.03.05 Output file: t-tte-lt-dipss3.pdf 24AUG2023:16:46

Table 2.6104: Analysis of Time to Leukemic Transformation by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Subjects with Event					
Leukemic Transformation, n(%)	0	0	2 (5.4%)	1 (3.1%)	
Censor					
Subjects Censored, n(%)	29 (100.0%)	7 (100.0%)	35 (94.6%)	31 (96.9%)	
Kaplan-Meier Estimate of Time to Leukemic Transformation (Months)					
25-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (5.55, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	1.48, 6.11	0.43, 5.78	0.92, 7.00	1.61, 6.14	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-lt-sub.sas V.03.05 Output file: t-tte-lt-geo.pdf 24AUG2023:16:46

Table 2.6107: Analysis of Time to Leukemic Transformation by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Subjects with Event					
Leukemic Transformation, n(%)	2 (7.4%)	0	0	1 (3.0%)	
Censor					
Subjects Censored, n(%)	25 (92.6%)	6 (100.0%)	39 (100.0%)	32 (97.0%)	
Kaplan-Meier Estimate of Time to Leukemic Transformation (Months)					
25-percentile (95% CI)	NE (2.89, NE)	NE (NE, NE)	NE (NE, NE)	NE (5.55, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	0.92, 6.11	1.64, 5.82	1.48, 7.00	0.43, 6.14	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.6108: Analysis of Time to Leukemic Transformation by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-ET Myelofibrosis		Post-PV Myelofibrosis	
	MMB (N=13)	BAT (N=8)	MMB (N=8)	BAT (N=8)
Subjects with Event				
Leukemic Transformation, n(%)	2 (15.4%)	0	0	0
Censor				
Subjects Censored, n(%)	11 (84.6%)	8 (100.0%)	8 (100.0%)	8 (100.0%)
Kaplan-Meier Estimate of Time to Leukemic Transformation (Months)				
25-percentile (95% CI)	NE (2.89, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Median (95% CI)	NE (2.89, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Min, Max	0.92, 5.75	0.43, 5.72	3.75, 5.78	1.77, 6.14
Stratified Log-Rank Test p-value	NA		NA	
Adjusted Hazard Ratio (95% CI)	NA		NA	
Unstratified Log-Rank Test p-value	NA		NA	
Unadjusted Hazard Ratio (95% CI)	NA		NA	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-lt-sub.sas V.03.05 Output file: t-tte-lt-mf.pdf 24AUG2023:16:46

Table 2.6108: Analysis of Time to Leukemic Transformation by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	Primary Myelofibrosis MMB (N=45)	Primary Myelofibrosis BAT (N=23)	p-value
Subjects with Event			
Leukemic Transformation, n(%)	0	1 (4.3%)	
Censor			
Subjects Censored, n(%)	45 (100.0%)	22 (95.7%)	
Kaplan-Meier Estimate of Time to Leukemic Transformation (Months)			
25-percentile (95% CI)	NE (NE, NE)	NE (5.55, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	
Min, Max	1.48, 7.00	1.61, 5.95	
Stratified Log-Rank Test p-value	NA		
Adjusted Hazard Ratio (95% CI)	NA		
Unstratified Log-Rank Test p-value	NA		
Unadjusted Hazard Ratio (95% CI)	NA		
P-value for interaction test			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-lt-sub.sas V.03.05 Output file: t-tte-lt-mf.pdf 24AUG2023:16:46

Table 2.6103: Analysis of Time to Leukemic Transformation by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Subjects with Event					
Leukemic Transformation, n(%)	1 (1.9%)	1 (5.6%)	1 (7.1%)	0	
Censor					
Subjects Censored, n(%)	51 (98.1%)	17 (94.4%)	13 (92.9%)	21 (100.0%)	
Kaplan-Meier Estimate of Time to Leukemic Transformation (Months)					
25-percentile (95% CI)	NE (NE, NE)	NE (5.55, NE)	NE (2.89, NE)	NE (NE, NE)	
Median (95% CI)	NE (NE, NE)	NE (5.55, NE)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	0.92, 7.00	0.43, 5.82	1.87, 6.47	1.77, 6.14	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.6110: Analysis of Time to Leukemic Transformation by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Subjects with Event					
Leukemic Transformation, n(%)	0	1 (4.2%)	2 (5.3%)	0	
Censor					
Subjects Censored, n(%)	28 (100.0%)	23 (95.8%)	36 (94.7%)	15 (100.0%)	
Kaplan-Meier Estimate of Time to Leukemic Transformation (Months)					
25-percentile (95% CI)	NE (NE, NE)	NE (5.55, NE)	NE (NE, NE)	NE (NE, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	1.87, 5.78	0.43, 5.95	0.92, 7.00	1.64, 6.14	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-lt-sub.sas V.03.05 Output file: t-tte-lt-svb.pdf 24AUG2023:16:46

Table 2.6109: Analysis of Time to Leukemic Transformation by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Subjects with Event					
Leukemic Transformation, n(%)	1 (2.4%)	1 (5.0%)	1 (4.2%)	0	
Censor					
Subjects Censored, n(%)	41 (97.6%)	19 (95.0%)	23 (95.8%)	19 (100.0%)	
Kaplan-Meier Estimate of Time to Leukemic Transformation (Months)					
25-percentile (95% CI)	NE (NE, NE)	NE (5.55, NE)	NE (2.89, NE)	NE (NE, NE)	
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	1.48, 7.00	0.43, 6.14	0.92, 6.47	1.64, 5.75	
Stratified Log-Rank Test p-value	NA		NA		
Adjusted Hazard Ratio (95% CI)	NA		NA		
Unstratified Log-Rank Test p-value	NA		NA		
Unadjusted Hazard Ratio (95% CI)	NA		NA		
P-value for interaction test					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment and baseline TD (yes,no).
Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-lt-sub.sas V.03.05 Output file: t-tte-lt-tss.pdf 24AUG2023:16:46

Table 2.0102: Analysis of Splenic Response Rate at Week 24 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Splenic Response Rate at Week 24					
Responder, n(%)	1 (4.2%)	0	5 (11.9%)	2 (6.7%)	
95% Exact CI	0.0011, 0.2112	0.0000, 0.3363	0.0398, 0.2563	0.0082, 0.2207	
Proportion Difference - Stratified CMH Method (95% CI)	0.02 (-0.30, 0.35)		0.07 (-0.11, 0.24)		
p-value	0.88		0.47		
Proportion Difference - Unstratified CMH Method (95% CI)	0.04 (-0.14, 0.22)		0.05 (-0.09, 0.19)		
p-value	0.65		0.47		
Proportion Difference - Unstratified Exact Method (95% CI)	0.04 (-0.34, 0.42)		0.05 (-0.18, 0.28)		
p-value	1.00		0.69		
Unadjusted Inverse Relative Risk (95% CI)	0.83 (0.04, 18.79)		0.56 (0.12, 2.70)		
p-value [1]	0.91		0.47		
Unadjusted interaction test for Treatment*Age Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.82 (0.03, 22.09)		0.53 (0.10, 2.93)		
p-value [1]	0.91		0.47		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.15, 0.17)		0.05 (-0.08, 0.18)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Age Group [3]					NA
Non-Responder, n(%)	23 (95.8%)	9 (100.0%)	37 (88.1%)	28 (93.3%)	
Baseline spleen volume not available	0	0	0	0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.0102: Analysis of Splenic Response Rate at Week 24 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Spleen volume at Week 24 not available	9 (37.5%)	3 (33.3%)	13 (31.0%)	6 (20.0%)	
>0% spleen volume increase at Week 24	8 (33.3%)	3 (33.3%)	12 (28.6%)	12 (40.0%)	
<35% spleen volume reduction at Week 24	14 (58.3%)	6 (66.7%)	24 (57.1%)	22 (73.3%)	
Last participation date < Day 141 in RT phase	7 (29.2%)	3 (33.3%)	8 (19.0%)	4 (13.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.0104: Analysis of Splenic Response Rate at Week 24 by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Splenic Response Rate at Week 24					
Responder, n(%)	4 (13.8%)	0	2 (5.4%)	2 (6.3%)	
95% Exact CI	0.0389, 0.3166	0.0000, 0.4096	0.0066, 0.1819	0.0077, 0.2081	
Proportion Difference - Stratified CMH Method (95% CI)	0.16 (-0.24, 0.56)		-0.01 (-0.17, 0.14)		
p-value	0.43		0.87		
Proportion Difference - Unstratified CMH Method (95% CI)	0.14 (-0.10, 0.37)		-0.01 (-0.13, 0.11)		
p-value	0.25		0.89		
Proportion Difference - Unstratified Exact Method (95% CI)	0.14 (-0.27, 0.52)		-0.01 (-0.24, 0.23)		
p-value	0.57		1.00		
Unadjusted Inverse Relative Risk (95% CI)	0.42 (0.02, 6.96)		1.16 (0.17, 7.75)		
p-value [1]	0.54		0.88		
Unadjusted interaction test for Treatment*Region [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.38 (0.02, 7.84)		1.17 (0.15, 8.79)		
p-value [1]	0.53		0.88		
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.12, 0.30)		-0.01 (-0.12, 0.10)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Region [3]					NA
Non-Responder, n(%)	25 (86.2%)	7 (100.0%)	35 (94.6%)	30 (93.8%)	
Baseline spleen volume not available	0	0	0	0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-srr24-gba-rt.sas V.03.05 Output file: t-subgrp-srr24-gba-Geo.pdf 24AUG2023:16:34

Table 2.0104: Analysis of Splenic Response Rate at Week 24 by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Spleen volume at Week 24 not available	8 (27.6%)	1 (14.3%)	14 (37.8%)	8 (25.0%)	
>0% spleen volume increase at Week 24	9 (31.0%)	6 (85.7%)	11 (29.7%)	9 (28.1%)	
<35% spleen volume reduction at Week 24	17 (58.6%)	6 (85.7%)	21 (56.8%)	22 (68.8%)	
Last participation date < Day 141 in RT phase	6 (20.7%)	1 (14.3%)	9 (24.3%)	6 (18.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.0107: Analysis of Splenic Response Rate at Week 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<8 g/dL		>=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Splenic Response Rate at Week 24					
Responder, n(%)	4 (14.8%)	0	2 (5.1%)	2 (6.1%)	
95% Exact CI	0.0419, 0.3373	0.0000, 0.4593	0.0063, 0.1732	0.0074, 0.2023	
Proportion Difference - Stratified CMH Method (95% CI)	0.14 (-0.21, 0.50)		-0.02 (-0.17, 0.14)		
p-value	0.44		0.84		
Proportion Difference - Unstratified CMH Method (95% CI)	0.15 (-0.12, 0.41)		-0.01 (-0.13, 0.11)		
p-value	0.28		0.88		
Proportion Difference - Unstratified Exact Method (95% CI)	0.15 (-0.30, 0.58)		-0.01 (-0.24, 0.22)		
p-value	1.00		1.00		
Unadjusted Inverse Relative Risk (95% CI)	0.44 (0.03, 7.32)		1.18 (0.18, 7.94)		
p-value [1]	0.57		0.86		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.40 (0.02, 8.47)		1.19 (0.16, 8.97)		
p-value [1]	0.56		0.86		
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.15, 0.32)		-0.01 (-0.12, 0.10)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-srr24-gba-rt.sas V.03.05 Output file: t-subgrp-srr24-gba-hgb.pdf 24AUG2023:16:34

Table 2.0107: Analysis of Splenic Response Rate at Week 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<8 g/dL		>=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Non-Responder, n(%)	23 (85.2%)	6 (100.0%)	37 (94.9%)	31 (93.9%)	
Baseline spleen volume not available	0	0	0	0	
Spleen volume at Week 24 not available	8 (29.6%)	2 (33.3%)	14 (35.9%)	7 (21.2%)	
>0% spleen volume increase at Week 24	7 (25.9%)	2 (33.3%)	13 (33.3%)	13 (39.4%)	
<35% spleen volume reduction at Week 24	15 (55.6%)	4 (66.7%)	23 (59.0%)	24 (72.7%)	
Last participation date < Day 141 in RT phase	6 (22.2%)	2 (33.3%)	9 (23.1%)	5 (15.2%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-srr24-gba-rt.sas V.03.05 Output file: t-subgrp-srr24-gba-hgb.pdf 24AUG2023:16:34

Table 2.0106: Analysis of Splenic Response Rate at Week 24 by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Splenic Response Rate at Week 24					
Responder, n(%)	5 (10.2%)	2 (6.5%)	1 (5.9%)	0	
95% Exact CI	0.0340, 0.2223	0.0079, 0.2142	0.0015, 0.2869	0.0000, 0.3694	
Proportion Difference - Stratified CMH Method (95% CI)	0.02 (-0.15, 0.18)		0.05 (-0.23, 0.33)		
p-value	0.85		0.73		
Proportion Difference - Unstratified CMH Method (95% CI)	0.04 (-0.09, 0.17)		0.06 (-0.16, 0.28)		
p-value	0.57		0.60		
Proportion Difference - Unstratified Exact Method (95% CI)	0.04 (-0.19, 0.26)		0.06 (-0.34, 0.45)		
p-value	0.70		1.00		
Unadjusted Inverse Relative Risk (95% CI)	0.63 (0.13, 3.06)		0.67 (0.03, 14.78)		
p-value [1]	0.57		0.80		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.61 (0.11, 3.34)		0.65 (0.02, 17.65)		
p-value [1]	0.57		0.80		
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.08, 0.16)		0.03 (-0.17, 0.22)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.0106: Analysis of Splenic Response Rate at Week 24 by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Non-Responder, n(%)	44 (89.8%)	29 (93.5%)	16 (94.1%)	8 (100.0%)	
Baseline spleen volume not available	0	0	0	0	
Spleen volume at Week 24 not available	14 (28.6%)	7 (22.6%)	8 (47.1%)	2 (25.0%)	
>0% spleen volume increase at Week 24	16 (32.7%)	12 (38.7%)	4 (23.5%)	3 (37.5%)	
<35% spleen volume reduction at Week 24	30 (61.2%)	22 (71.0%)	8 (47.1%)	6 (75.0%)	
Last participation date < Day 141 in RT phase	9 (18.4%)	6 (19.4%)	6 (35.3%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.0105: Analysis of Splenic Response Rate at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Splenic Response Rate at Week 24				
Responder, n(%)	1 (20.0%)	0	4 (9.1%)	2 (8.3%)
95% Exact CI	0.0051, 0.7164	0.0000, 0.4096	0.0253, 0.2167	0.0103, 0.2700
Proportion Difference - Stratified CMH Method (95% CI)	0.33 (-0.48, 1.15)		-0.02 (-0.23, 0.20)	
p-value	0.42		0.86	
Proportion Difference - Unstratified CMH Method (95% CI)	0.20 (-0.27, 0.67)		0.01 (-0.14, 0.16)	
p-value	0.40		0.92	
Proportion Difference - Unstratified Exact Method (95% CI)	0.20 (-0.36, 0.72)		0.01 (-0.24, 0.26)	
p-value	0.42		1.00	
Unadjusted Inverse Relative Risk (95% CI)	0.25 (0.01, 5.13)		0.92 (0.18, 4.65)	
p-value [1]	0.37		0.92	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	0.20 (0.01, 6.04)		0.91 (0.15, 5.37)	
p-value [1]	0.35		0.92	
Unadjusted Absolute Risk Difference (95% CI)	0.19 (-0.20, 0.57)		0.01 (-0.13, 0.15)	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.0105: Analysis of Splenic Response Rate at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=17)	High Risk BAT (N=8)	p-value
Splenic Response Rate at Week 24			
Responder, n(%)	1 (5.9%)	0	
95% Exact CI	0.0015, 0.2869	0.0000, 0.3694	
Proportion Difference - Stratified CMH Method (95% CI)	0.05 (-0.23, 0.33)		
p-value	0.73		
Proportion Difference - Unstratified CMH Method (95% CI)	0.06 (-0.16, 0.28)		
p-value	0.60		
Proportion Difference - Unstratified Exact Method (95% CI)	0.06 (-0.34, 0.45)		
p-value	1.00		
Unadjusted Inverse Relative Risk (95% CI)	0.67 (0.03, 14.78)		
p-value [1]	0.80		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	0.65 (0.02, 17.65)		
p-value [1]	0.80		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.17, 0.22)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.0105: Analysis of Splenic Response Rate at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Non-Responder, n(%)	4 (80.0%)	7 (100.0%)	40 (90.9%)	22 (91.7%)
Baseline spleen volume not available	0	0	0	0
Spleen volume at Week 24 not available	2 (40.0%)	2 (28.6%)	12 (27.3%)	5 (20.8%)
>0% spleen volume increase at Week 24	0	3 (42.9%)	16 (36.4%)	9 (37.5%)
<35% spleen volume reduction at Week 24	2 (40.0%)	5 (71.4%)	28 (63.6%)	17 (70.8%)
Last participation date < Day 141 in RT phase	1 (20.0%)	1 (14.3%)	8 (18.2%)	5 (20.8%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.0105: Analysis of Splenic Response Rate at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=17)	High Risk BAT (N=8)	p-value
Non-Responder, n(%)	16 (94.1%)	8 (100.0%)	
Baseline spleen volume not available	0	0	
Spleen volume at Week 24 not available	8 (47.1%)	2 (25.0%)	
>0% spleen volume increase at Week 24	4 (23.5%)	3 (37.5%)	
<35% spleen volume reduction at Week 24	8 (47.1%)	6 (75.0%)	
Last participation date < Day 141 in RT phase	6 (35.3%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.0108: Analysis of Splenic Response Rate at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
Splenic Response Rate at Week 24				
Responder, n(%)	3 (6.7%)	1 (4.3%)	3 (23.1%)	0
95% Exact CI	0.0140, 0.1827	0.0011, 0.2195	0.0504, 0.5381	0.0000, 0.3694
Proportion Difference - Stratified CMH Method (95% CI)	0.02 (-0.14, 0.18)		0.31 (-0.08, 0.70)	
p-value	0.82		0.11	
Proportion Difference - Unstratified CMH Method (95% CI)	0.02 (-0.10, 0.15)		0.23 (-0.07, 0.53)	
p-value	0.72		0.13	
Proportion Difference - Unstratified Exact Method (95% CI)	0.02 (-0.23, 0.27)		0.23 (-0.21, 0.62)	
p-value	1.00		0.26	
Unadjusted Inverse Relative Risk (95% CI)	0.65 (0.07, 5.93)		0.22 (0.01, 3.81)	
p-value [1]	0.70		0.30	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	0.64 (0.06, 6.48)		0.18 (0.01, 3.91)	
p-value [1]	0.70		0.27	
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.09, 0.13)		0.19 (-0.08, 0.47)	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-srr24-gba-rt.sas V.03.05 Output file: t-subgrp-srr24-gba-mf.pdf 24AUG2023:16:35

Table 2.0108: Analysis of Splenic Response Rate at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	Post-PV Myelofibrosis MMB (N=8)	Post-PV Myelofibrosis BAT (N=8)	p-value
Splenic Response Rate at Week 24			
Responder, n(%)	0	1 (12.5%)	
95% Exact CI	0.0000, 0.3694	0.0032, 0.5265	
Proportion Difference - Stratified CMH Method (95% CI)	-0.22 (-0.79, 0.35)		
p-value	0.45		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.13 (-0.45, 0.20)		
p-value	0.45		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.13 (-0.60, 0.40)		
p-value	1.00		
Unadjusted Inverse Relative Risk (95% CI)	3.00 (0.14, 64.27)		
p-value [1]	0.48		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	3.40 (0.12, 96.71)		
p-value [1]	0.47		
Unadjusted Absolute Risk Difference (95% CI)	-0.11 (-0.40, 0.17)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.0108: Analysis of Splenic Response Rate at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
Non-Responder, n(%)	42 (93.3%)	22 (95.7%)	10 (76.9%)	8 (100.0%)
Baseline spleen volume not available	0	0	0	0
Spleen volume at Week 24 not available	16 (35.6%)	5 (21.7%)	4 (30.8%)	3 (37.5%)
>0% spleen volume increase at Week 24	13 (28.9%)	12 (52.2%)	4 (30.8%)	2 (25.0%)
<35% spleen volume reduction at Week 24	26 (57.8%)	17 (73.9%)	6 (46.2%)	5 (62.5%)
Last participation date < Day 141 in RT phase	10 (22.2%)	4 (17.4%)	3 (23.1%)	2 (25.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.0108: Analysis of Splenic Response Rate at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	Post-PV Myelofibrosis MMB (N=8)	Post-PV Myelofibrosis BAT (N=8)	p-value
Non-Responder, n(%)	8 (100.0%)	7 (87.5%)	
Baseline spleen volume not available	0	0	
Spleen volume at Week 24 not available	2 (25.0%)	1 (12.5%)	
>0% spleen volume increase at Week 24	3 (37.5%)	1 (12.5%)	
<35% spleen volume reduction at Week 24	6 (75.0%)	6 (75.0%)	
Last participation date < Day 141 in RT phase	2 (25.0%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.0103: Analysis of Splenic Response Rate at Week 24 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Splenic Response Rate at Week 24					
Responder, n(%)	4 (7.7%)	1 (5.6%)	2 (14.3%)	1 (4.8%)	
95% Exact CI	0.0214, 0.1854	0.0014, 0.2729	0.0178, 0.4281	0.0012, 0.2382	
Proportion Difference - Stratified CMH Method (95% CI)	0.02 (-0.17, 0.22)		0.02 (-0.26, 0.30)		
p-value	0.82		0.88		
Proportion Difference - Unstratified CMH Method (95% CI)	0.02 (-0.13, 0.17)		0.10 (-0.14, 0.33)		
p-value	0.78		0.42		
Proportion Difference - Unstratified Exact Method (95% CI)	0.02 (-0.24, 0.29)		0.10 (-0.25, 0.43)		
p-value	1.00		0.55		
Unadjusted Inverse Relative Risk (95% CI)	0.72 (0.09, 6.05)		0.33 (0.03, 3.34)		
p-value [1]	0.76		0.35		
Unadjusted interaction test for Treatment*Gender [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.71 (0.07, 6.77)		0.30 (0.02, 3.67)		
p-value [1]	0.76		0.35		
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.11, 0.15)		0.10 (-0.11, 0.30)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Gender [3]					NA
Non-Responder, n(%)	48 (92.3%)	17 (94.4%)	12 (85.7%)	20 (95.2%)	
Baseline spleen volume not available	0	0	0	0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-srr24-gba-rt.sas V.03.05 Output file: t-subgrp-srr24-gba-sex.pdf 24AUG2023:16:34

Table 2.0103: Analysis of Splenic Response Rate at Week 24 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Spleen volume at Week 24 not available	19 (36.5%)	6 (33.3%)	3 (21.4%)	3 (14.3%)	
>0% spleen volume increase at Week 24	16 (30.8%)	7 (38.9%)	4 (28.6%)	8 (38.1%)	
<35% spleen volume reduction at Week 24	29 (55.8%)	11 (61.1%)	9 (64.3%)	17 (81.0%)	
Last participation date < Day 141 in RT phase	11 (21.2%)	4 (22.2%)	4 (28.6%)	3 (14.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.0110: Analysis of Splenic Response Rate at Week 24 by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Splenic Response Rate at Week 24					
Responder, n(%)	3 (10.7%)	2 (8.3%)	3 (7.9%)	0	
95% Exact CI	0.0227, 0.2823	0.0103, 0.2700	0.0166, 0.2138	0.0000, 0.2180	
Proportion Difference - Stratified CMH Method (95% CI)	0.02 (-0.19, 0.23)		0.06 (-0.20, 0.32)		
p-value	0.84		0.63		
Proportion Difference - Unstratified CMH Method (95% CI)	0.02 (-0.15, 0.20)		0.08 (-0.05, 0.21)		
p-value	0.79		0.23		
Proportion Difference - Unstratified Exact Method (95% CI)	0.02 (-0.25, 0.29)		0.08 (-0.22, 0.37)		
p-value	1.00		0.55		
Unadjusted Inverse Relative Risk (95% CI)	0.78 (0.14, 4.28)		0.35 (0.02, 6.36)		
p-value [1]	0.77		0.48		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.76 (0.12, 4.96)		0.33 (0.02, 6.72)		
p-value [1]	0.77		0.47		
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.14, 0.18)		0.06 (-0.07, 0.18)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.0110: Analysis of Splenic Response Rate at Week 24 by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Non-Responder, n(%)	25 (89.3%)	22 (91.7%)	35 (92.1%)	15 (100.0%)	
Baseline spleen volume not available	0	0	0	0	
Spleen volume at Week 24 not available	5 (17.9%)	3 (12.5%)	17 (44.7%)	6 (40.0%)	
>0% spleen volume increase at Week 24	13 (46.4%)	11 (45.8%)	7 (18.4%)	4 (26.7%)	
<35% spleen volume reduction at Week 24	20 (71.4%)	19 (79.2%)	18 (47.4%)	9 (60.0%)	
Last participation date < Day 141 in RT phase	4 (14.3%)	2 (8.3%)	11 (28.9%)	5 (33.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.0109: Analysis of Splenic Response Rate at Week 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Splenic Response Rate at Week 24					
Responder, n(%)	4 (9.5%)	2 (10.0%)	2 (8.3%)	0	
95% Exact CI	0.0266, 0.2262	0.0123, 0.3170	0.0103, 0.2700	0.0000, 0.1765	
Proportion Difference - Stratified CMH Method (95% CI)	-0.01 (-0.19, 0.17)		0.09 (-0.08, 0.26)		
p-value	0.93		0.31		
Proportion Difference - Unstratified CMH Method (95% CI)	0.00 (-0.18, 0.17)		0.08 (-0.06, 0.23)		
p-value	0.96		0.25		
Proportion Difference - Unstratified Exact Method (95% CI)	0.00 (-0.27, 0.26)		0.08 (-0.21, 0.37)		
p-value	1.00		0.50		
Unadjusted Inverse Relative Risk (95% CI)	1.05 (0.21, 5.26)		0.25 (0.01, 4.92)		
p-value [1]	0.95		0.36		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	1.06 (0.18, 6.31)		0.23 (0.01, 5.10)		
p-value [1]	0.95		0.35		
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.16, 0.15)		0.08 (-0.06, 0.21)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.0109: Analysis of Splenic Response Rate at Week 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Non-Responder, n(%)	38 (90.5%)	18 (90.0%)	22 (91.7%)	19 (100.0%)	
Baseline spleen volume not available	0	0	0	0	
Spleen volume at Week 24 not available	13 (31.0%)	4 (20.0%)	9 (37.5%)	5 (26.3%)	
>0% spleen volume increase at Week 24	15 (35.7%)	8 (40.0%)	5 (20.8%)	7 (36.8%)	
<35% spleen volume reduction at Week 24	25 (59.5%)	14 (70.0%)	13 (54.2%)	14 (73.7%)	
Last participation date < Day 141 in RT phase	8 (19.0%)	3 (15.0%)	7 (29.2%)	4 (21.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.7502: Analysis of Response Rate (improvement, 15% criterion) in Mean Symptom Score at Week 24 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	BAT (N = 9)	MMB (N = 42)	BAT (N = 30)	p-value
MPN-SAF at Week 24					
Responder, n(%)	1 (4.2%)	0	3 (7.1%)	1 (3.3%)	
Unadjusted Inverse Relative Risk (95% CI)	0.83 (0.04, 18.79)		0.47 (0.05, 4.27)		
p-value [1]	0.91		0.50		
Unadjusted interaction test for Treatment*Age Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.82 (0.03, 22.09)		0.45 (0.04, 4.53)		
p-value [1]	0.91		0.50		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.15, 0.17)		0.04 (-0.06, 0.14)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Age Group [3]					NA
Non-Responder, n(%)	23 (95.8%)	9 (100.0%)	39 (92.9%)	29 (96.7%)	
Non-missing	5 (20.8%)	4 (44.4%)	18 (42.9%)	18 (60.0%)	
Missing	18 (75.0%)	5 (55.6%)	21 (50.0%)	11 (36.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7504: Analysis of Response Rate (improvement, 15% criterion) in Mean Symptom Score at Week 24 by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N = 29)	BAT (N = 7)	MMB (N = 37)	BAT (N = 32)	p-value
MPN-SAF at Week 24					
Responder, n(%)	3 (10.3%)	0	1 (2.7%)	1 (3.1%)	
Unadjusted Inverse Relative Risk (95% CI)	0.54 (0.03, 9.34)		1.16 (0.08, 17.75)		
p-value [1]	0.67		0.92		
Unadjusted interaction test for Treatment*Region [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.50 (0.02, 10.90)		1.16 (0.07, 19.35)		
p-value [1]	0.66		0.92		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.15, 0.26)		0.00 (-0.08, 0.08)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Region [3]					NA
Non-Responder, n(%)	26 (89.7%)	7 (100.0%)	36 (97.3%)	31 (96.9%)	
Non-missing	6 (20.7%)	3 (42.9%)	17 (45.9%)	19 (59.4%)	
Missing	20 (69.0%)	4 (57.1%)	19 (51.4%)	12 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7507: Analysis of Response Rate (improvement, 15% criterion) in Mean Symptom Score at Week 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 27)	BAT (N = 6)	MMB (N = 39)	BAT (N = 33)	p-value
MPN-SAF at Week 24					
Responder, n(%)	2 (7.4%)	0	2 (5.1%)	1 (3.0%)	
Unadjusted Inverse Relative Risk (95% CI)	0.80 (0.04, 14.85)		0.59 (0.06, 6.23)		
p-value [1]	0.88		0.66		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.78 (0.03, 18.42)		0.58 (0.05, 6.68)		
p-value [1]	0.88		0.66		
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.20, 0.24)		0.02 (-0.07, 0.11)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Non-Responder, n(%)	25 (92.6%)	6 (100.0%)	37 (94.9%)	32 (97.0%)	
Non-missing	8 (29.6%)	2 (33.3%)	15 (38.5%)	20 (60.6%)	
Missing	17 (63.0%)	4 (66.7%)	22 (56.4%)	12 (36.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7506: Analysis of Response Rate (improvement, 15% criterion) in Mean Symptom Score at Week 24 by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 49)	BAT (N = 31)	MMB (N = 17)	BAT (N = 8)	p-value
MPN-SAF at Week 24					
Responder, n(%)	2 (4.1%)	1 (3.2%)	2 (11.8%)	0	
Unadjusted Inverse Relative Risk (95% CI)	0.79 (0.07, 8.35)		0.40 (0.02, 7.48)		
p-value [1]	0.84		0.54		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.78 (0.07, 9.02)		0.36 (0.02, 8.51)		
p-value [1]	0.84		0.53		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.07, 0.09)		0.08 (-0.14, 0.30)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Non-Responder, n(%)	47 (95.9%)	30 (96.8%)	15 (88.2%)	8 (100.0%)	
Non-missing	18 (36.7%)	17 (54.8%)	5 (29.4%)	5 (62.5%)	
Missing	29 (59.2%)	13 (41.9%)	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7505: Analysis of Response Rate (improvement, 15% criterion) in Mean Symptom Score at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 5)	BAT (N = 7)	MMB (N = 44)	BAT (N = 24)
MPN-SAF at Week 24				
Responder, n(%)	0	0	2 (4.5%)	1 (4.2%)
Unadjusted Inverse Relative Risk (95% CI)	NA		0.92 (0.09, 9.60)	
p-value [1]	NA		0.94	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	NA		0.91 (0.08, 10.62)	
p-value [1]	NA		0.94	
Unadjusted Absolute Risk Difference (95% CI)	NA		0.00 (-0.10, 0.10)	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Non-Responder, n(%)	5 (100.0%)	7 (100.0%)	42 (95.5%)	23 (95.8%)
Non-missing	1 (20.0%)	3 (42.9%)	17 (38.6%)	14 (58.3%)
Missing	4 (80.0%)	4 (57.1%)	25 (56.8%)	9 (37.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7505: Analysis of Response Rate (improvement, 15% criterion) in Mean Symptom Score at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 17)	BAT (N = 8)	p-value
MPN-SAF at Week 24			
Responder, n(%)	2 (11.8%)	0	
Unadjusted Inverse Relative Risk (95% CI)	0.40 (0.02, 7.48)		
p-value [1]	0.54		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	0.36 (0.02, 8.51)		
p-value [1]	0.53		
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.14, 0.30)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	15 (88.2%)	8 (100.0%)	
Non-missing	5 (29.4%)	5 (62.5%)	
Missing	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7508: Analysis of Response Rate (improvement, 15% criterion) in Mean Symptom Score at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 45)	BAT (N = 23)	MMB (N = 13)	BAT (N = 8)
MPN-SAF at Week 24				
Responder, n(%)	2 (4.4%)	1 (4.3%)	2 (15.4%)	0
Unadjusted Inverse Relative Risk (95% CI)	0.98 (0.09, 10.23)		0.31 (0.02, 5.76)	
p-value [1]	0.99		0.43	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	0.98 (0.08, 11.38)		0.27 (0.01, 6.40)	
p-value [1]	0.99		0.42	
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.10, 0.10)		0.12 (-0.13, 0.37)	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	43 (95.6%)	22 (95.7%)	11 (84.6%)	8 (100.0%)
Non-missing	17 (37.8%)	12 (52.2%)	3 (23.1%)	3 (37.5%)
Missing	26 (57.8%)	10 (43.5%)	8 (61.5%)	5 (62.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7508: Analysis of Response Rate (improvement, 15% criterion) in Mean Symptom Score at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 8)	BAT (N = 8)	p-value
MPN-SAF at Week 24			
Responder, n(%)	0	0	
Unadjusted Inverse Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Non-Responder, n(%)	8 (100.0%)	8 (100.0%)	
Non-missing	3 (37.5%)	7 (87.5%)	
Missing	5 (62.5%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7503: Analysis of Response Rate (improvement, 15% criterion) in Mean Symptom Score at Week 24 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 52)	BAT (N = 18)	MMB (N = 14)	BAT (N = 21)	p-value
MPN-SAF at Week 24					
Responder, n(%)	2 (3.8%)	1 (5.6%)	2 (14.3%)	0	
Unadjusted Inverse Relative Risk (95% CI)	1.44 (0.14, 14.99)		0.14 (0.01, 2.64)		
p-value [1]	0.76		0.19		
Unadjusted interaction test for Treatment*Gender [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	1.47 (0.13, 17.26)		0.12 (0.01, 2.62)		
p-value [1]	0.76		0.18		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.14, 0.10)		0.14 (-0.05, 0.34)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Gender [3]					NA
Non-Responder, n(%)	50 (96.2%)	17 (94.4%)	12 (85.7%)	21 (100.0%)	
Non-missing	16 (30.8%)	7 (38.9%)	7 (50.0%)	15 (71.4%)	
Missing	34 (65.4%)	10 (55.6%)	5 (35.7%)	6 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7510: Analysis of Response Rate (improvement, 15% criterion) in Mean Symptom Score at Week 24 by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N = 28)	BAT (N = 24)	MMB (N = 38)	BAT (N = 15)	p-value
MPN-SAF at Week 24					
Responder, n(%)	3 (10.7%)	1 (4.2%)	1 (2.6%)	0	
Unadjusted Inverse Relative Risk (95% CI)	0.39 (0.04, 3.50)		0.81 (0.03, 18.91)		
p-value [1]	0.40		0.90		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.36 (0.04, 3.74)		0.81 (0.03, 20.90)		
p-value [1]	0.39		0.90		
Unadjusted Absolute Risk Difference (95% CI)	0.07 (-0.07, 0.21)		0.01 (-0.10, 0.11)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Non-Responder, n(%)	25 (89.3%)	23 (95.8%)	37 (97.4%)	15 (100.0%)	
Non-missing	9 (32.1%)	15 (62.5%)	14 (36.8%)	7 (46.7%)	
Missing	16 (57.1%)	8 (33.3%)	23 (60.5%)	8 (53.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7509: Analysis of Response Rate (improvement, 15% criterion) in Mean Symptom Score at Week 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 42)	BAT (N = 20)	MMB (N = 24)	BAT (N = 19)	p-value
MPN-SAF at Week 24					
Responder, n(%)	1 (2.4%)	1 (5.0%)	3 (12.5%)	0	
Unadjusted Inverse Relative Risk (95% CI)	2.10 (0.14, 31.89)		0.18 (0.01, 3.26)		
p-value [1]	0.59		0.24		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	2.16 (0.13, 36.37)		0.16 (0.01, 3.25)		
p-value [1]	0.59		0.23		
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.13, 0.08)		0.12 (-0.04, 0.27)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Non-Responder, n(%)	41 (97.6%)	19 (95.0%)	21 (87.5%)	19 (100.0%)	
Non-missing	18 (42.9%)	10 (50.0%)	5 (20.8%)	12 (63.2%)	
Missing	23 (54.8%)	9 (45.0%)	16 (66.7%)	7 (36.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.1402: Analysis of Response Rate (improvement, 50% criterion) in TSS at Weeks 12 and 24 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Total Symptom Score Status					
Missing TSS at baseline (excluded from rate calculation)	0	0	0	0	
TSS = 0 at baseline	0	2 (22.2%)	1 (2.4%)	1 (3.3%)	
TSS > 0 at baseline	24 (100.0%)	7 (77.8%)	41 (97.6%)	29 (96.7%)	
Response Rate of Total Symptom Score at Week 12					
Subjects Evaluable at Week 12, n	24	8	41	30	
TSS = 0 at baseline and TSS > 0 or missing at Week 12	0	1 (12.5%)	0	1 (3.3%)	
Responder, n(%)	4 (16.7%)	0	15 (36.6%)	3 (10.0%)	
95% Exact CI	0.0474, 0.3738	0.0000, 0.3694	0.2212, 0.5306	0.0211, 0.2653	
Proportion Difference - Stratified CMH Method (95% CI)	0.20 (-0.11, 0.51)		0.25 (0.04, 0.47)		
Proportion Difference - Unstratified CMH Method (95% CI)	0.17 (-0.06, 0.40)		0.27 (0.08, 0.45)		
Proportion Difference - Unstratified Exact Method (95% CI)	0.17 (-0.25, 0.55)		0.27 (0.03, 0.48)		
Unadjusted Inverse Relative Risk (95% CI)	0.31 (0.02, 5.18)		0.27 (0.09, 0.86)		
p-value [1]	0.41		0.027		
Unadjusted interaction test for Treatment*Age Group [3]					NE

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. [3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.1402: Analysis of Response Rate (improvement, 50% criterion) in TSS at Weeks 12 and 24 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Unadjusted Inverse Odds Ratio (95% CI)	0.27 (0.01, 5.54)		0.19 (0.05, 0.74)		
p-value [1]	0.39		0.017		
Unadjusted Absolute Risk Difference (95% CI)	0.12 (-0.09, 0.34)		0.27 (0.08, 0.45)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Age Group [3]					NE
Non-Responder, n(%)	20 (83.3%)	8 (100.0%)	26 (63.4%)	27 (90.0%)	
Last participation date < Day 78 in RT Phase	2 (8.3%)	3 (37.5%)	5 (12.2%)	3 (10.0%)	
Last participation date >= Day 78 and TSS at Week 12 not available	2 (8.3%)	0	0	0	
>0% increase from baseline at Week 12	8 (33.3%)	4 (50.0%)	10 (24.4%)	13 (43.3%)	
<50% reduction from baseline at Week 12	16 (66.7%)	4 (50.0%)	21 (51.2%)	23 (76.7%)	
Return Rate (%)	83%	67%	88%	90%	
Number of Subjects in Risk	22	6	37	27	
Return Rate in Risk (%)	91%	100%	100%	100%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. [3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.1402: Analysis of Response Rate (improvement, 50% criterion) in TSS at Weeks 12 and 24 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Response Rate of Total Symptom Score at Week 24					
Subjects Evaluable at Week 24, n	24	9	41	29	
TSS = 0 at baseline and TSS > 0 or missing at Week 24	0	2 (22.2%)	0	0	
Responder, n(%)	5 (20.8%)	0	16 (39.0%)	1 (3.4%)	
95% Exact CI	0.0713, 0.4215	0.0000, 0.3363	0.2420, 0.5550	0.0009, 0.1776	
Proportion Difference - Stratified CMH Method (95% CI)	0.23 (-0.13, 0.59)		0.36 (0.16, 0.56)		
Proportion Difference - Unstratified CMH Method (95% CI)	0.21 (-0.02, 0.44)		0.36 (0.18, 0.53)		
Proportion Difference - Unstratified Exact Method (95% CI)	0.21 (-0.18, 0.57)		0.36 (0.12, 0.56)		
Unadjusted Inverse Relative Risk (95% CI)	0.23 (0.01, 3.74)		0.09 (0.01, 0.63)		
p-value [1]	0.30		0.015		
Unadjusted interaction test for Treatment*Age Group [3]					NE

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. [3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.1402: Analysis of Response Rate (improvement, 50% criterion) in TSS at Weeks 12 and 24 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Unadjusted Inverse Odds Ratio (95% CI)	0.19 (0.01, 3.74)		0.06 (0.01, 0.45)		
p-value [1]	0.27		0.007		
Unadjusted Absolute Risk Difference (95% CI)	0.17 (-0.04, 0.38)		0.36 (0.19, 0.52)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Age Group [3]					NE
Non-Responder, n(%)	19 (79.2%)	9 (100.0%)	25 (61.0%)	28 (96.6%)	
Last participation date < Day 162 in RT Phase	8 (33.3%)	3 (33.3%)	10 (24.4%)	4 (13.8%)	
Last participation date >= Day 162 and TSS at Week 24 not available	0	1 (11.1%)	1 (2.4%)	2 (6.9%)	
>0% increase from baseline at Week 24	6 (25.0%)	4 (44.4%)	9 (22.0%)	13 (44.8%)	
<50% reduction from baseline at Week 24	11 (45.8%)	4 (44.4%)	14 (34.1%)	22 (75.9%)	
Return Rate (%)	67%	56%	74%	80%	
Number of Subjects in Risk	16	6	32	26	
Return Rate in Risk (%)	100%	83%	97%	92%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. [3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.1404: Analysis of Response Rate (improvement, 50% criterion) in TSS at Weeks 12 and 24 by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Total Symptom Score Status					
Missing TSS at baseline (excluded from rate calculation)	0	0	0	0	
TSS = 0 at baseline	0	1 (14.3%)	1 (2.7%)	2 (6.3%)	
TSS > 0 at baseline	29 (100.0%)	6 (85.7%)	36 (97.3%)	30 (93.8%)	
Response Rate of Total Symptom Score at Week 12					
Subjects Evaluable at Week 12, n	29	7	36	31	
TSS = 0 at baseline and TSS > 0 or missing at Week 12	0	1 (14.3%)	0	1 (3.2%)	
Responder, n(%)	12 (41.4%)	1 (14.3%)	7 (19.4%)	2 (6.5%)	
95% Exact CI	0.2352, 0.6106	0.0036, 0.5787	0.0819, 0.3602	0.0079, 0.2142	
Proportion Difference - Stratified CMH Method (95% CI)	0.30 (-0.17, 0.78)		0.14 (-0.05, 0.33)		
Proportion Difference - Unstratified CMH Method (95% CI)	0.27 (-0.09, 0.63)		0.13 (-0.03, 0.29)		
Proportion Difference - Unstratified Exact Method (95% CI)	0.27 (-0.15, 0.65)		0.13 (-0.11, 0.36)		
Unadjusted Inverse Relative Risk (95% CI)	0.35 (0.05, 2.23)		0.33 (0.07, 1.48)		
p-value [1]	0.26		0.15		
Unadjusted interaction test for Treatment*Region [3]					0.97

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. [3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.1404: Analysis of Response Rate (improvement, 50% criterion) in TSS at Weeks 12 and 24 by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Unadjusted Inverse Odds Ratio (95% CI)	0.24 (0.03, 2.22)		0.29 (0.05, 1.49)		
p-value [1]	0.21		0.14		
Unadjusted Absolute Risk Difference (95% CI)	0.27 (-0.04, 0.59)		0.13 (-0.03, 0.29)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.31 (0.07, 1.36)		
p-value [2]	NE		0.12		
Adjusted interaction test for Treatment*Region [3]					0.95
Non-Responder, n(%)	17 (58.6%)	6 (85.7%)	29 (80.6%)	29 (93.5%)	
Last participation date < Day 78 in RT Phase	3 (10.3%)	1 (14.3%)	4 (11.1%)	5 (16.1%)	
Last participation date >= Day 78 and TSS at Week 12 not available	1 (3.4%)	0	1 (2.8%)	0	
>0% increase from baseline at Week 12	7 (24.1%)	2 (28.6%)	11 (30.6%)	15 (48.4%)	
<50% reduction from baseline at Week 12	13 (44.8%)	4 (57.1%)	24 (66.7%)	23 (74.2%)	
Return Rate (%)	86%	86%	86%	84%	
Number of Subjects in Risk	26	6	33	27	
Return Rate in Risk (%)	96%	100%	97%	100%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. [3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.1404: Analysis of Response Rate (improvement, 50% criterion) in TSS at Weeks 12 and 24 by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Response Rate of Total Symptom Score at Week 24					
Subjects Evaluable at Week 24, n	29	7	36	31	
TSS = 0 at baseline and TSS > 0 or missing at Week 24	0	1 (14.3%)	0	1 (3.2%)	
Responder, n(%)	14 (48.3%)	0	7 (19.4%)	1 (3.2%)	
95% Exact CI	0.2945, 0.6747	0.0000, 0.4096	0.0819, 0.3602	0.0008, 0.1670	
Proportion Difference - Stratified CMH Method (95% CI)	0.54 (0.13, 0.96)		0.16 (-0.01, 0.34)		
Proportion Difference - Unstratified CMH Method (95% CI)	0.48 (0.21, 0.75)		0.16 (0.01, 0.32)		
Proportion Difference - Unstratified Exact Method (95% CI)	0.48 (0.08, 0.82)		0.16 (-0.08, 0.39)		
Unadjusted Inverse Relative Risk (95% CI)	0.13 (0.01, 1.94)		0.17 (0.02, 1.28)		
p-value [1]	0.14		0.084		
Unadjusted interaction test for Treatment*Region [3]					NE

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. [3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.1404: Analysis of Response Rate (improvement, 50% criterion) in TSS at Weeks 12 and 24 by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Unadjusted Inverse Odds Ratio (95% CI)	0.07 (0.00, 1.36)		0.14 (0.02, 1.19)		
p-value [1]	0.079		0.072		
Unadjusted Absolute Risk Difference (95% CI)	0.42 (0.18, 0.67)		0.16 (0.02, 0.31)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.17 (0.02, 1.12)		
p-value [2]	NE		0.065		
Adjusted interaction test for Treatment*Region [3]					NE
Non-Responder, n(%)	15 (51.7%)	7 (100.0%)	29 (80.6%)	30 (96.8%)	
Last participation date < Day 162 in RT Phase	6 (20.7%)	1 (14.3%)	12 (33.3%)	6 (19.4%)	
Last participation date >= Day 162 and TSS at Week 24 not available	1 (3.4%)	2 (28.6%)	0	1 (3.2%)	
>0% increase from baseline at Week 24	5 (17.2%)	3 (42.9%)	10 (27.8%)	14 (45.2%)	
<50% reduction from baseline at Week 24	8 (27.6%)	4 (57.1%)	17 (47.2%)	22 (71.0%)	
Return Rate (%)	76%	57%	68%	78%	
Number of Subjects in Risk	23	6	25	26	
Return Rate in Risk (%)	96%	67%	100%	96%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. [3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.1407: Analysis of Response Rate (improvement, 50% criterion) in TSS at Weeks 12 and 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<8 g/dL		>=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Total Symptom Score Status					
Missing TSS at baseline (excluded from rate calculation)	0	0	0	0	
TSS = 0 at baseline	0	1 (16.7%)	1 (2.6%)	2 (6.1%)	
TSS > 0 at baseline	27 (100.0%)	5 (83.3%)	38 (97.4%)	31 (93.9%)	
Response Rate of Total Symptom Score at Week 12					
Subjects Evaluable at Week 12, n	27	6	38	32	
TSS = 0 at baseline and TSS > 0 or missing at Week 12	0	1 (16.7%)	0	1 (3.1%)	
Responder, n(%)	9 (33.3%)	2 (33.3%)	10 (26.3%)	1 (3.1%)	
95% Exact CI	0.1652, 0.5396	0.0433, 0.7772	0.1340, 0.4310	0.0008, 0.1622	
Proportion Difference - Stratified CMH Method (95% CI)	-0.01 (-0.52, 0.50)		0.22 (0.05, 0.40)		
Proportion Difference - Unstratified CMH Method (95% CI)	0.00 (-0.46, 0.46)		0.23 (0.07, 0.39)		
Proportion Difference - Unstratified Exact Method (95% CI)	0.00 (-0.46, 0.46)		0.23 (0.00, 0.45)		
Unadjusted Inverse Relative Risk (95% CI)	1.00 (0.29, 3.49)		0.12 (0.02, 0.88)		
p-value [1]	1.00		0.037		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.16

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. [3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.1407: Analysis of Response Rate (improvement, 50% criterion) in TSS at Weeks 12 and 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<8 g/dL		>=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Unadjusted Inverse Odds Ratio (95% CI)	1.00 (0.15, 6.53)		0.09 (0.01, 0.75)		
p-value [1]	1.00		0.026		
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.42, 0.42)		0.23 (0.08, 0.38)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.02 (0.29, 3.59)		NE		
p-value [2]	0.97		NE		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.15
Non-Responder, n(%)	18 (66.7%)	4 (66.7%)	28 (73.7%)	31 (96.9%)	
Last participation date < Day 78 in RT Phase	3 (11.1%)	2 (33.3%)	4 (10.5%)	4 (12.5%)	
Last participation date >= Day 78 and TSS at Week 12 not available	0	0	2 (5.3%)	0	
>0% increase from baseline at Week 12	8 (29.6%)	0	10 (26.3%)	17 (53.1%)	
<50% reduction from baseline at Week 12	15 (55.6%)	1 (16.7%)	22 (57.9%)	26 (81.3%)	
Return Rate (%)	89%	67%	85%	88%	
Number of Subjects in Risk	24	4	35	29	
Return Rate in Risk (%)	100%	100%	94%	100%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. [3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.1407: Analysis of Response Rate (improvement, 50% criterion) in TSS at Weeks 12 and 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<8 g/dL		>=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Response Rate of Total Symptom Score at Week 24					
Subjects Evaluable at Week 24, n	27	6	38	32	
TSS = 0 at baseline and TSS > 0 or missing at Week 24	0	1 (16.7%)	0	1 (3.1%)	
Responder, n(%)	11 (40.7%)	0	10 (26.3%)	1 (3.1%)	
95% Exact CI	0.2239, 0.6120	0.0000, 0.4593	0.1340, 0.4310	0.0008, 0.1622	
Proportion Difference - Stratified CMH Method (95% CI)	0.41 (0.03, 0.79)		0.23 (0.05, 0.41)		
Proportion Difference - Unstratified CMH Method (95% CI)	0.41 (0.11, 0.70)		0.23 (0.07, 0.39)		
Proportion Difference - Unstratified Exact Method (95% CI)	0.41 (-0.04, 0.78)		0.23 (0.00, 0.45)		
Unadjusted Inverse Relative Risk (95% CI)	0.17 (0.01, 2.61)		0.12 (0.02, 0.88)		
p-value [1]	0.21		0.037		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. [3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.1407: Analysis of Response Rate (improvement, 50% criterion) in TSS at Weeks 12 and 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<8 g/dL		>=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Unadjusted Inverse Odds Ratio (95% CI)	0.11 (0.01, 2.16)		0.09 (0.01, 0.75)		
p-value [1]	0.15		0.026		
Unadjusted Absolute Risk Difference (95% CI)	0.34 (0.08, 0.60)		0.23 (0.08, 0.38)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.12 (0.02, 0.85)		
p-value [2]	NE		0.034		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE
Non-Responder, n(%)	16 (59.3%)	6 (100.0%)	28 (73.7%)	31 (96.9%)	
Last participation date < Day 162 in RT Phase	8 (29.6%)	2 (33.3%)	10 (26.3%)	5 (15.6%)	
Last participation date >= Day 162 and TSS at Week 24 not available	0	3 (50.0%)	1 (2.6%)	0	
>0% increase from baseline at Week 24	4 (14.8%)	0	11 (28.9%)	17 (53.1%)	
<50% reduction from baseline at Week 24	8 (29.6%)	1 (16.7%)	17 (44.7%)	25 (78.1%)	
Return Rate (%)	70%	17%	72%	85%	
Number of Subjects in Risk	19	4	29	28	
Return Rate in Risk (%)	100%	25%	97%	100%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. [3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.1406: Analysis of Response Rate (improvement, 50% criterion) in TSS at Weeks 12 and 24 by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Total Symptom Score Status					
Missing TSS at baseline (excluded from rate calculation)	0	0	0	0	
TSS = 0 at baseline	1 (2.0%)	3 (9.7%)	0	0	
TSS > 0 at baseline	48 (98.0%)	28 (90.3%)	17 (100.0%)	8 (100.0%)	
Response Rate of Total Symptom Score at Week 12					
Subjects Evaluable at Week 12, n	48	30	17	8	
TSS = 0 at baseline and TSS > 0 or missing at Week 12	0	2 (6.7%)	0	0	
Responder, n(%)	13 (27.1%)	1 (3.3%)	6 (35.3%)	2 (25.0%)	
95% Exact CI	0.1528, 0.4185	0.0008, 0.1722	0.1421, 0.6167	0.0319, 0.6509	
Proportion Difference - Stratified CMH Method (95% CI)	0.21 (0.04, 0.39)		0.10 (-0.34, 0.54)		
Proportion Difference - Unstratified CMH Method (95% CI)	0.24 (0.09, 0.39)		0.10 (-0.30, 0.51)		
Proportion Difference - Unstratified Exact Method (95% CI)	0.24 (0.01, 0.45)		0.10 (-0.32, 0.50)		
Unadjusted Inverse Relative Risk (95% CI)	0.12 (0.02, 0.89)		0.71 (0.18, 2.77)		
p-value [1]	0.038		0.62		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					0.21

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. [3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.1406: Analysis of Response Rate (improvement, 50% criterion) in TSS at Weeks 12 and 24 by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Unadjusted Inverse Odds Ratio (95% CI)	0.09 (0.01, 0.75)		0.61 (0.09, 4.02)		
p-value [1]	0.026		0.61		
Unadjusted Absolute Risk Difference (95% CI)	0.24 (0.10, 0.38)		0.10 (-0.27, 0.48)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.71 (0.17, 3.02)		
p-value [2]	NE		0.65		
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					0.23
Non-Responder, n(%)	35 (72.9%)	29 (96.7%)	11 (64.7%)	6 (75.0%)	
Last participation date < Day 78 in RT Phase	4 (8.3%)	5 (16.7%)	3 (17.6%)	1 (12.5%)	
Last participation date >= Day 78 and TSS at Week 12 not available	2 (4.2%)	0	0	0	
>0% increase from baseline at Week 12	14 (29.2%)	15 (50.0%)	4 (23.5%)	2 (25.0%)	
<50% reduction from baseline at Week 12	29 (60.4%)	22 (73.3%)	8 (47.1%)	5 (62.5%)	
Return Rate (%)	88%	84%	82%	88%	
Number of Subjects in Risk	45	26	14	7	
Return Rate in Risk (%)	96%	100%	100%	100%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. [3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.1406: Analysis of Response Rate (improvement, 50% criterion) in TSS at Weeks 12 and 24 by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Response Rate of Total Symptom Score at Week 24					
Subjects Evaluable at Week 24, n	48	30	17	8	
TSS = 0 at baseline and TSS > 0 or missing at Week 24	0	2 (6.7%)	0	0	
Responder, n(%)	14 (29.2%)	1 (3.3%)	7 (41.2%)	0	
95% Exact CI	0.1695, 0.4406	0.0008, 0.1722	0.1844, 0.6708	0.0000, 0.3694	
Proportion Difference - Stratified CMH Method (95% CI)	0.24 (0.07, 0.42)		0.43 (0.06, 0.80)		
Proportion Difference - Unstratified CMH Method (95% CI)	0.26 (0.11, 0.41)		0.41 (0.12, 0.71)		
Proportion Difference - Unstratified Exact Method (95% CI)	0.26 (0.03, 0.47)		0.41 (0.01, 0.76)		
Unadjusted Inverse Relative Risk (95% CI)	0.11 (0.02, 0.83)		0.13 (0.01, 2.08)		
p-value [1]	0.032		0.15		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NE

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. [3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.1406: Analysis of Response Rate (improvement, 50% criterion) in TSS at Weeks 12 and 24 by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Unadjusted Inverse Odds Ratio (95% CI)	0.08 (0.01, 0.68)		0.08 (0.00, 1.66)		
p-value [1]	0.020		0.10		
Unadjusted Absolute Risk Difference (95% CI)	0.26 (0.11, 0.40)		0.36 (0.09, 0.63)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NE
Non-Responder, n(%)	34 (70.8%)	29 (96.7%)	10 (58.8%)	8 (100.0%)	
Last participation date < Day 162 in RT Phase	12 (25.0%)	6 (20.0%)	6 (35.3%)	1 (12.5%)	
Last participation date >= Day 162 and TSS at Week 24 not available	1 (2.1%)	1 (3.3%)	0	2 (25.0%)	
>0% increase from baseline at Week 24	11 (22.9%)	13 (43.3%)	4 (23.5%)	4 (50.0%)	
<50% reduction from baseline at Week 24	21 (43.8%)	21 (70.0%)	4 (23.5%)	5 (62.5%)	
Return Rate (%)	73%	77%	65%	63%	
Number of Subjects in Risk	37	25	11	7	
Return Rate in Risk (%)	97%	96%	100%	71%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. [3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.1405: Analysis of Response Rate (improvement, 50% criterion) in TSS at Weeks 12 and 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Total Symptom Score Status				
Missing TSS at baseline (excluded from rate calculation)	0	0	0	0
TSS = 0 at baseline	0	1 (14.3%)	1 (2.3%)	2 (8.3%)
TSS > 0 at baseline	5 (100.0%)	6 (85.7%)	43 (97.7%)	22 (91.7%)
Response Rate of Total Symptom Score at Week 12				
Subjects Evaluable at Week 12, n	5	7	43	23
TSS = 0 at baseline and TSS > 0 or missing at Week 12	0	1 (14.3%)	0	1 (4.3%)
Responder, n(%)	2 (40.0%)	0	11 (25.6%)	1 (4.3%)
95% Exact CI	0.0527, 0.8534	0.0000, 0.4096	0.1352, 0.4117	0.0011, 0.2195
Proportion Difference - Stratified CMH Method (95% CI)	0.33 (-0.48, 1.15)		0.16 (-0.05, 0.38)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.40 (-0.12, 0.92)		0.21 (0.05, 0.38)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.40 (-0.17, 0.85)		0.21 (-0.04, 0.45)	
Unadjusted Inverse Relative Risk (95% CI)	0.15 (0.01, 2.58)		0.17 (0.02, 1.24)	
p-value [1]	0.19		0.080	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. [3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.1405: Analysis of Response Rate (improvement, 50% criterion) in TSS at Weeks 12 and 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=17)	High Risk BAT (N=8)	p-value
Total Symptom Score Status			
Missing TSS at baseline (excluded from rate calculation)	0	0	
TSS = 0 at baseline	0	0	
TSS > 0 at baseline	17 (100.0%)	8 (100.0%)	
Response Rate of Total Symptom Score at Week 12			
Subjects Evaluable at Week 12, n	17	8	
TSS = 0 at baseline and TSS > 0 or missing at Week 12	0	0	
Responder, n(%)	6 (35.3%)	2 (25.0%)	
95% Exact CI	0.1421, 0.6167	0.0319, 0.6509	
Proportion Difference - Stratified CMH Method (95% CI)	0.10 (-0.34, 0.54)		
Proportion Difference - Unstratified CMH Method (95% CI)	0.10 (-0.30, 0.51)		
Proportion Difference - Unstratified Exact Method (95% CI)	0.10 (-0.32, 0.50)		
Unadjusted Inverse Relative Risk (95% CI)	0.71 (0.18, 2.77)		
p-value [1]	0.62		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NE

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. [3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.1405: Analysis of Response Rate (improvement, 50% criterion) in TSS at Weeks 12 and 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Unadjusted Inverse Odds Ratio (95% CI)	0.09 (0.00, 2.51)		0.13 (0.02, 1.10)	
p-value [1]	0.16		0.061	
Unadjusted Absolute Risk Difference (95% CI)	0.35 (-0.07, 0.78)		0.21 (0.06, 0.37)	
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE	
p-value [2]	NE		NE	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Non-Responder, n(%)	3 (60.0%)	7 (100.0%)	32 (74.4%)	22 (95.7%)
Last participation date < Day 78 in RT Phase	1 (20.0%)	1 (14.3%)	3 (7.0%)	4 (17.4%)
Last participation date >= Day 78 and TSS at Week 12 not available	0	0	2 (4.7%)	0
>0% increase from baseline at Week 12	2 (40.0%)	4 (57.1%)	12 (27.9%)	11 (47.8%)
<50% reduction from baseline at Week 12	2 (40.0%)	5 (71.4%)	27 (62.8%)	17 (73.9%)
Return Rate (%)	80%	86%	89%	83%
Number of Subjects in Risk	4	6	41	20
Return Rate in Risk (%)	100%	100%	95%	100%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. [3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.1405: Analysis of Response Rate (improvement, 50% criterion) in TSS at Weeks 12 and 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=17)	High Risk BAT (N=8)	p-value
Unadjusted Inverse Odds Ratio (95% CI)	0.61 (0.09, 4.02)		
p-value [1]	0.61		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.27, 0.48)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.71 (0.17, 3.02)		
p-value [2]	0.65		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NE
Non-Responder, n(%)	11 (64.7%)	6 (75.0%)	
Last participation date < Day 78 in RT Phase	3 (17.6%)	1 (12.5%)	
Last participation date >= Day 78 and TSS at Week 12 not available	0	0	
>0% increase from baseline at Week 12	4 (23.5%)	2 (25.0%)	
<50% reduction from baseline at Week 12	8 (47.1%)	5 (62.5%)	
Return Rate (%)	82%	88%	
Number of Subjects in Risk	14	7	
Return Rate in Risk (%)	100%	100%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. [3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.1405: Analysis of Response Rate (improvement, 50% criterion) in TSS at Weeks 12 and 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Response Rate of Total Symptom Score at Week 24				
Subjects Evaluable at Week 24, n	5	7	43	23
TSS = 0 at baseline and TSS > 0 or missing at Week 24	0	1 (14.3%)	0	1 (4.3%)
Responder, n(%)	2 (40.0%)	0	12 (27.9%)	1 (4.3%)
95% Exact CI	0.0527, 0.8534	0.0000, 0.4096	0.1533, 0.4367	0.0011, 0.2195
Proportion Difference - Stratified CMH Method (95% CI)	0.33 (-0.48, 1.15)		0.20 (-0.02, 0.41)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.40 (-0.12, 0.92)		0.24 (0.07, 0.41)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.40 (-0.17, 0.85)		0.24 (-0.02, 0.47)	
Unadjusted Inverse Relative Risk (95% CI)	0.15 (0.01, 2.58)		0.16 (0.02, 1.12)	
p-value [1]	0.19		0.065	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. [3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.1405: Analysis of Response Rate (improvement, 50% criterion) in TSS at Weeks 12 and 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=17)	High Risk BAT (N=8)	p-value
Response Rate of Total Symptom Score at Week 24			
Subjects Evaluable at Week 24, n	17	8	
TSS = 0 at baseline and TSS > 0 or missing at Week 24	0	0	
Responder, n(%)	7 (41.2%)	0	
95% Exact CI	0.1844, 0.6708	0.0000, 0.3694	
Proportion Difference - Stratified CMH Method (95% CI)	0.43 (0.06, 0.80)		
Proportion Difference - Unstratified CMH Method (95% CI)	0.41 (0.12, 0.71)		
Proportion Difference - Unstratified Exact Method (95% CI)	0.41 (0.01, 0.76)		
Unadjusted Inverse Relative Risk (95% CI)	0.13 (0.01, 2.08)		
p-value [1]	0.15		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NE

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. [3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.1405: Analysis of Response Rate (improvement, 50% criterion) in TSS at Weeks 12 and 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Unadjusted Inverse Odds Ratio (95% CI)	0.09 (0.00, 2.51)		0.12 (0.01, 0.97)	
p-value [1]	0.16		0.047	
Unadjusted Absolute Risk Difference (95% CI)	0.35 (-0.07, 0.78)		0.24 (0.08, 0.39)	
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE	
p-value [2]	NE		NE	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Non-Responder, n(%)	3 (60.0%)	7 (100.0%)	31 (72.1%)	22 (95.7%)
Last participation date < Day 162 in RT Phase	1 (20.0%)	1 (14.3%)	11 (25.6%)	5 (21.7%)
Last participation date >= Day 162 and TSS at Week 24 not available	0	1 (14.3%)	1 (2.3%)	0
>0% increase from baseline at Week 24	2 (40.0%)	4 (57.1%)	9 (20.9%)	9 (39.1%)
<50% reduction from baseline at Week 24	2 (40.0%)	5 (71.4%)	19 (44.2%)	16 (69.6%)
Return Rate (%)	80%	71%	73%	79%
Number of Subjects in Risk	4	6	33	19
Return Rate in Risk (%)	100%	83%	97%	100%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. [3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.1405: Analysis of Response Rate (improvement, 50% criterion) in TSS at Weeks 12 and 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=17)	High Risk BAT (N=8)	p-value
Unadjusted Inverse Odds Ratio (95% CI)	0.08 (0.00, 1.66)		
p-value [1]	0.10		
Unadjusted Absolute Risk Difference (95% CI)	0.36 (0.09, 0.63)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NE
Non-Responder, n(%)	10 (58.8%)	8 (100.0%)	
Last participation date < Day 162 in RT Phase	6 (35.3%)	1 (12.5%)	
Last participation date >= Day 162 and TSS at Week 24 not available	0	2 (25.0%)	
>0% increase from baseline at Week 24	4 (23.5%)	4 (50.0%)	
<50% reduction from baseline at Week 24	4 (23.5%)	5 (62.5%)	
Return Rate (%)	65%	63%	
Number of Subjects in Risk	11	7	
Return Rate in Risk (%)	100%	71%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. [3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.1408: Analysis of Response Rate (improvement, 50% criterion) in TSS at Weeks 12 and 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
Total Symptom Score Status				
Missing TSS at baseline (excluded from rate calculation)	0	0	0	0
TSS = 0 at baseline	1 (2.2%)	2 (8.7%)	0	0
TSS > 0 at baseline	44 (97.8%)	21 (91.3%)	13 (100.0%)	8 (100.0%)
Response Rate of Total Symptom Score at Week 12				
Subjects Evaluable at Week 12, n	44	23	13	8
TSS = 0 at baseline and TSS > 0 or missing at Week 12	0	2 (8.7%)	0	0
Responder, n(%)	12 (27.3%)	3 (13.0%)	3 (23.1%)	0
95% Exact CI	0.1496, 0.4279	0.0278, 0.3359	0.0504, 0.5381	0.0000, 0.3694
Proportion Difference - Stratified CMH Method (95% CI)	0.14 (-0.08, 0.37)		0.31 (-0.08, 0.70)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.14 (-0.06, 0.34)		0.23 (-0.07, 0.53)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.14 (-0.11, 0.39)		0.23 (-0.21, 0.62)	
Unadjusted Inverse Relative Risk (95% CI)	0.48 (0.15, 1.53)		0.22 (0.01, 3.81)	
p-value [1]	0.21		0.30	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. [3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.1408: Analysis of Response Rate (improvement, 50% criterion) in TSS at Weeks 12 and 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	Post-PV Myelofibrosis MMB (N=8)	Post-PV Myelofibrosis BAT (N=8)	p-value
Total Symptom Score Status			
Missing TSS at baseline (excluded from rate calculation)	0	0	
TSS = 0 at baseline	0	1 (12.5%)	
TSS > 0 at baseline	8 (100.0%)	7 (87.5%)	
Response Rate of Total Symptom Score at Week 12			
Subjects Evaluable at Week 12, n	8	7	
TSS = 0 at baseline and TSS > 0 or missing at Week 12	0	0	
Responder, n(%)	4 (50.0%)	0	
95% Exact CI	0.1570, 0.8430	0.0000, 0.4096	
Proportion Difference - Stratified CMH Method (95% CI)	0.40 (-0.08, 0.88)		
Proportion Difference - Unstratified CMH Method (95% CI)	0.50 (0.08, 0.92)		
Proportion Difference - Unstratified Exact Method (95% CI)	0.50 (0.02, 0.85)		
Unadjusted Inverse Relative Risk (95% CI)	0.13 (0.01, 1.98)		
p-value [1]	0.14		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NE

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. [3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.1408: Analysis of Response Rate (improvement, 50% criterion) in TSS at Weeks 12 and 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
Unadjusted Inverse Odds Ratio (95% CI)	0.40 (0.10, 1.59)		0.18 (0.01, 3.91)	
p-value [1]	0.19		0.27	
Unadjusted Absolute Risk Difference (95% CI)	0.14 (-0.05, 0.33)		0.19 (-0.08, 0.47)	
Adjusted Inverse Relative Risk (95% CI) [2]	0.48 (0.15, 1.49)		NE	
p-value [2]	0.20		NE	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	32 (72.7%)	20 (87.0%)	10 (76.9%)	8 (100.0%)
Last participation date < Day 78 in RT Phase	5 (11.4%)	3 (13.0%)	2 (15.4%)	2 (25.0%)
Last participation date >= Day 78 and TSS at Week 12 not available	1 (2.3%)	0	1 (7.7%)	0
>0% increase from baseline at Week 12	13 (29.5%)	9 (39.1%)	4 (30.8%)	5 (62.5%)
<50% reduction from baseline at Week 12	26 (59.1%)	15 (65.2%)	7 (53.8%)	6 (75.0%)
Return Rate (%)	87%	87%	77%	75%
Number of Subjects in Risk	40	20	11	6
Return Rate in Risk (%)	98%	100%	91%	100%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. [3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.1408: Analysis of Response Rate (improvement, 50% criterion) in TSS at Weeks 12 and 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	Post-PV Myelofibrosis MMB (N=8)	Post-PV Myelofibrosis BAT (N=8)	p-value
Unadjusted Inverse Odds Ratio (95% CI)	0.07 (0.00, 1.55)		
p-value [1]	0.092		
Unadjusted Absolute Risk Difference (95% CI)	0.44 (0.07, 0.80)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NE
Non-Responder, n(%)	4 (50.0%)	7 (100.0%)	
Last participation date < Day 78 in RT Phase	0	1 (14.3%)	
Last participation date >= Day 78 and TSS at Week 12 not available	0	0	
>0% increase from baseline at Week 12	1 (12.5%)	3 (42.9%)	
<50% reduction from baseline at Week 12	4 (50.0%)	6 (85.7%)	
Return Rate (%)	100%	88%	
Number of Subjects in Risk	8	7	
Return Rate in Risk (%)	100%	100%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. [3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.1408: Analysis of Response Rate (improvement, 50% criterion) in TSS at Weeks 12 and 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
Response Rate of Total Symptom Score at Week 24				
Subjects Evaluable at Week 24, n	44	22	13	8
TSS = 0 at baseline and TSS > 0 or missing at Week 24	0	1 (4.5%)	0	0
Responder, n(%)	13 (29.5%)	1 (4.5%)	4 (30.8%)	0
95% Exact CI	0.1676, 0.4520	0.0012, 0.2284	0.0909, 0.6143	0.0000, 0.3694
Proportion Difference - Stratified CMH Method (95% CI)	0.26 (0.05, 0.46)		0.38 (-0.02, 0.78)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.25 (0.08, 0.42)		0.31 (-0.01, 0.62)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.25 (-0.02, 0.49)		0.31 (-0.14, 0.68)	
Unadjusted Inverse Relative Risk (95% CI)	0.15 (0.02, 1.10)		0.17 (0.01, 2.84)	
p-value [1]	0.062		0.22	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. [3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.1408: Analysis of Response Rate (improvement, 50% criterion) in TSS at Weeks 12 and 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	Post-PV Myelofibrosis MMB (N=8)	Post-PV Myelofibrosis BAT (N=8)	p-value
Response Rate of Total Symptom Score at Week 24			
Subjects Evaluable at Week 24, n	8	8	
TSS = 0 at baseline and TSS > 0 or missing at Week 24	0	1 (12.5%)	
Responder, n(%)	4 (50.0%)	0	
95% Exact CI	0.1570, 0.8430	0.0000, 0.3694	
Proportion Difference - Stratified CMH Method (95% CI)	0.48 (-0.08, 1.05)		
Proportion Difference - Unstratified CMH Method (95% CI)	0.50 (0.09, 0.91)		
Proportion Difference - Unstratified Exact Method (95% CI)	0.50 (-0.05, 0.85)		
Unadjusted Inverse Relative Risk (95% CI)	0.11 (0.01, 1.78)		
p-value [1]	0.12		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NE

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. [3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.1408: Analysis of Response Rate (improvement, 50% criterion) in TSS at Weeks 12 and 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
Unadjusted Inverse Odds Ratio (95% CI)	0.11 (0.01, 0.93)		0.12 (0.01, 2.66)	
p-value [1]	0.043		0.18	
Unadjusted Absolute Risk Difference (95% CI)	0.25 (0.09, 0.41)		0.27 (-0.02, 0.55)	
Adjusted Inverse Relative Risk (95% CI) [2]	0.15 (0.02, 0.99)		NE	
p-value [2]	0.049		NE	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	31 (70.5%)	21 (95.5%)	9 (69.2%)	8 (100.0%)
Last participation date < Day 162 in RT Phase	12 (27.3%)	4 (18.2%)	4 (30.8%)	2 (25.0%)
Last participation date >= Day 162 and TSS at Week 24 not available	1 (2.3%)	3 (13.6%)	0	0
>0% increase from baseline at Week 24	11 (25.0%)	9 (40.9%)	3 (23.1%)	5 (62.5%)
<50% reduction from baseline at Week 24	18 (40.9%)	14 (63.6%)	5 (38.5%)	6 (75.0%)
Return Rate (%)	71%	70%	69%	75%
Number of Subjects in Risk	33	19	9	6
Return Rate in Risk (%)	97%	84%	100%	100%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. [3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.1408: Analysis of Response Rate (improvement, 50% criterion) in TSS at Weeks 12 and 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	Post-PV Myelofibrosis MMB (N=8)	Post-PV Myelofibrosis BAT (N=8)	p-value
Unadjusted Inverse Odds Ratio (95% CI)	0.06 (0.00, 1.36)		
p-value [1]	0.077		
Unadjusted Absolute Risk Difference (95% CI)	0.44 (0.09, 0.80)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NE
Non-Responder, n(%)	4 (50.0%)	8 (100.0%)	
Last participation date < Day 162 in RT Phase	2 (25.0%)	1 (12.5%)	
Last participation date >= Day 162 and TSS at Week 24 not available	0	0	
>0% increase from baseline at Week 24	1 (12.5%)	3 (37.5%)	
<50% reduction from baseline at Week 24	2 (25.0%)	6 (75.0%)	
Return Rate (%)	75%	88%	
Number of Subjects in Risk	6	7	
Return Rate in Risk (%)	100%	100%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. [3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.1403: Analysis of Response Rate (improvement, 50% criterion) in TSS at Weeks 12 and 24 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Total Symptom Score Status					
Missing TSS at baseline (excluded from rate calculation)	0	0	0	0	
TSS = 0 at baseline	1 (1.9%)	2 (11.1%)	0	1 (4.8%)	
TSS > 0 at baseline	51 (98.1%)	16 (88.9%)	14 (100.0%)	20 (95.2%)	
Response Rate of Total Symptom Score at Week 12					
Subjects Evaluable at Week 12, n	51	18	14	20	
TSS = 0 at baseline and TSS > 0 or missing at Week 12	0	2 (11.1%)	0	0	
Responder, n(%)	15 (29.4%)	3 (16.7%)	4 (28.6%)	0	
95% Exact CI	0.1749, 0.4383	0.0358, 0.4142	0.0839, 0.5810	0.0000, 0.1684	
Proportion Difference - Stratified CMH Method (95% CI)	0.14 (-0.12, 0.39)		0.21 (-0.05, 0.47)		
Proportion Difference - Unstratified CMH Method (95% CI)	0.13 (-0.10, 0.35)		0.29 (0.03, 0.54)		
Proportion Difference - Unstratified Exact Method (95% CI)	0.13 (-0.14, 0.39)		0.29 (-0.06, 0.58)		
Unadjusted Inverse Relative Risk (95% CI)	0.57 (0.19, 1.73)		0.08 (0.00, 1.37)		
p-value [1]	0.32		0.081		
Unadjusted interaction test for Treatment*Gender [3]					NE

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. [3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.1403: Analysis of Response Rate (improvement, 50% criterion) in TSS at Weeks 12 and 24 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Unadjusted Inverse Odds Ratio (95% CI)	0.48 (0.12, 1.90)		0.06 (0.00, 1.16)		
p-value [1]	0.30		0.062		
Unadjusted Absolute Risk Difference (95% CI)	0.13 (-0.09, 0.34)		0.28 (0.04, 0.52)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.54 (0.18, 1.61)		NE		
p-value [2]	0.27		NE		
Adjusted interaction test for Treatment*Gender [3]					NE
Non-Responder, n(%)	36 (70.6%)	15 (83.3%)	10 (71.4%)	20 (100.0%)	
Last participation date < Day 78 in RT Phase	6 (11.8%)	4 (22.2%)	1 (7.1%)	2 (10.0%)	
Last participation date >= Day 78 and TSS at Week 12 not available	2 (3.9%)	0	0	0	
>0% increase from baseline at Week 12	16 (31.4%)	6 (33.3%)	2 (14.3%)	11 (55.0%)	
<50% reduction from baseline at Week 12	28 (54.9%)	9 (50.0%)	9 (64.3%)	18 (90.0%)	
Return Rate (%)	85%	78%	93%	90%	
Number of Subjects in Risk	46	14	13	19	
Return Rate in Risk (%)	96%	100%	100%	100%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. [3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.1403: Analysis of Response Rate (improvement, 50% criterion) in TSS at Weeks 12 and 24 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Response Rate of Total Symptom Score at Week 24					
Subjects Evaluable at Week 24, n	51	17	14	21	
TSS = 0 at baseline and TSS > 0 or missing at Week 24	0	1 (5.9%)	0	1 (4.8%)	
Responder, n(%)	17 (33.3%)	1 (5.9%)	4 (28.6%)	0	
95% Exact CI	0.2076, 0.4792	0.0015, 0.2869	0.0839, 0.5810	0.0000, 0.1611	
Proportion Difference - Stratified CMH Method (95% CI)	0.29 (0.08, 0.50)		0.25 (-0.03, 0.54)		
Proportion Difference - Unstratified CMH Method (95% CI)	0.27 (0.09, 0.46)		0.29 (0.03, 0.54)		
Proportion Difference - Unstratified Exact Method (95% CI)	0.27 (-0.01, 0.53)		0.29 (-0.06, 0.59)		
Unadjusted Inverse Relative Risk (95% CI)	0.18 (0.03, 1.23)		0.08 (0.00, 1.31)		
p-value [1]	0.080		0.076		
Unadjusted interaction test for Treatment*Gender [3]					NE

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. [3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.1403: Analysis of Response Rate (improvement, 50% criterion) in TSS at Weeks 12 and 24 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Unadjusted Inverse Odds Ratio (95% CI)	0.13 (0.02, 1.02)		0.05 (0.00, 1.10)		
p-value [1]	0.053		0.058		
Unadjusted Absolute Risk Difference (95% CI)	0.27 (0.10, 0.45)		0.28 (0.04, 0.52)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.17 (0.03, 1.09)		NE		
p-value [2]	0.061		NE		
Adjusted interaction test for Treatment*Gender [3]					NE
Non-Responder, n(%)	34 (66.7%)	16 (94.1%)	10 (71.4%)	21 (100.0%)	
Last participation date < Day 162 in RT Phase	14 (27.5%)	4 (23.5%)	4 (28.6%)	3 (14.3%)	
Last participation date >= Day 162 and TSS at Week 24 not available	1 (2.0%)	3 (17.6%)	0	0	
>0% increase from baseline at Week 24	11 (21.6%)	5 (29.4%)	4 (28.6%)	12 (57.1%)	
<50% reduction from baseline at Week 24	19 (37.3%)	9 (52.9%)	6 (42.9%)	17 (81.0%)	
Return Rate (%)	71%	61%	71%	86%	
Number of Subjects in Risk	38	14	10	18	
Return Rate in Risk (%)	97%	79%	100%	100%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. [3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.1410: Analysis of Response Rate (improvement, 50% criterion) in TSS at Weeks 12 and 24 by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Total Symptom Score Status					
Missing TSS at baseline (excluded from rate calculation)	0	0	0	0	
TSS = 0 at baseline	1 (3.6%)	3 (12.5%)	0	0	
TSS > 0 at baseline	27 (96.4%)	21 (87.5%)	38 (100.0%)	15 (100.0%)	
Response Rate of Total Symptom Score at Week 12					
Subjects Evaluable at Week 12, n	27	23	38	15	
TSS = 0 at baseline and TSS > 0 or missing at Week 12	0	2 (8.7%)	0	0	
Responder, n(%)	12 (44.4%)	3 (13.0%)	7 (18.4%)	0	
95% Exact CI	0.2548, 0.6467	0.0278, 0.3359	0.0774, 0.3433	0.0000, 0.2180	
Proportion Difference - Stratified CMH Method (95% CI)	0.28 (0.01, 0.54)		0.14 (-0.13, 0.41)		
Proportion Difference - Unstratified CMH Method (95% CI)	0.31 (0.07, 0.56)		0.18 (0.03, 0.34)		
Proportion Difference - Unstratified Exact Method (95% CI)	0.31 (0.04, 0.56)		0.18 (-0.11, 0.46)		
Unadjusted Inverse Relative Risk (95% CI)	0.29 (0.09, 0.91)		0.16 (0.01, 2.68)		
p-value [1]	0.034		0.20		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NE

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. [3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.1410: Analysis of Response Rate (improvement, 50% criterion) in TSS at Weeks 12 and 24 by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Unadjusted Inverse Odds Ratio (95% CI)	0.19 (0.04, 0.78)		0.14 (0.01, 2.53)		
p-value [1]	0.022		0.18		
Unadjusted Absolute Risk Difference (95% CI)	0.31 (0.08, 0.55)		0.16 (0.01, 0.31)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NE
Non-Responder, n(%)	15 (55.6%)	20 (87.0%)	31 (81.6%)	15 (100.0%)	
Last participation date < Day 78 in RT Phase	1 (3.7%)	2 (8.7%)	6 (15.8%)	4 (26.7%)	
Last participation date >= Day 78 and TSS at Week 12 not available	1 (3.7%)	0	1 (2.6%)	0	
>0% increase from baseline at Week 12	5 (18.5%)	8 (34.8%)	13 (34.2%)	9 (60.0%)	
<50% reduction from baseline at Week 12	13 (48.1%)	16 (69.6%)	24 (63.2%)	11 (73.3%)	
Return Rate (%)	93%	92%	82%	73%	
Number of Subjects in Risk	27	22	32	11	
Return Rate in Risk (%)	96%	100%	97%	100%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. [3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.1410: Analysis of Response Rate (improvement, 50% criterion) in TSS at Weeks 12 and 24 by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Response Rate of Total Symptom Score at Week 24					
Subjects Evaluable at Week 24, n	27	23	38	15	
TSS = 0 at baseline and TSS > 0 or missing at Week 24	0	2 (8.7%)	0	0	
Responder, n(%)	12 (44.4%)	1 (4.3%)	9 (23.7%)	0	
95% Exact CI	0.2548, 0.6467	0.0011, 0.2195	0.1144, 0.4024	0.0000, 0.2180	
Proportion Difference - Stratified CMH Method (95% CI)	0.39 (0.15, 0.62)		0.21 (-0.07, 0.48)		
Proportion Difference - Unstratified CMH Method (95% CI)	0.40 (0.18, 0.62)		0.24 (0.07, 0.40)		
Proportion Difference - Unstratified Exact Method (95% CI)	0.40 (0.13, 0.63)		0.24 (-0.06, 0.51)		
Unadjusted Inverse Relative Risk (95% CI)	0.10 (0.01, 0.70)		0.13 (0.01, 2.08)		
p-value [1]	0.020		0.15		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NE

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. [3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.1410: Analysis of Response Rate (improvement, 50% criterion) in TSS at Weeks 12 and 24 by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Unadjusted Inverse Odds Ratio (95% CI)	0.06 (0.01, 0.48)		0.10 (0.01, 1.84)		
p-value [1]	0.009		0.12		
Unadjusted Absolute Risk Difference (95% CI)	0.40 (0.20, 0.61)		0.21 (0.05, 0.37)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NE
Non-Responder, n(%)	15 (55.6%)	22 (95.7%)	29 (76.3%)	15 (100.0%)	
Last participation date < Day 162 in RT Phase	5 (18.5%)	2 (8.7%)	13 (34.2%)	5 (33.3%)	
Last participation date >= Day 162 and TSS at Week 24 not available	0	3 (13.0%)	1 (2.6%)	0	
>0% increase from baseline at Week 24	6 (22.2%)	10 (43.5%)	9 (23.7%)	7 (46.7%)	
<50% reduction from baseline at Week 24	10 (37.0%)	16 (69.6%)	15 (39.5%)	10 (66.7%)	
Return Rate (%)	82%	79%	63%	67%	
Number of Subjects in Risk	23	22	25	10	
Return Rate in Risk (%)	100%	86%	96%	100%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. [3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.1409: Analysis of Response Rate (improvement, 50% criterion) in TSS at Weeks 12 and 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Total Symptom Score Status					
Missing TSS at baseline (excluded from rate calculation)	0	0	0	0	
TSS = 0 at baseline	1 (2.4%)	3 (15.0%)	0	0	
TSS > 0 at baseline	41 (97.6%)	17 (85.0%)	24 (100.0%)	19 (100.0%)	
Response Rate of Total Symptom Score at Week 12					
Subjects Evaluable at Week 12, n	41	19	24	19	
TSS = 0 at baseline and TSS > 0 or missing at Week 12	0	2 (10.5%)	0	0	
Responder, n(%)	13 (31.7%)	1 (5.3%)	6 (25.0%)	2 (10.5%)	
95% Exact CI	0.1808, 0.4809	0.0013, 0.2603	0.0977, 0.4671	0.0130, 0.3314	
Proportion Difference - Stratified CMH Method (95% CI)	0.24 (0.04, 0.45)		0.16 (-0.09, 0.41)		
Proportion Difference - Unstratified CMH Method (95% CI)	0.26 (0.08, 0.45)		0.14 (-0.09, 0.38)		
Proportion Difference - Unstratified Exact Method (95% CI)	0.26 (-0.01, 0.51)		0.14 (-0.15, 0.43)		
Unadjusted Inverse Relative Risk (95% CI)	0.17 (0.02, 1.18)		0.42 (0.10, 1.85)		
p-value [1]	0.073		0.25		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.45

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates. [3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.1409: Analysis of Response Rate (improvement, 50% criterion) in TSS at Weeks 12 and 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Unadjusted Inverse Odds Ratio (95% CI)	0.12 (0.01, 1.00)		0.35 (0.06, 2.00)		
p-value [1]	0.049		0.24		
Unadjusted Absolute Risk Difference (95% CI)	0.26 (0.09, 0.44)		0.14 (-0.08, 0.37)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.19 (0.03, 1.35)		0.38 (0.09, 1.69)		
p-value [2]	0.097		0.20		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					0.45
Non-Responder, n(%)	28 (68.3%)	18 (94.7%)	18 (75.0%)	17 (89.5%)	
Last participation date < Day 78 in RT Phase	3 (7.3%)	2 (10.5%)	4 (16.7%)	4 (21.1%)	
Last participation date >= Day 78 and TSS at Week 12 not available	2 (4.9%)	0	0	0	
>0% increase from baseline at Week 12	14 (34.1%)	8 (42.1%)	4 (16.7%)	9 (47.4%)	
<50% reduction from baseline at Week 12	23 (56.1%)	14 (73.7%)	14 (58.3%)	13 (68.4%)	
Return Rate (%)	88%	90%	83%	79%	
Number of Subjects in Risk	39	18	20	15	
Return Rate in Risk (%)	95%	100%	100%	100%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates. [3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.1409: Analysis of Response Rate (improvement, 50% criterion) in TSS at Weeks 12 and 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Response Rate of Total Symptom Score at Week 24					
Subjects Evaluable at Week 24, n	41	19	24	19	
TSS = 0 at baseline and TSS > 0 or missing at Week 24	0	2 (10.5%)	0	0	
Responder, n(%)	13 (31.7%)	0	8 (33.3%)	1 (5.3%)	
95% Exact CI	0.1808, 0.4809	0.0000, 0.1765	0.1563, 0.5532	0.0013, 0.2603	
Proportion Difference - Stratified CMH Method (95% CI)	0.31 (0.13, 0.48)		0.28 (0.05, 0.52)		
Proportion Difference - Unstratified CMH Method (95% CI)	0.32 (0.16, 0.48)		0.28 (0.05, 0.51)		
Proportion Difference - Unstratified Exact Method (95% CI)	0.32 (0.04, 0.57)		0.28 (-0.02, 0.55)		
Unadjusted Inverse Relative Risk (95% CI)	0.08 (0.00, 1.24)		0.16 (0.02, 1.15)		
p-value [1]	0.071		0.069		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					NE

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates. [3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.1409: Analysis of Response Rate (improvement, 50% criterion) in TSS at Weeks 12 and 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Unadjusted Inverse Odds Ratio (95% CI)	0.05 (0.00, 0.97)		0.11 (0.01, 0.99)		
p-value [1]	0.047		0.049		
Unadjusted Absolute Risk Difference (95% CI)	0.30 (0.14, 0.45)		0.28 (0.07, 0.49)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.16 (0.02, 1.06)		
p-value [2]	NE		0.057		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NE
Non-Responder, n(%)	28 (68.3%)	19 (100.0%)	16 (66.7%)	18 (94.7%)	
Last participation date < Day 162 in RT Phase	9 (22.0%)	3 (15.8%)	9 (37.5%)	4 (21.1%)	
Last participation date >= Day 162 and TSS at Week 24 not available	1 (2.4%)	2 (10.5%)	0	1 (5.3%)	
>0% increase from baseline at Week 24	12 (29.3%)	8 (42.1%)	3 (12.5%)	9 (47.4%)	
<50% reduction from baseline at Week 24	18 (43.9%)	13 (68.4%)	7 (29.2%)	13 (68.4%)	
Return Rate (%)	76%	75%	63%	74%	
Number of Subjects in Risk	33	17	15	15	
Return Rate in Risk (%)	97%	88%	100%	93%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. TSS = Total Symptom Score, CMH = Cochran-Mantel-Haenszel.
Response rate analysis at each visit only includes subjects with TSS > 0 at baseline or (TSS = 0 at baseline and [TSS > 0 or missing]).
Subjects with TSS = 0 at baseline and = 0 at the visit are excluded from response rate analysis but are included in return rate calculations.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates. [3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term. Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.2002: Analysis of Time to First Response (50% criterion) in TSS by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Subjects with Event					
Response (50% criterion) in TSS, n(%)	6 (25.0%)	0	21 (50.0%)	4 (13.3%)	
Censor					
Subjects Censored, n(%)	18 (75.0%)	9 (100.0%)	21 (50.0%)	26 (86.7%)	
Non-Responder: Censored at Last Daily mMPN-SAF TSS Assessment Date on or before Day 176	18 (100.0%)	9 (100.0%)	21 (100.0%)	26 (100.0%)	
No Post-Baseline TSS data: Censored at Randomization Date	0	0	0	0	
Kaplan-Meier Estimate of Time to First Response (50% criterion) in TSS (Weeks)					
25-percentile (95% CI)	24.86 (8.14, NE)	NE (NE, NE)	8.14 (4.14, 12.14)	NE (8.14, NE)	
Median (95% CI)	NE (24.86, NE)	NE (NE, NE)	16.14 (12.14, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (25.00, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	6.14, 25.14	2.00, 25.14	3.86, 25.14	1.71, 25.14	
Stratified Log-Rank Test p-value	0.12		0.002		
Adjusted Inverse Hazard Ratio (95% CI)	0.00 (0.00, NE)		0.16 (0.04, 0.56)		
Unstratified Log-Rank Test p-value	0.13		0.001		
Unadjusted Inverse Hazard Ratio (95% CI)	0.00 (0.00, NE)		0.20 (0.07, 0.59)		
P-value for interaction test					0.99

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Response is defined as >=50% reduction in TSS from baseline.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-tss50-sub.sas V.03.05 Output file: t-tte-tss50-age.pdf 24AUG2023:16:40

Table 2.2006: Analysis of Time to First Response (50% criterion) in TSS by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Subjects with Event					
Response (50% criterion) in TSS, n(%)	19 (38.8%)	2 (6.5%)	8 (47.1%)	2 (25.0%)	
Censor					
Subjects Censored, n(%)	30 (61.2%)	29 (93.5%)	9 (52.9%)	6 (75.0%)	
Non-Responder: Censored at Last Daily mMPN-SAF TSS Assessment Date on or before Day 176	30 (100.0%)	29 (100.0%)	9 (100.0%)	6 (100.0%)	
No Post-Baseline TSS data: Censored at Randomization Date	0	0	0	0	
Kaplan-Meier Estimate of Time to First Response (50% criterion) in TSS (Weeks)					
25-percentile (95% CI)	12.14 (8.14, 20.14)	NE (NE, NE)	12.14 (4.14, 16.14)	12.14 (8.14, NE)	
Median (95% CI)	25.00 (16.14, NE)	NE (NE, NE)	16.14 (12.14, NE)	NE (8.14, NE)	
75-percentile (95% CI)	NE (25.00, NE)	NE (NE, NE)	NE (16.14, NE)	NE (NE, NE)	
Min, Max	4.00, 25.14	2.00, 25.14	3.86, 25.14	1.71, 25.14	
Stratified Log-Rank Test p-value	0.006		0.28		
Adjusted Inverse Hazard Ratio (95% CI)	0.17 (0.04, 0.75)		0.34 (0.07, 1.75)		
Unstratified Log-Rank Test p-value	0.003		0.25		
Unadjusted Inverse Hazard Ratio (95% CI)	0.15 (0.03, 0.64)		0.42 (0.09, 1.98)		
P-value for interaction test					0.38

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Response is defined as >=50% reduction in TSS from baseline.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-tss50-sub.sas V.03.05 Output file: t-tte-tss50-dipss2.pdf 24AUG2023:16:40

Table 2.2005: Analysis of Time to First Response (50% criterion) in TSS by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Subjects with Event				
Response (50% criterion) in TSS, n(%)	2 (40.0%)	0	17 (38.6%)	2 (8.3%)
Censor				
Subjects Censored, n(%)	3 (60.0%)	7 (100.0%)	27 (61.4%)	22 (91.7%)
Non-Responder: Censored at Last Daily mMPN-SAF TSS Assessment Date on or before Day 176	3 (100.0%)	7 (100.0%)	27 (100.0%)	22 (100.0%)
No Post-Baseline TSS data: Censored at Randomization Date	0	0	0	0
Kaplan-Meier Estimate of Time to First Response (50% criterion) in TSS (Weeks)				
25-percentile (95% CI)	12.14 (8.14, NE)	NE (NE, NE)	12.14 (8.14, 24.86)	NE (4.14, NE)
Median (95% CI)	NE (8.14, NE)	NE (NE, NE)	25.00 (16.14, NE)	NE (NE, NE)
75-percentile (95% CI)	NE (8.14, NE)	NE (NE, NE)	NE (25.00, NE)	NE (NE, NE)
Min, Max	8.14, 24.57	2.00, 25.14	4.00, 25.14	4.14, 25.14
Stratified Log-Rank Test p-value	0.32		0.039	
Adjusted Inverse Hazard Ratio (95% CI)	0.00 (0.00, NE)		0.25 (0.06, 1.14)	
Unstratified Log-Rank Test p-value	0.077		0.015	
Unadjusted Inverse Hazard Ratio (95% CI)	0.00 (0.00, NE)		0.20 (0.05, 0.85)	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Response is defined as >=50% reduction in TSS from baseline.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-tss50-sub.sas V.03.05 Output file: t-tte-tss50-dipss3.pdf 24AUG2023:16:40

Table 2.2005: Analysis of Time to First Response (50% criterion) in TSS by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=17)	High Risk BAT (N=8)	p-value
Subjects with Event			
Response (50% criterion) in TSS, n(%)	8 (47.1%)	2 (25.0%)	
Censor			
Subjects Censored, n(%)	9 (52.9%)	6 (75.0%)	
Non-Responder: Censored at Last Daily mMPN-SAF TSS Assessment Date on or before Day 176	9 (100.0%)	6 (100.0%)	
No Post-Baseline TSS data: Censored at Randomization Date	0	0	
Kaplan-Meier Estimate of Time to First Response (50% criterion) in TSS (Weeks)			
25-percentile (95% CI)	12.14 (4.14, 16.14)	12.14 (8.14, NE)	
Median (95% CI)	16.14 (12.14, NE)	NE (8.14, NE)	
75-percentile (95% CI)	NE (16.14, NE)	NE (NE, NE)	
Min, Max	3.86, 25.14	1.71, 25.14	
Stratified Log-Rank Test p-value	0.28		
Adjusted Inverse Hazard Ratio (95% CI)	0.34 (0.07, 1.75)		
Unstratified Log-Rank Test p-value	0.25		
Unadjusted Inverse Hazard Ratio (95% CI)	0.42 (0.09, 1.98)		
P-value for interaction test			0.84

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Response is defined as >=50% reduction in TSS from baseline.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-tss50-sub.sas V.03.05 Output file: t-tte-tss50-dipss3.pdf 24AUG2023:16:40

Table 2.2004: Analysis of Time to First Response (50% criterion) in TSS by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Subjects with Event					
Response (50% criterion) in TSS, n(%)	17 (58.6%)	1 (14.3%)	10 (27.0%)	3 (9.4%)	
Censor					
Subjects Censored, n(%)	12 (41.4%)	6 (85.7%)	27 (73.0%)	29 (90.6%)	
Non-Responder: Censored at Last Daily mMPN-SAF TSS Assessment Date on or before Day 176	12 (100.0%)	6 (100.0%)	27 (100.0%)	29 (100.0%)	
No Post-Baseline TSS data: Censored at Randomization Date	0	0	0	0	
Kaplan-Meier Estimate of Time to First Response (50% criterion) in TSS (Weeks)					
25-percentile (95% CI)	8.14 (4.14, 12.14)	NE (8.14, NE)	20.14 (12.14, NE)	NE (12.14, NE)	
Median (95% CI)	12.14 (8.14, NE)	NE (8.14, NE)	NE (25.00, NE)	NE (NE, NE)	
75-percentile (95% CI)	24.86 (16.14, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	4.00, 24.86	1.71, 25.14	3.86, 25.14	2.00, 25.14	
Stratified Log-Rank Test p-value	0.064		0.075		
Adjusted Inverse Hazard Ratio (95% CI)	0.14 (0.02, 1.26)		0.32 (0.09, 1.18)		
Unstratified Log-Rank Test p-value	0.059		0.079		
Unadjusted Inverse Hazard Ratio (95% CI)	0.19 (0.02, 1.41)		0.33 (0.09, 1.22)		
P-value for interaction test					0.53

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Response is defined as >=50% reduction in TSS from baseline.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-tss50-sub.sas V.03.05 Output file: t-tte-tss50-geo.pdf 24AUG2023:16:40

Table 2.2007: Analysis of Time to First Response (50% criterion) in TSS by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Subjects with Event					
Response (50% criterion) in TSS, n(%)	13 (48.1%)	2 (33.3%)	14 (35.9%)	2 (6.1%)	
Censor					
Subjects Censored, n(%)	14 (51.9%)	4 (66.7%)	25 (64.1%)	31 (93.9%)	
Non-Responder: Censored at Last Daily mMPN-SAF TSS Assessment Date on or before Day 176	14 (100.0%)	4 (100.0%)	25 (100.0%)	31 (100.0%)	
No Post-Baseline TSS data: Censored at Randomization Date	0	0	0	0	
Kaplan-Meier Estimate of Time to First Response (50% criterion) in TSS (Weeks)					
25-percentile (95% CI)	12.14 (4.14, 16.14)	10.14 (8.14, NE)	12.14 (8.14, 20.14)	NE (NE, NE)	
Median (95% CI)	24.86 (12.14, NE)	NE (8.14, NE)	NE (16.14, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (24.86, NE)	NE (8.14, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	3.86, 25.14	2.00, 24.00	4.00, 25.14	1.71, 25.14	
Stratified Log-Rank Test p-value	0.88		0.004		
Adjusted Inverse Hazard Ratio (95% CI)	1.10 (0.24, 5.03)		0.14 (0.03, 0.64)		
Unstratified Log-Rank Test p-value	0.95		0.003		
Unadjusted Inverse Hazard Ratio (95% CI)	1.08 (0.24, 4.88)		0.14 (0.03, 0.63)		
P-value for interaction test					0.076

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Response is defined as >=50% reduction in TSS from baseline.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-tss50-sub.sas V.03.05 Output file: t-tte-tss50-hgb.pdf 24AUG2023:16:40

Table 2.2008: Analysis of Time to First Response (50% criterion) in TSS by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-ET Myelofibrosis		Post-PV Myelofibrosis	
	MMB (N=13)	BAT (N=8)	MMB (N=8)	BAT (N=8)
Subjects with Event				
Response (50% criterion) in TSS, n(%)	6 (46.2%)	0	5 (62.5%)	1 (12.5%)
Censor				
Subjects Censored, n(%)	7 (53.8%)	8 (100.0%)	3 (37.5%)	7 (87.5%)
Non-Responder: Censored at Last Daily mMPN-SAF TSS Assessment Date on or before Day 176	7 (100.0%)	8 (100.0%)	3 (100.0%)	7 (100.0%)
No Post-Baseline TSS data: Censored at Randomization Date	0	0	0	0
Kaplan-Meier Estimate of Time to First Response (50% criterion) in TSS (Weeks)				
25-percentile (95% CI)	8.14 (4.00, NE)	NE (NE, NE)	6.14 (4.14, 16.14)	NE (4.14, NE)
Median (95% CI)	24.86 (4.14, NE)	NE (NE, NE)	14.14 (4.14, NE)	NE (4.14, NE)
75-percentile (95% CI)	24.86 (20.14, NE)	NE (NE, NE)	NE (8.14, NE)	NE (NE, NE)
Min, Max	3.86, 24.86	1.71, 24.86	4.14, 25.14	4.14, 25.14
Stratified Log-Rank Test p-value	0.024		0.082	
Adjusted Inverse Hazard Ratio (95% CI)	0.00 (0.00, NE)		<0.01 (<0.01, NE)	
Unstratified Log-Rank Test p-value	0.020		0.069	
Unadjusted Inverse Hazard Ratio (95% CI)	0.00 (0.00, NE)		0.18 (0.02, 1.51)	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Response is defined as >=50% reduction in TSS from baseline.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-tss50-sub.sas V.03.05 Output file: t-tte-tss50-mf.pdf 24AUG2023:16:40

Table 2.2008: Analysis of Time to First Response (50% criterion) in TSS by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	Primary Myelofibrosis MMB (N=45)	Primary Myelofibrosis BAT (N=23)	p-value
Subjects with Event			
Response (50% criterion) in TSS, n(%)	16 (35.6%)	3 (13.0%)	
Censor			
Subjects Censored, n(%)	29 (64.4%)	20 (87.0%)	
Non-Responder: Censored at Last Daily mMPN-SAF TSS Assessment Date on or before Day 176	29 (100.0%)	20 (100.0%)	
No Post-Baseline TSS data: Censored at Randomization Date	0	0	
Kaplan-Meier Estimate of Time to First Response (50% criterion) in TSS (Weeks)			
25-percentile (95% CI)	12.14 (8.14, 16.14)	NE (4.14, NE)	
Median (95% CI)	NE (16.14, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	
Min, Max	4.00, 25.14	2.00, 25.14	
Stratified Log-Rank Test p-value	0.058		
Adjusted Inverse Hazard Ratio (95% CI)	0.33 (0.10, 1.15)		
Unstratified Log-Rank Test p-value	0.072		
Unadjusted Inverse Hazard Ratio (95% CI)	0.34 (0.10, 1.17)		
P-value for interaction test			0.87

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Response is defined as >=50% reduction in TSS from baseline.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-tss50-sub.sas V.03.05 Output file: t-tte-tss50-mf.pdf 24AUG2023:16:40

Table 2.2003: Analysis of Time to First Response (50% criterion) in TSS by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Subjects with Event					
Response (50% criterion) in TSS, n(%)	20 (38.5%)	3 (16.7%)	7 (50.0%)	1 (4.8%)	
Censor					
Subjects Censored, n(%)	32 (61.5%)	15 (83.3%)	7 (50.0%)	20 (95.2%)	
Non-Responder: Censored at Last Daily mMPN-SAF TSS Assessment Date on or before Day 176	32 (100.0%)	15 (100.0%)	7 (100.0%)	20 (100.0%)	
No Post-Baseline TSS data: Censored at Randomization Date	0	0	0	0	
Kaplan-Meier Estimate of Time to First Response (50% criterion) in TSS (Weeks)					
25-percentile (95% CI)	12.14 (8.14, 16.14)	NE (4.14, NE)	12.14 (4.14, 20.14)	NE (4.14, NE)	
Median (95% CI)	25.00 (16.14, NE)	NE (12.14, NE)	20.14 (8.14, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (16.14, NE)	NE (NE, NE)	
Min, Max	3.86, 25.14	1.71, 25.00	4.14, 24.43	4.14, 25.14	
Stratified Log-Rank Test p-value	0.22		0.005		
Adjusted Inverse Hazard Ratio (95% CI)	0.47 (0.14, 1.59)		<0.01 (<0.01, NE)		
Unstratified Log-Rank Test p-value	0.21		0.001		
Unadjusted Inverse Hazard Ratio (95% CI)	0.47 (0.14, 1.59)		0.07 (<0.01, 0.58)		
P-value for interaction test					0.13

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Response is defined as >=50% reduction in TSS from baseline.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-tss50-sub.sas V.03.05 Output file: t-tte-tss50-sex.pdf 24AUG2023:16:40

Table 2.2010: Analysis of Time to First Response (50% criterion) in TSS by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Subjects with Event					
Response (50% criterion) in TSS, n(%)	16 (57.1%)	3 (12.5%)	11 (28.9%)	1 (6.7%)	
Censor					
Subjects Censored, n(%)	12 (42.9%)	21 (87.5%)	27 (71.1%)	14 (93.3%)	
Non-Responder: Censored at Last Daily mMPN-SAF TSS Assessment Date on or before Day 176	12 (100.0%)	21 (100.0%)	27 (100.0%)	14 (100.0%)	
No Post-Baseline TSS data: Censored at Randomization Date	0	0	0	0	
Kaplan-Meier Estimate of Time to First Response (50% criterion) in TSS (Weeks)					
25-percentile (95% CI)	8.14 (4.14, 12.14)	NE (4.14, NE)	16.14 (8.14, NE)	NE (4.14, NE)	
Median (95% CI)	16.14 (12.14, NE)	NE (NE, NE)	NE (16.14, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (20.14, NE)	NE (NE, NE)	NE (25.00, NE)	NE (NE, NE)	
Min, Max	4.14, 25.14	1.71, 25.14	3.86, 25.14	2.00, 25.14	
Stratified Log-Rank Test p-value	0.004		0.20		
Adjusted Inverse Hazard Ratio (95% CI)	0.20 (0.06, 0.69)		0.32 (0.04, 2.53)		
Unstratified Log-Rank Test p-value	0.002		0.11		
Unadjusted Inverse Hazard Ratio (95% CI)	0.18 (0.05, 0.61)		0.22 (0.03, 1.74)		
P-value for interaction test					0.87

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Response is defined as >=50% reduction in TSS from baseline.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-tss50-sub.sas V.03.05 Output file: t-tte-tss50-svb.pdf 24AUG2023:16:40

Table 2.2009: Analysis of Time to First Response (50% criterion) in TSS by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Subjects with Event					
Response (50% criterion) in TSS, n(%)	17 (40.5%)	2 (10.0%)	10 (41.7%)	2 (10.5%)	
Censor					
Subjects Censored, n(%)	25 (59.5%)	18 (90.0%)	14 (58.3%)	17 (89.5%)	
Non-Responder: Censored at Last Daily mMPN-SAF TSS Assessment Date on or before Day 176	25 (100.0%)	18 (100.0%)	14 (100.0%)	17 (100.0%)	
No Post-Baseline TSS data: Censored at Randomization Date	0	0	0	0	
Kaplan-Meier Estimate of Time to First Response (50% criterion) in TSS (Weeks)					
25-percentile (95% CI)	12.14 (8.14, 20.14)	NE (4.14, NE)	12.14 (4.14, 16.14)	NE (4.14, NE)	
Median (95% CI)	NE (12.14, NE)	NE (NE, NE)	25.00 (12.14, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (25.00, NE)	NE (NE, NE)	
Min, Max	4.00, 25.14	1.71, 25.14	3.86, 25.14	2.00, 25.14	
Stratified Log-Rank Test p-value	0.036		0.019		
Adjusted Inverse Hazard Ratio (95% CI)	0.23 (0.05, 1.02)		0.20 (0.04, 0.95)		
Unstratified Log-Rank Test p-value	0.024		0.026		
Unadjusted Inverse Hazard Ratio (95% CI)	0.22 (0.05, 0.94)		0.21 (0.05, 0.96)		
P-value for interaction test					0.94

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Response is defined as >=50% reduction in TSS from baseline.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no).
Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-tss50-sub.sas V.03.05 Output file: t-tte-tss50-tss.pdf 24AUG2023:16:40

Table 2.7702: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	BAT (N = 9)	MMB (N = 42)	BAT (N = 30)	p-value
BFI Total Score at Week 24					
Responder, n(%)	1 (4.2%)	0	5 (11.9%)	3 (10.0%)	
Unadjusted Relative Risk (95% CI)	1.20 (0.05, 27.05)		1.19 (0.31, 4.60)		
p-value [1]	0.91		0.80		
Unadjusted interaction test for Treatment*Age Group [3]					NA
Unadjusted Odds Ratio (95% CI)	1.21 (0.05, 32.49)		1.22 (0.27, 5.53)		
p-value [1]	0.91		0.80		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.15, 0.17)		0.02 (-0.13, 0.16)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Age Group [3]					NA
Non-Responder, n(%)	23 (95.8%)	9 (100.0%)	37 (88.1%)	27 (90.0%)	
Non-missing	5 (20.8%)	4 (44.4%)	16 (38.1%)	16 (53.3%)	
Missing	18 (75.0%)	5 (55.6%)	21 (50.0%)	11 (36.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.7702: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	BAT (N = 9)	MMB (N = 42)	BAT (N = 30)	p-value
BFI Fatigue Score at Week 24					
Responder, n(%)	2 (8.3%)	2 (22.2%)	6 (14.3%)	3 (10.0%)	
Unadjusted Relative Risk (95% CI)	0.38 (0.06, 2.28)		1.43 (0.39, 5.26)		
p-value [1]	0.29		0.59		
Unadjusted interaction test for Treatment*Age Group [3]					NA
Unadjusted Odds Ratio (95% CI)	0.32 (0.04, 2.70)		1.50 (0.34, 6.54)		
p-value [1]	0.29		0.59		
Unadjusted Absolute Risk Difference (95% CI)	-0.14 (-0.43, 0.15)		0.04 (-0.11, 0.19)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Age Group [3]					NA
Non-Responder, n(%)	22 (91.7%)	7 (77.8%)	36 (85.7%)	27 (90.0%)	
Non-missing	4 (16.7%)	2 (22.2%)	15 (35.7%)	16 (53.3%)	
Missing	18 (75.0%)	5 (55.6%)	21 (50.0%)	11 (36.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.7702: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	BAT (N = 9)	MMB (N = 42)	BAT (N = 30)	p-value
BFI Interference Score at Week 24					
Responder, n(%)	2 (8.3%)	0	5 (11.9%)	6 (20.0%)	
Unadjusted Relative Risk (95% CI)	2.00 (0.11, 38.08)		0.60 (0.20, 1.77)		
p-value [1]	0.64		0.35		
Unadjusted interaction test for Treatment*Age Group [3]					NE
Unadjusted Odds Ratio (95% CI)	2.11 (0.09, 48.27)		0.54 (0.15, 1.97)		
p-value [1]	0.64		0.35		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.13, 0.23)		-0.08 (-0.25, 0.09)		
Adjusted Relative Risk (95% CI) [2]	NE		0.63 (0.22, 1.82)		
p-value [2]	NE		0.40		
Adjusted interaction test for Treatment*Age Group [3]					NE
Non-Responder, n(%)	22 (91.7%)	9 (100.0%)	37 (88.1%)	24 (80.0%)	
Non-missing	4 (16.7%)	4 (44.4%)	16 (38.1%)	13 (43.3%)	
Missing	18 (75.0%)	5 (55.6%)	21 (50.0%)	11 (36.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.7704: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N = 29)	BAT (N = 7)	MMB (N = 37)	BAT (N = 32)	p-value
BFI Total Score at Week 24					
Responder, n(%)	1 (3.4%)	2 (28.6%)	5 (13.5%)	1 (3.1%)	
Unadjusted Relative Risk (95% CI)	0.12 (0.01, 1.15)		4.32 (0.53, 35.11)		
p-value [1]	0.066		0.17		
Unadjusted interaction test for Treatment*Region [3]					NA
Unadjusted Odds Ratio (95% CI)	0.09 (0.01, 1.18)		4.84 (0.54, 43.85)		
p-value [1]	0.067		0.16		
Unadjusted Absolute Risk Difference (95% CI)	-0.25 (-0.59, 0.09)		0.10 (-0.02, 0.23)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Region [3]					NA
Non-Responder, n(%)	28 (96.6%)	5 (71.4%)	32 (86.5%)	31 (96.9%)	
Non-missing	8 (27.6%)	1 (14.3%)	13 (35.1%)	19 (59.4%)	
Missing	20 (69.0%)	4 (57.1%)	19 (51.4%)	12 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.7704: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N = 29)	BAT (N = 7)	MMB (N = 37)	BAT (N = 32)	p-value
BFI Fatigue Score at Week 24					
Responder, n(%)	2 (6.9%)	1 (14.3%)	6 (16.2%)	4 (12.5%)	
Unadjusted Relative Risk (95% CI)	0.48 (0.05, 4.60)		1.30 (0.40, 4.19)		
p-value [1]	0.53		0.66		
Unadjusted interaction test for Treatment*Region [3]					0.53
Unadjusted Odds Ratio (95% CI)	0.44 (0.03, 5.74)		1.35 (0.35, 5.30)		
p-value [1]	0.53		0.66		
Unadjusted Absolute Risk Difference (95% CI)	-0.07 (-0.35, 0.20)		0.04 (-0.13, 0.20)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Region [3]					NE
Non-Responder, n(%)	27 (93.1%)	6 (85.7%)	31 (83.8%)	28 (87.5%)	
Non-missing	7 (24.1%)	2 (28.6%)	12 (32.4%)	16 (50.0%)	
Missing	20 (69.0%)	4 (57.1%)	19 (51.4%)	12 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.7704: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N = 29)	BAT (N = 7)	MMB (N = 37)	BAT (N = 32)	p-value
BFI Interference Score at Week 24					
Responder, n(%)	1 (3.4%)	2 (28.6%)	6 (16.2%)	4 (12.5%)	
Unadjusted Relative Risk (95% CI)	0.12 (0.01, 1.15)		1.30 (0.40, 4.19)		
p-value [1]	0.066		0.66		
Unadjusted interaction test for Treatment*Region [3]					0.14
Unadjusted Odds Ratio (95% CI)	0.09 (0.01, 1.18)		1.35 (0.35, 5.30)		
p-value [1]	0.067		0.66		
Unadjusted Absolute Risk Difference (95% CI)	-0.25 (-0.59, 0.09)		0.04 (-0.13, 0.20)		
Adjusted Relative Risk (95% CI) [2]	NE		1.25 (0.40, 3.89)		
p-value [2]	NE		0.70		
Adjusted interaction test for Treatment*Region [3]					0.14
Non-Responder, n(%)	28 (96.6%)	5 (71.4%)	31 (83.8%)	28 (87.5%)	
Non-missing	8 (27.6%)	1 (14.3%)	12 (32.4%)	16 (50.0%)	
Missing	20 (69.0%)	4 (57.1%)	19 (51.4%)	12 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.7707: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 27)	BAT (N = 6)	MMB (N = 39)	BAT (N = 33)	p-value
BFI Total Score at Week 24					
Responder, n(%)	2 (7.4%)	0	4 (10.3%)	3 (9.1%)	
Unadjusted Relative Risk (95% CI)	1.25 (0.07, 23.21)		1.13 (0.27, 4.68)		
p-value [1]	0.88		0.87		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Unadjusted Odds Ratio (95% CI)	1.27 (0.05, 29.93)		1.14 (0.24, 5.52)		
p-value [1]	0.88		0.87		
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.20, 0.24)		0.01 (-0.13, 0.15)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Non-Responder, n(%)	25 (92.6%)	6 (100.0%)	35 (89.7%)	30 (90.9%)	
Non-missing	8 (29.6%)	2 (33.3%)	13 (33.3%)	18 (54.5%)	
Missing	17 (63.0%)	4 (66.7%)	22 (56.4%)	12 (36.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.7707: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 27)	BAT (N = 6)	MMB (N = 39)	BAT (N = 33)	p-value
BFI Fatigue Score at Week 24					
Responder, n(%)	3 (11.1%)	0	5 (12.8%)	5 (15.2%)	
Unadjusted Relative Risk (95% CI)	1.75 (0.10, 30.11)		0.85 (0.27, 2.67)		
p-value [1]	0.70		0.78		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE
Unadjusted Odds Ratio (95% CI)	1.86 (0.08, 40.69)		0.82 (0.22, 3.13)		
p-value [1]	0.69		0.78		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.17, 0.28)		-0.02 (-0.18, 0.14)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE
Non-Responder, n(%)	24 (88.9%)	6 (100.0%)	34 (87.2%)	28 (84.8%)	
Non-missing	7 (25.9%)	2 (33.3%)	12 (30.8%)	16 (48.5%)	
Missing	17 (63.0%)	4 (66.7%)	22 (56.4%)	12 (36.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.7707: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 27)	BAT (N = 6)	MMB (N = 39)	BAT (N = 33)	p-value
BFI Interference Score at Week 24					
Responder, n(%)	2 (7.4%)	1 (16.7%)	5 (12.8%)	5 (15.2%)	
Unadjusted Relative Risk (95% CI)	0.44 (0.05, 4.14)		0.85 (0.27, 2.67)		
p-value [1]	0.48		0.78		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.65
Unadjusted Odds Ratio (95% CI)	0.40 (0.03, 5.31)		0.82 (0.22, 3.13)		
p-value [1]	0.49		0.78		
Unadjusted Absolute Risk Difference (95% CI)	-0.09 (-0.41, 0.22)		-0.02 (-0.18, 0.14)		
Adjusted Relative Risk (95% CI) [2]	0.43 (0.05, 3.65)		0.85 (0.27, 2.61)		
p-value [2]	0.44		0.77		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.65
Non-Responder, n(%)	25 (92.6%)	5 (83.3%)	34 (87.2%)	28 (84.8%)	
Non-missing	8 (29.6%)	1 (16.7%)	12 (30.8%)	16 (48.5%)	
Missing	17 (63.0%)	4 (66.7%)	22 (56.4%)	12 (36.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-bfi-gba-deter.sas V.03.05 Output file: t-sgp-bfi-gba-det-hgb.pdf 24AUG2023:16:58

Table 2.7706: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 49)	BAT (N = 31)	MMB (N = 17)	BAT (N = 8)	p-value
BFI Total Score at Week 24					
Responder, n(%)	3 (6.1%)	1 (3.2%)	3 (17.6%)	2 (25.0%)	
Unadjusted Relative Risk (95% CI)	1.90 (0.21, 17.44)		0.71 (0.15, 3.43)		
p-value [1]	0.57		0.67		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Unadjusted Odds Ratio (95% CI)	1.96 (0.19, 19.70)		0.64 (0.08, 4.89)		
p-value [1]	0.57		0.67		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.06, 0.12)		-0.07 (-0.42, 0.28)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Non-Responder, n(%)	46 (93.9%)	30 (96.8%)	14 (82.4%)	6 (75.0%)	
Non-missing	17 (34.7%)	17 (54.8%)	4 (23.5%)	3 (37.5%)	
Missing	29 (59.2%)	13 (41.9%)	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-bfi-gba-deter.sas V.03.05 Output file: t-sgp-bfi-gba-det-ip2.pdf 24AUG2023:16:58

Table 2.7706: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 49)	BAT (N = 31)	MMB (N = 17)	BAT (N = 8)	p-value
BFI Fatigue Score at Week 24					
Responder, n(%)	6 (12.2%)	3 (9.7%)	2 (11.8%)	2 (25.0%)	
Unadjusted Relative Risk (95% CI)	1.27 (0.34, 4.69)		0.47 (0.08, 2.76)		
p-value [1]	0.72		0.40		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Unadjusted Odds Ratio (95% CI)	1.30 (0.30, 5.64)		0.40 (0.05, 3.53)		
p-value [1]	0.72		0.41		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.11, 0.16)		-0.13 (-0.47, 0.20)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Non-Responder, n(%)	43 (87.8%)	28 (90.3%)	15 (88.2%)	6 (75.0%)	
Non-missing	14 (28.6%)	15 (48.4%)	5 (29.4%)	3 (37.5%)	
Missing	29 (59.2%)	13 (41.9%)	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7706: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 49)	BAT (N = 31)	MMB (N = 17)	BAT (N = 8)	p-value
BFI Interference Score at Week 24					
Responder, n(%)	4 (8.2%)	3 (9.7%)	3 (17.6%)	3 (37.5%)	
Unadjusted Relative Risk (95% CI)	0.84 (0.20, 3.52)		0.47 (0.12, 1.84)		
p-value [1]	0.82		0.28		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Unadjusted Odds Ratio (95% CI)	0.83 (0.17, 3.99)		0.36 (0.05, 2.38)		
p-value [1]	0.82		0.29		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.14, 0.11)		-0.20 (-0.58, 0.18)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Non-Responder, n(%)	45 (91.8%)	28 (90.3%)	14 (82.4%)	5 (62.5%)	
Non-missing	16 (32.7%)	15 (48.4%)	4 (23.5%)	2 (25.0%)	
Missing	29 (59.2%)	13 (41.9%)	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7705: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 5)	BAT (N = 7)	MMB (N = 44)	BAT (N = 24)
BFI Total Score at Week 24				
Responder, n(%)	0	0	3 (6.8%)	1 (4.2%)
Unadjusted Relative Risk (95% CI)	NA		1.64 (0.18, 14.89)	
p-value [1]	NA		0.66	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Unadjusted Odds Ratio (95% CI)	NA		1.68 (0.17, 17.13)	
p-value [1]	NA		0.66	
Unadjusted Absolute Risk Difference (95% CI)	NA		0.03 (-0.08, 0.14)	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Non-Responder, n(%)	5 (100.0%)	7 (100.0%)	41 (93.2%)	23 (95.8%)
Non-missing	1 (20.0%)	3 (42.9%)	16 (36.4%)	14 (58.3%)
Missing	4 (80.0%)	4 (57.1%)	25 (56.8%)	9 (37.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-bfi-gba-deter.sas V.03.05 Output file: t-sgp-bfi-gba-det-ip3.pdf 24AUG2023:16:57

Table 2.7705: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 17)	BAT (N = 8)	p-value
BFI Total Score at Week 24			
Responder, n(%)	3 (17.6%)	2 (25.0%)	
Unadjusted Relative Risk (95% CI)	0.71 (0.15, 3.43)		
p-value [1]	0.67		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Unadjusted Odds Ratio (95% CI)	0.64 (0.08, 4.89)		
p-value [1]	0.67		
Unadjusted Absolute Risk Difference (95% CI)	-0.07 (-0.42, 0.28)		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	14 (82.4%)	6 (75.0%)	
Non-missing	4 (23.5%)	3 (37.5%)	
Missing	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7705: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 5)	BAT (N = 7)	MMB (N = 44)	BAT (N = 24)
BFI Fatigue Score at Week 24				
Responder, n(%)	1 (20.0%)	1 (14.3%)	5 (11.4%)	2 (8.3%)
Unadjusted Relative Risk (95% CI)	1.40 (0.11, 17.45)		1.36 (0.29, 6.51)	
p-value [1]	0.79		0.70	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Unadjusted Odds Ratio (95% CI)	1.50 (0.07, 31.58)		1.41 (0.25, 7.88)	
p-value [1]	0.79		0.70	
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.38, 0.49)		0.03 (-0.11, 0.18)	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Non-Responder, n(%)	4 (80.0%)	6 (85.7%)	39 (88.6%)	22 (91.7%)
Non-missing	0	2 (28.6%)	14 (31.8%)	13 (54.2%)
Missing	4 (80.0%)	4 (57.1%)	25 (56.8%)	9 (37.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7705: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 17)	BAT (N = 8)	p-value
BFI Fatigue Score at Week 24			
Responder, n(%)	2 (11.8%)	2 (25.0%)	
Unadjusted Relative Risk (95% CI)	0.47 (0.08, 2.76)		
p-value [1]	0.40		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Unadjusted Odds Ratio (95% CI)	0.40 (0.05, 3.53)		
p-value [1]	0.41		
Unadjusted Absolute Risk Difference (95% CI)	-0.13 (-0.47, 0.20)		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	15 (88.2%)	6 (75.0%)	
Non-missing	5 (29.4%)	3 (37.5%)	
Missing	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7705: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 5)	BAT (N = 7)	MMB (N = 44)	BAT (N = 24)
BFI Interference Score at Week 24				
Responder, n(%)	0	0	4 (9.1%)	3 (12.5%)
Unadjusted Relative Risk (95% CI)	NA		0.73 (0.18, 2.98)	
p-value [1]	NA		0.66	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Unadjusted Odds Ratio (95% CI)	NA		0.70 (0.14, 3.42)	
p-value [1]	NA		0.66	
Unadjusted Absolute Risk Difference (95% CI)	NA		-0.03 (-0.19, 0.12)	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Non-Responder, n(%)	5 (100.0%)	7 (100.0%)	40 (90.9%)	21 (87.5%)
Non-missing	1 (20.0%)	3 (42.9%)	15 (34.1%)	12 (50.0%)
Missing	4 (80.0%)	4 (57.1%)	25 (56.8%)	9 (37.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-bfi-gba-deter.sas V.03.05 Output file: t-sgp-bfi-gba-det-ip3.pdf 24AUG2023:16:57

Table 2.7705: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 17)	BAT (N = 8)	p-value
BFI Interference Score at Week 24			
Responder, n(%)	3 (17.6%)	3 (37.5%)	
Unadjusted Relative Risk (95% CI)	0.47 (0.12, 1.84)		
p-value [1]	0.28		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Unadjusted Odds Ratio (95% CI)	0.36 (0.05, 2.38)		
p-value [1]	0.29		
Unadjusted Absolute Risk Difference (95% CI)	-0.20 (-0.58, 0.18)		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	14 (82.4%)	5 (62.5%)	
Non-missing	4 (23.5%)	2 (25.0%)	
Missing	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7708: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 45)	BAT (N = 23)	MMB (N = 13)	BAT (N = 8)
BFI Total Score at Week 24				
Responder, n(%)	4 (8.9%)	3 (13.0%)	1 (7.7%)	0
Unadjusted Relative Risk (95% CI)	0.68 (0.17, 2.79)		1.93 (0.09, 42.35)	
p-value [1]	0.59		0.68	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Odds Ratio (95% CI)	0.65 (0.13, 3.19)		2.04 (0.07, 56.27)	
p-value [1]	0.60		0.67	
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.20, 0.12)		0.05 (-0.17, 0.27)	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	41 (91.1%)	20 (87.0%)	12 (92.3%)	8 (100.0%)
Non-missing	15 (33.3%)	10 (43.5%)	4 (30.8%)	3 (37.5%)
Missing	26 (57.8%)	10 (43.5%)	8 (61.5%)	5 (62.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.7708: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 8)	BAT (N = 8)	p-value
BFI Total Score at Week 24			
Responder, n(%)	1 (12.5%)	0	
Unadjusted Relative Risk (95% CI)	3.00 (0.14, 64.27)		
p-value [1]	0.48		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Unadjusted Odds Ratio (95% CI)	3.40 (0.12, 96.71)		
p-value [1]	0.47		
Unadjusted Absolute Risk Difference (95% CI)	0.11 (-0.17, 0.40)		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Non-Responder, n(%)	7 (87.5%)	8 (100.0%)	
Non-missing	2 (25.0%)	7 (87.5%)	
Missing	5 (62.5%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.7708: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 45)	BAT (N = 23)	MMB (N = 13)	BAT (N = 8)
BFI Fatigue Score at Week 24				
Responder, n(%)	6 (13.3%)	3 (13.0%)	1 (7.7%)	0
Unadjusted Relative Risk (95% CI)	1.02 (0.28, 3.72)		1.93 (0.09, 42.35)	
p-value [1]	0.97		0.68	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Odds Ratio (95% CI)	1.03 (0.23, 4.54)		2.04 (0.07, 56.27)	
p-value [1]	0.97		0.67	
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.17, 0.17)		0.05 (-0.17, 0.27)	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	39 (86.7%)	20 (87.0%)	12 (92.3%)	8 (100.0%)
Non-missing	13 (28.9%)	10 (43.5%)	4 (30.8%)	3 (37.5%)
Missing	26 (57.8%)	10 (43.5%)	8 (61.5%)	5 (62.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.7708: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 8)	BAT (N = 8)	p-value
BFI Fatigue Score at Week 24			
Responder, n(%)	1 (12.5%)	2 (25.0%)	
Unadjusted Relative Risk (95% CI)	0.50 (0.06, 4.47)		
p-value [1]	0.54		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Unadjusted Odds Ratio (95% CI)	0.43 (0.03, 5.99)		
p-value [1]	0.53		
Unadjusted Absolute Risk Difference (95% CI)	-0.13 (-0.50, 0.25)		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Non-Responder, n(%)	7 (87.5%)	6 (75.0%)	
Non-missing	2 (25.0%)	5 (62.5%)	
Missing	5 (62.5%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.7708: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 45)	BAT (N = 23)	MMB (N = 13)	BAT (N = 8)
BFI Interference Score at Week 24				
Responder, n(%)	5 (11.1%)	5 (21.7%)	1 (7.7%)	0
Unadjusted Relative Risk (95% CI)	0.51 (0.16, 1.59)		1.93 (0.09, 42.35)	
p-value [1]	0.25		0.68	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Odds Ratio (95% CI)	0.45 (0.12, 1.75)		2.04 (0.07, 56.27)	
p-value [1]	0.25		0.67	
Unadjusted Absolute Risk Difference (95% CI)	-0.11 (-0.30, 0.09)		0.05 (-0.17, 0.27)	
Adjusted Relative Risk (95% CI) [2]	0.54 (0.18, 1.57)		NE	
p-value [2]	0.26		NE	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	40 (88.9%)	18 (78.3%)	12 (92.3%)	8 (100.0%)
Non-missing	14 (31.1%)	8 (34.8%)	4 (30.8%)	3 (37.5%)
Missing	26 (57.8%)	10 (43.5%)	8 (61.5%)	5 (62.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.7708: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 8)	BAT (N = 8)	p-value
BFI Interference Score at Week 24			
Responder, n(%)	1 (12.5%)	1 (12.5%)	
Unadjusted Relative Risk (95% CI)	1.00 (0.07, 13.37)		
p-value [1]	1.00		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NE
Unadjusted Odds Ratio (95% CI)	1.00 (0.05, 19.36)		
p-value [1]	1.00		
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.32, 0.32)		
Adjusted Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NE
Non-Responder, n(%)	7 (87.5%)	7 (87.5%)	
Non-missing	2 (25.0%)	6 (75.0%)	
Missing	5 (62.5%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.7703: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 52)	BAT (N = 18)	MMB (N = 14)	BAT (N = 21)	p-value
BFI Total Score at Week 24					
Responder, n(%)	3 (5.8%)	1 (5.6%)	3 (21.4%)	2 (9.5%)	
Unadjusted Relative Risk (95% CI)	1.04 (0.12, 9.36)		2.25 (0.43, 11.79)		
p-value [1]	0.97		0.34		
Unadjusted interaction test for Treatment*Gender [3]					NA
Unadjusted Odds Ratio (95% CI)	1.04 (0.10, 10.69)		2.59 (0.37, 17.98)		
p-value [1]	0.97		0.34		
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.12, 0.13)		0.12 (-0.13, 0.37)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Gender [3]					NA
Non-Responder, n(%)	49 (94.2%)	17 (94.4%)	11 (78.6%)	19 (90.5%)	
Non-missing	15 (28.8%)	7 (38.9%)	6 (42.9%)	13 (61.9%)	
Missing	34 (65.4%)	10 (55.6%)	5 (35.7%)	6 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7703: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 52)	BAT (N = 18)	MMB (N = 14)	BAT (N = 21)	p-value
BFI Fatigue Score at Week 24					
Responder, n(%)	5 (9.6%)	2 (11.1%)	3 (21.4%)	3 (14.3%)	
Unadjusted Relative Risk (95% CI)	0.87 (0.18, 4.08)		1.50 (0.35, 6.40)		
p-value [1]	0.85		0.58		
Unadjusted interaction test for Treatment*Gender [3]					NA
Unadjusted Odds Ratio (95% CI)	0.85 (0.15, 4.83)		1.64 (0.28, 9.58)		
p-value [1]	0.86		0.58		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.18, 0.15)		0.07 (-0.19, 0.33)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Gender [3]					NA
Non-Responder, n(%)	47 (90.4%)	16 (88.9%)	11 (78.6%)	18 (85.7%)	
Non-missing	13 (25.0%)	6 (33.3%)	6 (42.9%)	12 (57.1%)	
Missing	34 (65.4%)	10 (55.6%)	5 (35.7%)	6 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7703: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 52)	BAT (N = 18)	MMB (N = 14)	BAT (N = 21)	p-value
BFI Interference Score at Week 24					
Responder, n(%)	4 (7.7%)	3 (16.7%)	3 (21.4%)	3 (14.3%)	
Unadjusted Relative Risk (95% CI)	0.46 (0.11, 1.87)		1.50 (0.35, 6.40)		
p-value [1]	0.28		0.58		
Unadjusted interaction test for Treatment*Gender [3]					NA
Unadjusted Odds Ratio (95% CI)	0.42 (0.08, 2.07)		1.64 (0.28, 9.58)		
p-value [1]	0.29		0.58		
Unadjusted Absolute Risk Difference (95% CI)	-0.09 (-0.28, 0.10)		0.07 (-0.19, 0.33)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Gender [3]					NA
Non-Responder, n(%)	48 (92.3%)	15 (83.3%)	11 (78.6%)	18 (85.7%)	
Non-missing	14 (26.9%)	5 (27.8%)	6 (42.9%)	12 (57.1%)	
Missing	34 (65.4%)	10 (55.6%)	5 (35.7%)	6 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7710: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N = 28)	BAT (N = 24)	MMB (N = 38)	BAT (N = 15)	p-value
BFI Total Score at Week 24					
Responder, n(%)	3 (10.7%)	1 (4.2%)	3 (7.9%)	2 (13.3%)	
Unadjusted Relative Risk (95% CI)	2.57 (0.29, 23.13)		0.59 (0.11, 3.20)		
p-value [1]	0.40		0.54		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Odds Ratio (95% CI)	2.76 (0.27, 28.45)		0.56 (0.08, 3.72)		
p-value [1]	0.39		0.55		
Unadjusted Absolute Risk Difference (95% CI)	0.07 (-0.07, 0.21)		-0.05 (-0.25, 0.14)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Non-Responder, n(%)	25 (89.3%)	23 (95.8%)	35 (92.1%)	13 (86.7%)	
Non-missing	9 (32.1%)	15 (62.5%)	12 (31.6%)	5 (33.3%)	
Missing	16 (57.1%)	8 (33.3%)	23 (60.5%)	8 (53.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7710: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N = 28)	BAT (N = 24)	MMB (N = 38)	BAT (N = 15)	p-value
BFI Fatigue Score at Week 24					
Responder, n(%)	2 (7.1%)	2 (8.3%)	6 (15.8%)	3 (20.0%)	
Unadjusted Relative Risk (95% CI)	0.86 (0.13, 5.63)		0.79 (0.23, 2.76)		
p-value [1]	0.87		0.71		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Odds Ratio (95% CI)	0.85 (0.11, 6.51)		0.75 (0.16, 3.49)		
p-value [1]	0.87		0.71		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.16, 0.13)		-0.04 (-0.28, 0.19)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Non-Responder, n(%)	26 (92.9%)	22 (91.7%)	32 (84.2%)	12 (80.0%)	
Non-missing	10 (35.7%)	14 (58.3%)	9 (23.7%)	4 (26.7%)	
Missing	16 (57.1%)	8 (33.3%)	23 (60.5%)	8 (53.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-bfi-gba-deter.sas V.03.05 Output file: t-sgp-bfi-gba-det-svb.pdf 24AUG2023:16:58

Table 2.7710: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N = 28)	BAT (N = 24)	MMB (N = 38)	BAT (N = 15)	p-value
BFI Interference Score at Week 24					
Responder, n(%)	4 (14.3%)	3 (12.5%)	3 (7.9%)	3 (20.0%)	
Unadjusted Relative Risk (95% CI)	1.14 (0.28, 4.61)		0.39 (0.09, 1.74)		
p-value [1]	0.85		0.22		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Odds Ratio (95% CI)	1.17 (0.23, 5.82)		0.34 (0.06, 1.93)		
p-value [1]	0.85		0.23		
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.17, 0.20)		-0.12 (-0.34, 0.10)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Non-Responder, n(%)	24 (85.7%)	21 (87.5%)	35 (92.1%)	12 (80.0%)	
Non-missing	8 (28.6%)	13 (54.2%)	12 (31.6%)	4 (26.7%)	
Missing	16 (57.1%)	8 (33.3%)	23 (60.5%)	8 (53.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7709: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 42)	BAT (N = 20)	MMB (N = 24)	BAT (N = 19)	p-value
BFI Total Score at Week 24					
Responder, n(%)	5 (11.9%)	1 (5.0%)	1 (4.2%)	2 (10.5%)	
Unadjusted Relative Risk (95% CI)	2.38 (0.30, 19.06)		0.40 (0.04, 4.04)		
p-value [1]	0.41		0.43		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Unadjusted Odds Ratio (95% CI)	2.57 (0.28, 23.57)		0.37 (0.03, 4.42)		
p-value [1]	0.40		0.43		
Unadjusted Absolute Risk Difference (95% CI)	0.07 (-0.07, 0.21)		-0.06 (-0.22, 0.10)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Non-Responder, n(%)	37 (88.1%)	19 (95.0%)	23 (95.8%)	17 (89.5%)	
Non-missing	14 (33.3%)	10 (50.0%)	7 (29.2%)	10 (52.6%)	
Missing	23 (54.8%)	9 (45.0%)	16 (66.7%)	7 (36.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7709: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 42)	BAT (N = 20)	MMB (N = 24)	BAT (N = 19)	p-value
BFI Fatigue Score at Week 24					
Responder, n(%)	4 (9.5%)	2 (10.0%)	4 (16.7%)	3 (15.8%)	
Unadjusted Relative Risk (95% CI)	0.95 (0.19, 4.77)		1.06 (0.27, 4.16)		
p-value [1]	0.95		0.94		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Unadjusted Odds Ratio (95% CI)	0.95 (0.16, 5.66)		1.07 (0.21, 5.47)		
p-value [1]	0.95		0.94		
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.16, 0.15)		0.01 (-0.21, 0.23)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Non-Responder, n(%)	38 (90.5%)	18 (90.0%)	20 (83.3%)	16 (84.2%)	
Non-missing	15 (35.7%)	9 (45.0%)	4 (16.7%)	9 (47.4%)	
Missing	23 (54.8%)	9 (45.0%)	16 (66.7%)	7 (36.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7709: Analysis of Response Rate (deterioration, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 42)	BAT (N = 20)	MMB (N = 24)	BAT (N = 19)	p-value
BFI Interference Score at Week 24					
Responder, n(%)	6 (14.3%)	2 (10.0%)	1 (4.2%)	4 (21.1%)	
Unadjusted Relative Risk (95% CI)	1.43 (0.32, 6.46)		0.20 (0.02, 1.63)		
p-value [1]	0.64		0.13		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Unadjusted Odds Ratio (95% CI)	1.50 (0.27, 8.19)		0.16 (0.02, 1.60)		
p-value [1]	0.64		0.12		
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.13, 0.21)		-0.17 (-0.37, 0.03)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Non-Responder, n(%)	36 (85.7%)	18 (90.0%)	23 (95.8%)	15 (78.9%)	
Non-missing	13 (31.0%)	9 (45.0%)	7 (29.2%)	8 (42.1%)	
Missing	23 (54.8%)	9 (45.0%)	16 (66.7%)	7 (36.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7602: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	BAT (N = 9)	MMB (N = 42)	BAT (N = 30)	p-value
BFI Total Score at Week 24					
Responder, n(%)	1 (4.2%)	0	5 (11.9%)	1 (3.3%)	
Unadjusted Inverse Relative Risk (95% CI)	0.83 (0.04, 18.79)		0.28 (0.03, 2.28)		
p-value [1]	0.91		0.23		
Unadjusted interaction test for Treatment*Age Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.82 (0.03, 22.09)		0.26 (0.03, 2.31)		
p-value [1]	0.91		0.22		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.15, 0.17)		0.09 (-0.03, 0.20)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Age Group [3]					NA
Non-Responder, n(%)	23 (95.8%)	9 (100.0%)	37 (88.1%)	29 (96.7%)	
Non-missing	5 (20.8%)	4 (44.4%)	16 (38.1%)	18 (60.0%)	
Missing	18 (75.0%)	5 (55.6%)	21 (50.0%)	11 (36.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7602: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	BAT (N = 9)	MMB (N = 42)	BAT (N = 30)	p-value
BFI Fatigue Score at Week 24					
Responder, n(%)	2 (8.3%)	0	6 (14.3%)	1 (3.3%)	
Unadjusted Inverse Relative Risk (95% CI)	0.50 (0.03, 9.52)		0.23 (0.03, 1.84)		
p-value [1]	0.64		0.17		
Unadjusted interaction test for Treatment*Age Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.47 (0.02, 10.83)		0.21 (0.02, 1.82)		
p-value [1]	0.64		0.16		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.13, 0.23)		0.11 (-0.01, 0.23)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Age Group [3]					NA
Non-Responder, n(%)	22 (91.7%)	9 (100.0%)	36 (85.7%)	29 (96.7%)	
Non-missing	4 (16.7%)	4 (44.4%)	15 (35.7%)	18 (60.0%)	
Missing	18 (75.0%)	5 (55.6%)	21 (50.0%)	11 (36.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7602: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	BAT (N = 9)	MMB (N = 42)	BAT (N = 30)	p-value
BFI Interference Score at Week 24					
Responder, n(%)	1 (4.2%)	0	5 (11.9%)	2 (6.7%)	
Unadjusted Inverse Relative Risk (95% CI)	0.83 (0.04, 18.79)		0.56 (0.12, 2.70)		
p-value [1]	0.91		0.47		
Unadjusted interaction test for Treatment*Age Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.82 (0.03, 22.09)		0.53 (0.10, 2.93)		
p-value [1]	0.91		0.47		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.15, 0.17)		0.05 (-0.08, 0.18)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Age Group [3]					NA
Non-Responder, n(%)	23 (95.8%)	9 (100.0%)	37 (88.1%)	28 (93.3%)	
Non-missing	5 (20.8%)	4 (44.4%)	16 (38.1%)	17 (56.7%)	
Missing	18 (75.0%)	5 (55.6%)	21 (50.0%)	11 (36.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7604: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N = 29)	BAT (N = 7)	MMB (N = 37)	BAT (N = 32)	p-value
BFI Total Score at Week 24					
Responder, n(%)	4 (13.8%)	0	2 (5.4%)	1 (3.1%)	
Unadjusted Inverse Relative Risk (95% CI)	0.42 (0.02, 6.96)		0.58 (0.05, 6.08)		
p-value [1]	0.54		0.65		
Unadjusted interaction test for Treatment*Region [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.38 (0.02, 7.84)		0.56 (0.05, 6.53)		
p-value [1]	0.53		0.65		
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.12, 0.30)		0.02 (-0.07, 0.12)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Region [3]					NA
Non-Responder, n(%)	25 (86.2%)	7 (100.0%)	35 (94.6%)	31 (96.9%)	
Non-missing	5 (17.2%)	3 (42.9%)	16 (43.2%)	19 (59.4%)	
Missing	20 (69.0%)	4 (57.1%)	19 (51.4%)	12 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7604: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N = 29)	BAT (N = 7)	MMB (N = 37)	BAT (N = 32)	p-value
BFI Fatigue Score at Week 24					
Responder, n(%)	5 (17.2%)	1 (14.3%)	3 (8.1%)	0	
Unadjusted Inverse Relative Risk (95% CI)	0.83 (0.11, 6.01)		0.16 (0.01, 3.07)		
p-value [1]	0.85		0.23		
Unadjusted interaction test for Treatment*Region [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.80 (0.08, 8.19)		0.15 (0.01, 3.05)		
p-value [1]	0.85		0.22		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.26, 0.32)		0.08 (-0.02, 0.18)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Region [3]					NA
Non-Responder, n(%)	24 (82.8%)	6 (85.7%)	34 (91.9%)	32 (100.0%)	
Non-missing	4 (13.8%)	2 (28.6%)	15 (40.5%)	20 (62.5%)	
Missing	20 (69.0%)	4 (57.1%)	19 (51.4%)	12 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7604: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N = 29)	BAT (N = 7)	MMB (N = 37)	BAT (N = 32)	p-value
BFI Interference Score at Week 24					
Responder, n(%)	4 (13.8%)	0	2 (5.4%)	2 (6.3%)	
Unadjusted Inverse Relative Risk (95% CI)	0.42 (0.02, 6.96)		1.16 (0.17, 7.75)		
p-value [1]	0.54		0.88		
Unadjusted interaction test for Treatment*Region [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.38 (0.02, 7.84)		1.17 (0.15, 8.79)		
p-value [1]	0.53		0.88		
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.12, 0.30)		-0.01 (-0.12, 0.10)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Region [3]					NA
Non-Responder, n(%)	25 (86.2%)	7 (100.0%)	35 (94.6%)	30 (93.8%)	
Non-missing	5 (17.2%)	3 (42.9%)	16 (43.2%)	18 (56.3%)	
Missing	20 (69.0%)	4 (57.1%)	19 (51.4%)	12 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7607: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 27)	BAT (N = 6)	MMB (N = 39)	BAT (N = 33)	p-value
BFI Total Score at Week 24					
Responder, n(%)	3 (11.1%)	0	3 (7.7%)	1 (3.0%)	
Unadjusted Inverse Relative Risk (95% CI)	0.57 (0.03, 9.83)		0.39 (0.04, 3.61)		
p-value [1]	0.70		0.41		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.54 (0.02, 11.80)		0.38 (0.04, 3.79)		
p-value [1]	0.69		0.41		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.17, 0.28)		0.05 (-0.06, 0.15)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Non-Responder, n(%)	24 (88.9%)	6 (100.0%)	36 (92.3%)	32 (97.0%)	
Non-missing	7 (25.9%)	2 (33.3%)	14 (35.9%)	20 (60.6%)	
Missing	17 (63.0%)	4 (66.7%)	22 (56.4%)	12 (36.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7607: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 27)	BAT (N = 6)	MMB (N = 39)	BAT (N = 33)	p-value
BFI Fatigue Score at Week 24					
Responder, n(%)	3 (11.1%)	0	5 (12.8%)	1 (3.0%)	
Unadjusted Inverse Relative Risk (95% CI)	0.57 (0.03, 9.83)		0.24 (0.03, 1.92)		
p-value [1]	0.70		0.18		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.54 (0.02, 11.80)		0.21 (0.02, 1.92)		
p-value [1]	0.69		0.17		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.17, 0.28)		0.10 (-0.02, 0.22)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Non-Responder, n(%)	24 (88.9%)	6 (100.0%)	34 (87.2%)	32 (97.0%)	
Non-missing	7 (25.9%)	2 (33.3%)	12 (30.8%)	20 (60.6%)	
Missing	17 (63.0%)	4 (66.7%)	22 (56.4%)	12 (36.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7607: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 27)	BAT (N = 6)	MMB (N = 39)	BAT (N = 33)	p-value
BFI Interference Score at Week 24					
Responder, n(%)	3 (11.1%)	0	3 (7.7%)	2 (6.1%)	
Unadjusted Inverse Relative Risk (95% CI)	0.57 (0.03, 9.83)		0.79 (0.14, 4.44)		
p-value [1]	0.70		0.79		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.54 (0.02, 11.80)		0.77 (0.12, 4.94)		
p-value [1]	0.69		0.79		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.17, 0.28)		0.02 (-0.10, 0.13)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Non-Responder, n(%)	24 (88.9%)	6 (100.0%)	36 (92.3%)	31 (93.9%)	
Non-missing	7 (25.9%)	2 (33.3%)	14 (35.9%)	19 (57.6%)	
Missing	17 (63.0%)	4 (66.7%)	22 (56.4%)	12 (36.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7606: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 49)	BAT (N = 31)	MMB (N = 17)	BAT (N = 8)	p-value
BFI Total Score at Week 24					
Responder, n(%)	4 (8.2%)	1 (3.2%)	2 (11.8%)	0	
Unadjusted Inverse Relative Risk (95% CI)	0.40 (0.05, 3.37)		0.40 (0.02, 7.48)		
p-value [1]	0.40		0.54		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.38 (0.04, 3.52)		0.36 (0.02, 8.51)		
p-value [1]	0.39		0.53		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.05, 0.15)		0.08 (-0.14, 0.30)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Non-Responder, n(%)	45 (91.8%)	30 (96.8%)	15 (88.2%)	8 (100.0%)	
Non-missing	16 (32.7%)	17 (54.8%)	5 (29.4%)	5 (62.5%)	
Missing	29 (59.2%)	13 (41.9%)	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7606: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 49)	BAT (N = 31)	MMB (N = 17)	BAT (N = 8)	p-value
BFI Fatigue Score at Week 24					
Responder, n(%)	5 (10.2%)	1 (3.2%)	3 (17.6%)	0	
Unadjusted Inverse Relative Risk (95% CI)	0.32 (0.04, 2.58)		0.29 (0.02, 4.96)		
p-value [1]	0.28		0.39		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.29 (0.03, 2.64)		0.24 (0.01, 5.31)		
p-value [1]	0.27		0.37		
Unadjusted Absolute Risk Difference (95% CI)	0.07 (-0.04, 0.17)		0.14 (-0.10, 0.38)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Non-Responder, n(%)	44 (89.8%)	30 (96.8%)	14 (82.4%)	8 (100.0%)	
Non-missing	15 (30.6%)	17 (54.8%)	4 (23.5%)	5 (62.5%)	
Missing	29 (59.2%)	13 (41.9%)	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7606: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 49)	BAT (N = 31)	MMB (N = 17)	BAT (N = 8)	p-value
BFI Interference Score at Week 24					
Responder, n(%)	4 (8.2%)	2 (6.5%)	2 (11.8%)	0	
Unadjusted Inverse Relative Risk (95% CI)	0.79 (0.15, 4.06)		0.40 (0.02, 7.48)		
p-value [1]	0.78		0.54		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.78 (0.13, 4.51)		0.36 (0.02, 8.51)		
p-value [1]	0.78		0.53		
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.10, 0.13)		0.08 (-0.14, 0.30)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Non-Responder, n(%)	45 (91.8%)	29 (93.5%)	15 (88.2%)	8 (100.0%)	
Non-missing	16 (32.7%)	16 (51.6%)	5 (29.4%)	5 (62.5%)	
Missing	29 (59.2%)	13 (41.9%)	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7605: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 5)	BAT (N = 7)	MMB (N = 44)	BAT (N = 24)
BFI Total Score at Week 24				
Responder, n(%)	0	0	4 (9.1%)	1 (4.2%)
Unadjusted Inverse Relative Risk (95% CI)	NA		0.46 (0.05, 3.87)	
p-value [1]	NA		0.47	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	NA		0.43 (0.05, 4.13)	
p-value [1]	NA		0.47	
Unadjusted Absolute Risk Difference (95% CI)	NA		0.05 (-0.07, 0.17)	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Non-Responder, n(%)	5 (100.0%)	7 (100.0%)	40 (90.9%)	23 (95.8%)
Non-missing	1 (20.0%)	3 (42.9%)	15 (34.1%)	14 (58.3%)
Missing	4 (80.0%)	4 (57.1%)	25 (56.8%)	9 (37.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-bfi-gba-improv.sas V.03.05 Output file: t-sgp-bfi-gba-imp-ip3.pdf 24AUG2023:16:57

Table 2.7605: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 17)	BAT (N = 8)	p-value
BFI Total Score at Week 24			
Responder, n(%)	2 (11.8%)	0	
Unadjusted Inverse Relative Risk (95% CI)	0.40 (0.02, 7.48)		
p-value [1]	0.54		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	0.36 (0.02, 8.51)		
p-value [1]	0.53		
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.14, 0.30)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	15 (88.2%)	8 (100.0%)	
Non-missing	5 (29.4%)	5 (62.5%)	
Missing	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7605: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 5)	BAT (N = 7)	MMB (N = 44)	BAT (N = 24)
BFI Fatigue Score at Week 24				
Responder, n(%)	0	0	5 (11.4%)	1 (4.2%)
Unadjusted Inverse Relative Risk (95% CI)	NA		0.37 (0.05, 2.96)	
p-value [1]	NA		0.35	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	NA		0.34 (0.04, 3.09)	
p-value [1]	NA		0.34	
Unadjusted Absolute Risk Difference (95% CI)	NA		0.07 (-0.05, 0.20)	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Non-Responder, n(%)	5 (100.0%)	7 (100.0%)	39 (88.6%)	23 (95.8%)
Non-missing	1 (20.0%)	3 (42.9%)	14 (31.8%)	14 (58.3%)
Missing	4 (80.0%)	4 (57.1%)	25 (56.8%)	9 (37.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7605: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 17)	BAT (N = 8)	p-value
BFI Fatigue Score at Week 24			
Responder, n(%)	3 (17.6%)	0	
Unadjusted Inverse Relative Risk (95% CI)	0.29 (0.02, 4.96)		
p-value [1]	0.39		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	0.24 (0.01, 5.31)		
p-value [1]	0.37		
Unadjusted Absolute Risk Difference (95% CI)	0.14 (-0.10, 0.38)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	14 (82.4%)	8 (100.0%)	
Non-missing	4 (23.5%)	5 (62.5%)	
Missing	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7605: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 5)	BAT (N = 7)	MMB (N = 44)	BAT (N = 24)
BFI Interference Score at Week 24				
Responder, n(%)	0	0	4 (9.1%)	2 (8.3%)
Unadjusted Inverse Relative Risk (95% CI)	NA		0.92 (0.18, 4.65)	
p-value [1]	NA		0.92	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	NA		0.91 (0.15, 5.37)	
p-value [1]	NA		0.92	
Unadjusted Absolute Risk Difference (95% CI)	NA		0.01 (-0.13, 0.15)	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Non-Responder, n(%)	5 (100.0%)	7 (100.0%)	40 (90.9%)	22 (91.7%)
Non-missing	1 (20.0%)	3 (42.9%)	15 (34.1%)	13 (54.2%)
Missing	4 (80.0%)	4 (57.1%)	25 (56.8%)	9 (37.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-bfi-gba-improv.sas V.03.05 Output file: t-sgp-bfi-gba-imp-ip3.pdf 24AUG2023:16:57

Table 2.7605: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 17)	BAT (N = 8)	p-value
BFI Interference Score at Week 24			
Responder, n(%)	2 (11.8%)	0	
Unadjusted Inverse Relative Risk (95% CI)	0.40 (0.02, 7.48)		
p-value [1]	0.54		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	0.36 (0.02, 8.51)		
p-value [1]	0.53		
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.14, 0.30)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	15 (88.2%)	8 (100.0%)	
Non-missing	5 (29.4%)	5 (62.5%)	
Missing	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7608: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 45)	BAT (N = 23)	MMB (N = 13)	BAT (N = 8)
BFI Total Score at Week 24				
Responder, n(%)	3 (6.7%)	1 (4.3%)	3 (23.1%)	0
Unadjusted Inverse Relative Risk (95% CI)	0.65 (0.07, 5.93)		0.22 (0.01, 3.81)	
p-value [1]	0.70		0.30	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	0.64 (0.06, 6.48)		0.18 (0.01, 3.91)	
p-value [1]	0.70		0.27	
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.09, 0.13)		0.19 (-0.08, 0.47)	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	42 (93.3%)	22 (95.7%)	10 (76.9%)	8 (100.0%)
Non-missing	16 (35.6%)	12 (52.2%)	2 (15.4%)	3 (37.5%)
Missing	26 (57.8%)	10 (43.5%)	8 (61.5%)	5 (62.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-bfi-gba-improv.sas V.03.05 Output file: t-sgp-bfi-gba-imp-mf.pdf 24AUG2023:16:57

Table 2.7608: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 8)	BAT (N = 8)	p-value
BFI Total Score at Week 24			
Responder, n(%)	0	0	
Unadjusted Inverse Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Non-Responder, n(%)	8 (100.0%)	8 (100.0%)	
Non-missing	3 (37.5%)	7 (87.5%)	
Missing	5 (62.5%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7608: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 45)	BAT (N = 23)	MMB (N = 13)	BAT (N = 8)
BFI Fatigue Score at Week 24				
Responder, n(%)	5 (11.1%)	0	3 (23.1%)	1 (12.5%)
Unadjusted Inverse Relative Risk (95% CI)	0.17 (0.01, 3.02)		0.54 (0.07, 4.36)	
p-value [1]	0.23		0.56	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	0.16 (0.01, 2.96)		0.48 (0.04, 5.58)	
p-value [1]	0.22		0.55	
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.01, 0.21)		0.11 (-0.22, 0.43)	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	40 (88.9%)	23 (100.0%)	10 (76.9%)	7 (87.5%)
Non-missing	14 (31.1%)	13 (56.5%)	2 (15.4%)	2 (25.0%)
Missing	26 (57.8%)	10 (43.5%)	8 (61.5%)	5 (62.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7608: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 8)	BAT (N = 8)	p-value
BFI Fatigue Score at Week 24			
Responder, n(%)	0	0	
Unadjusted Inverse Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Non-Responder, n(%)	8 (100.0%)	8 (100.0%)	
Non-missing	3 (37.5%)	7 (87.5%)	
Missing	5 (62.5%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7608: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 45)	BAT (N = 23)	MMB (N = 13)	BAT (N = 8)
BFI Interference Score at Week 24				
Responder, n(%)	3 (6.7%)	2 (8.7%)	3 (23.1%)	0
Unadjusted Inverse Relative Risk (95% CI)	1.30 (0.23, 7.26)		0.22 (0.01, 3.81)	
p-value [1]	0.76		0.30	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	1.33 (0.21, 8.60)		0.18 (0.01, 3.91)	
p-value [1]	0.76		0.27	
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.16, 0.12)		0.19 (-0.08, 0.47)	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	42 (93.3%)	21 (91.3%)	10 (76.9%)	8 (100.0%)
Non-missing	16 (35.6%)	11 (47.8%)	2 (15.4%)	3 (37.5%)
Missing	26 (57.8%)	10 (43.5%)	8 (61.5%)	5 (62.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7608: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 8)	BAT (N = 8)	p-value
BFI Interference Score at Week 24			
Responder, n(%)	0	0	
Unadjusted Inverse Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Non-Responder, n(%)	8 (100.0%)	8 (100.0%)	
Non-missing	3 (37.5%)	7 (87.5%)	
Missing	5 (62.5%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7603: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 52)	BAT (N = 18)	MMB (N = 14)	BAT (N = 21)	p-value
BFI Total Score at Week 24					
Responder, n(%)	4 (7.7%)	1 (5.6%)	2 (14.3%)	0	
Unadjusted Inverse Relative Risk (95% CI)	0.72 (0.09, 6.05)		0.14 (0.01, 2.64)		
p-value [1]	0.76		0.19		
Unadjusted interaction test for Treatment*Gender [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.71 (0.07, 6.77)		0.12 (0.01, 2.62)		
p-value [1]	0.76		0.18		
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.11, 0.15)		0.14 (-0.05, 0.34)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Gender [3]					NA
Non-Responder, n(%)	48 (92.3%)	17 (94.4%)	12 (85.7%)	21 (100.0%)	
Non-missing	14 (26.9%)	7 (38.9%)	7 (50.0%)	15 (71.4%)	
Missing	34 (65.4%)	10 (55.6%)	5 (35.7%)	6 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-bfi-gba-improv.sas V.03.05 Output file: t-sgp-bfi-gba-imp-sex.pdf 24AUG2023:16:56

Table 2.7603: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 52)	BAT (N = 18)	MMB (N = 14)	BAT (N = 21)	p-value
BFI Fatigue Score at Week 24					
Responder, n(%)	6 (11.5%)	0	2 (14.3%)	1 (4.8%)	
Unadjusted Inverse Relative Risk (95% CI)	0.21 (0.01, 3.63)		0.33 (0.03, 3.34)		
p-value [1]	0.29		0.35		
Unadjusted interaction test for Treatment*Gender [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.19 (0.01, 3.61)		0.30 (0.02, 3.67)		
p-value [1]	0.27		0.35		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.02, 0.21)		0.10 (-0.11, 0.30)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Gender [3]					NA
Non-Responder, n(%)	46 (88.5%)	18 (100.0%)	12 (85.7%)	20 (95.2%)	
Non-missing	12 (23.1%)	8 (44.4%)	7 (50.0%)	14 (66.7%)	
Missing	34 (65.4%)	10 (55.6%)	5 (35.7%)	6 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7603: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 52)	BAT (N = 18)	MMB (N = 14)	BAT (N = 21)	p-value
BFI Interference Score at Week 24					
Responder, n(%)	4 (7.7%)	2 (11.1%)	2 (14.3%)	0	
Unadjusted Inverse Relative Risk (95% CI)	1.44 (0.29, 7.23)		0.14 (0.01, 2.64)		
p-value [1]	0.65		0.19		
Unadjusted interaction test for Treatment*Gender [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	1.50 (0.25, 8.98)		0.12 (0.01, 2.62)		
p-value [1]	0.66		0.18		
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.20, 0.13)		0.14 (-0.05, 0.34)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Gender [3]					NA
Non-Responder, n(%)	48 (92.3%)	16 (88.9%)	12 (85.7%)	21 (100.0%)	
Non-missing	14 (26.9%)	6 (33.3%)	7 (50.0%)	15 (71.4%)	
Missing	34 (65.4%)	10 (55.6%)	5 (35.7%)	6 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7610: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N = 28)	BAT (N = 24)	MMB (N = 38)	BAT (N = 15)	p-value
BFI Total Score at Week 24					
Responder, n(%)	3 (10.7%)	1 (4.2%)	3 (7.9%)	0	
Unadjusted Inverse Relative Risk (95% CI)	0.39 (0.04, 3.50)		0.35 (0.02, 6.36)		
p-value [1]	0.40		0.48		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.36 (0.04, 3.74)		0.33 (0.02, 6.72)		
p-value [1]	0.39		0.47		
Unadjusted Absolute Risk Difference (95% CI)	0.07 (-0.07, 0.21)		0.06 (-0.07, 0.18)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Non-Responder, n(%)	25 (89.3%)	23 (95.8%)	35 (92.1%)	15 (100.0%)	
Non-missing	9 (32.1%)	15 (62.5%)	12 (31.6%)	7 (46.7%)	
Missing	16 (57.1%)	8 (33.3%)	23 (60.5%)	8 (53.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7610: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N = 28)	BAT (N = 24)	MMB (N = 38)	BAT (N = 15)	p-value
BFI Fatigue Score at Week 24					
Responder, n(%)	4 (14.3%)	1 (4.2%)	4 (10.5%)	0	
Unadjusted Inverse Relative Risk (95% CI)	0.29 (0.03, 2.44)		0.27 (0.02, 4.74)		
p-value [1]	0.26		0.37		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.26 (0.03, 2.51)		0.25 (0.01, 4.88)		
p-value [1]	0.24		0.36		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.05, 0.25)		0.08 (-0.05, 0.22)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Non-Responder, n(%)	24 (85.7%)	23 (95.8%)	34 (89.5%)	15 (100.0%)	
Non-missing	8 (28.6%)	15 (62.5%)	11 (28.9%)	7 (46.7%)	
Missing	16 (57.1%)	8 (33.3%)	23 (60.5%)	8 (53.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7610: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N = 28)	BAT (N = 24)	MMB (N = 38)	BAT (N = 15)	p-value
BFI Interference Score at Week 24					
Responder, n(%)	3 (10.7%)	2 (8.3%)	3 (7.9%)	0	
Unadjusted Inverse Relative Risk (95% CI)	0.78 (0.14, 4.28)		0.35 (0.02, 6.36)		
p-value [1]	0.77		0.48		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.76 (0.12, 4.96)		0.33 (0.02, 6.72)		
p-value [1]	0.77		0.47		
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.14, 0.18)		0.06 (-0.07, 0.18)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Non-Responder, n(%)	25 (89.3%)	22 (91.7%)	35 (92.1%)	15 (100.0%)	
Non-missing	9 (32.1%)	14 (58.3%)	12 (31.6%)	7 (46.7%)	
Missing	16 (57.1%)	8 (33.3%)	23 (60.5%)	8 (53.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7609: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 42)	BAT (N = 20)	MMB (N = 24)	BAT (N = 19)	p-value
BFI Total Score at Week 24					
Responder, n(%)	3 (7.1%)	0	3 (12.5%)	1 (5.3%)	
Unadjusted Inverse Relative Risk (95% CI)	0.29 (0.02, 5.41)		0.42 (0.05, 3.73)		
p-value [1]	0.41		0.44		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.28 (0.01, 5.59)		0.39 (0.04, 4.07)		
p-value [1]	0.40		0.43		
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.05, 0.16)		0.07 (-0.09, 0.24)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Non-Responder, n(%)	39 (92.9%)	20 (100.0%)	21 (87.5%)	18 (94.7%)	
Non-missing	16 (38.1%)	11 (55.0%)	5 (20.8%)	11 (57.9%)	
Missing	23 (54.8%)	9 (45.0%)	16 (66.7%)	7 (36.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7609: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 42)	BAT (N = 20)	MMB (N = 24)	BAT (N = 19)	p-value
BFI Fatigue Score at Week 24					
Responder, n(%)	5 (11.9%)	0	3 (12.5%)	1 (5.3%)	
Unadjusted Inverse Relative Risk (95% CI)	0.19 (0.01, 3.21)		0.42 (0.05, 3.73)		
p-value [1]	0.25		0.44		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.17 (0.01, 3.16)		0.39 (0.04, 4.07)		
p-value [1]	0.23		0.43		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.02, 0.22)		0.07 (-0.09, 0.24)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Non-Responder, n(%)	37 (88.1%)	20 (100.0%)	21 (87.5%)	18 (94.7%)	
Non-missing	14 (33.3%)	11 (55.0%)	5 (20.8%)	11 (57.9%)	
Missing	23 (54.8%)	9 (45.0%)	16 (66.7%)	7 (36.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7609: Analysis of Response Rate (improvement, 15% criterion) in Brief Fatigue Inventory Score and both subdomains at Week 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 42)	BAT (N = 20)	MMB (N = 24)	BAT (N = 19)	p-value
BFI Interference Score at Week 24					
Responder, n(%)	3 (7.1%)	1 (5.0%)	3 (12.5%)	1 (5.3%)	
Unadjusted Inverse Relative Risk (95% CI)	0.70 (0.08, 6.32)		0.42 (0.05, 3.73)		
p-value [1]	0.75		0.44		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.68 (0.07, 7.02)		0.39 (0.04, 4.07)		
p-value [1]	0.75		0.43		
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.10, 0.14)		0.07 (-0.09, 0.24)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Non-Responder, n(%)	39 (92.9%)	19 (95.0%)	21 (87.5%)	18 (94.7%)	
Non-missing	16 (38.1%)	10 (50.0%)	5 (20.8%)	11 (57.9%)	
Missing	23 (54.8%)	9 (45.0%)	16 (66.7%)	7 (36.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.5702: Analysis of response rate of no RBC Transfusion for 24 weeks by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
RBC Transfusion Free Rate					
Responder, n(%)	5 (20.8%)	1 (11.1%)	7 (16.7%)	3 (10.0%)	
95% Exact CI	0.0713, 0.4215	0.0028, 0.4825	0.0697, 0.3136	0.0211, 0.2653	
Proportion Difference - Stratified CMH Method (95% CI)	0.04 (-0.30, 0.39)		0.11 (-0.06, 0.28)		
p-value	0.80		0.21		
Proportion Difference - Unstratified CMH Method (95% CI)	0.10 (-0.20, 0.40)		0.07 (-0.10, 0.23)		
p-value	0.53		0.42		
Proportion Difference - Unstratified Exact Method (95% CI)	0.10 (-0.29, 0.46)		0.07 (-0.17, 0.30)		
p-value	1.00		0.51		
Unadjusted Inverse Relative Risk (95% CI)	0.53 (0.07, 3.96)		0.60 (0.17, 2.13)		
p-value [1]	0.54		0.43		
Unadjusted interaction test for Treatment*Age Group [3]					0.92
Unadjusted Inverse Odds Ratio (95% CI)	0.48 (0.05, 4.74)		0.56 (0.13, 2.35)		
p-value [1]	0.53		0.42		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.16, 0.36)		0.07 (-0.09, 0.22)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.43 (0.15, 1.23)		
p-value [2]	NE		0.12		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.5702: Analysis of response rate of no RBC Transfusion for 24 weeks by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Adjusted interaction test for Treatment*Age Group [3]					0.88
Non-responder, n(%)	19 (79.2%)	8 (88.9%)	35 (83.3%)	27 (90.0%)	
RBC Transfusion within 24 weeks	19 (79.2%)	7 (77.8%)	33 (78.6%)	26 (86.7%)	
Discontinued prior to week 24	0	1 (11.1%)	2 (4.8%)	1 (3.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.5707: Analysis of response rate of no RBC Transfusion for 24 weeks by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8g/dL		HGB >=8g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
RBC Transfusion Free Rate					
Responder, n(%)	1 (3.7%)	0	11 (28.2%)	4 (12.1%)	
95% Exact CI	0.0009, 0.1897	0.0000, 0.4593	0.1500, 0.4487	0.0340, 0.2820	
Proportion Difference - Stratified CMH Method (95% CI)	0.04 (-0.30, 0.39)		0.17 (-0.03, 0.36)		
p-value	0.80		0.097		
Proportion Difference - Unstratified CMH Method (95% CI)	0.04 (-0.20, 0.28)		0.16 (-0.02, 0.35)		
p-value	0.76		0.090		
Proportion Difference - Unstratified Exact Method (95% CI)	0.04 (-0.41, 0.48)		0.16 (-0.07, 0.38)		
p-value	1.00		0.15		
Unadjusted Inverse Relative Risk (95% CI)	1.33 (0.06, 29.35)		0.43 (0.15, 1.22)		
p-value [1]	0.86		0.11		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE
Unadjusted Inverse Odds Ratio (95% CI)	1.36 (0.05, 37.35)		0.35 (0.10, 1.23)		
p-value [1]	0.86		0.10		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.23, 0.19)		0.16 (-0.02, 0.34)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.42 (0.16, 1.14)		
p-value [2]	NE		0.089		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.5707: Analysis of response rate of no RBC Transfusion for 24 weeks by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8g/dL		HGB >=8g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE
Non-responder, n(%)	26 (96.3%)	6 (100.0%)	28 (71.8%)	29 (87.9%)	
RBC Transfusion within 24 weeks	25 (92.6%)	6 (100.0%)	27 (69.2%)	27 (81.8%)	
Discontinued prior to week 24	1 (3.7%)	0	1 (2.6%)	2 (6.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.5706: Analysis of response rate of no RBC Transfusion for 24 weeks by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
RBC Transfusion Free Rate					
Responder, n(%)	8 (16.3%)	4 (12.9%)	4 (23.5%)	0	
95% Exact CI	0.0732, 0.2966	0.0363, 0.2983	0.0681, 0.4990	0.0000, 0.3694	
Proportion Difference - Stratified CMH Method (95% CI)	0.10 (-0.07, 0.28)		0.22 (-0.13, 0.57)		
p-value	0.26		0.21		
Proportion Difference - Unstratified CMH Method (95% CI)	0.03 (-0.13, 0.20)		0.24 (-0.04, 0.51)		
p-value	0.68		0.090		
Proportion Difference - Unstratified Exact Method (95% CI)	0.03 (-0.19, 0.25)		0.24 (-0.17, 0.60)		
p-value	0.76		0.27		
Unadjusted Inverse Relative Risk (95% CI)	0.79 (0.26, 2.40)		0.22 (0.01, 3.69)		
p-value [1]	0.68		0.29		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NE
Unadjusted Inverse Odds Ratio (95% CI)	0.76 (0.21, 2.77)		0.18 (0.01, 3.71)		
p-value [1]	0.68		0.26		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.12, 0.19)		0.19 (-0.06, 0.44)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.51 (0.20, 1.32)		NE		
p-value [2]	0.17		NE		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.5706: Analysis of response rate of no RBC Transfusion for 24 weeks by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NE
Non-responder, n(%)	41 (83.7%)	27 (87.1%)	13 (76.5%)	8 (100.0%)	
RBC Transfusion within 24 weeks	40 (81.6%)	26 (83.9%)	12 (70.6%)	7 (87.5%)	
Discontinued prior to week 24	1 (2.0%)	1 (3.2%)	1 (5.9%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.5705: Analysis of response rate of no RBC Transfusion for 24 weeks by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
RBC Transfusion Free Rate				
Responder, n(%)	2 (40.0%)	0	6 (13.6%)	4 (16.7%)
95% Exact CI	0.0527, 0.8534	0.0000, 0.4096	0.0517, 0.2735	0.0474, 0.3738
Proportion Difference - Stratified CMH Method (95% CI)	0.00 (-0.65, 0.65)		0.04 (-0.17, 0.25)	
p-value	1.00		0.72	
Proportion Difference - Unstratified CMH Method (95% CI)	0.40 (-0.12, 0.92)		-0.03 (-0.22, 0.16)	
p-value	0.13		0.75	
Proportion Difference - Unstratified Exact Method (95% CI)	0.40 (-0.17, 0.85)		-0.03 (-0.28, 0.22)	
p-value	0.15		0.73	
Unadjusted Inverse Relative Risk (95% CI)	0.15 (0.01, 2.58)		1.22 (0.38, 3.91)	
p-value [1]	0.19		0.74	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	0.09 (0.00, 2.51)		1.27 (0.32, 5.02)	
p-value [1]	0.16		0.74	
Unadjusted Absolute Risk Difference (95% CI)	0.35 (-0.07, 0.78)		-0.03 (-0.21, 0.15)	
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.77 (0.29, 2.07)	
p-value [2]	NE		0.61	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.5705: Analysis of response rate of no RBC Transfusion for 24 weeks by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=17)	High Risk BAT (N=8)	p-value
RBC Transfusion Free Rate			
Responder, n(%)	4 (23.5%)	0	
95% Exact CI	0.0681, 0.4990	0.0000, 0.3694	
Proportion Difference - Stratified CMH Method (95% CI)	0.22 (-0.13, 0.57)		
p-value	0.21		
Proportion Difference - Unstratified CMH Method (95% CI)	0.24 (-0.04, 0.51)		
p-value	0.090		
Proportion Difference - Unstratified Exact Method (95% CI)	0.24 (-0.17, 0.60)		
p-value	0.27		
Unadjusted Inverse Relative Risk (95% CI)	0.22 (0.01, 3.69)		
p-value [1]	0.29		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NE
Unadjusted Inverse Odds Ratio (95% CI)	0.18 (0.01, 3.71)		
p-value [1]	0.26		
Unadjusted Absolute Risk Difference (95% CI)	0.19 (-0.06, 0.44)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NE

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.5705: Analysis of response rate of no RBC Transfusion for 24 weeks by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Non-responder, n(%)	3 (60.0%)	7 (100.0%)	38 (86.4%)	20 (83.3%)
RBC Transfusion within 24 weeks	3 (60.0%)	7 (100.0%)	37 (84.1%)	19 (79.2%)
Discontinued prior to week 24	0	0	1 (2.3%)	1 (4.2%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.5705: Analysis of response rate of no RBC Transfusion for 24 weeks by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=17)	High Risk BAT (N=8)	p-value
Non-responder, n(%)	13 (76.5%)	8 (100.0%)	
RBC Transfusion within 24 weeks	12 (70.6%)	7 (87.5%)	
Discontinued prior to week 24	1 (5.9%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.5708: Analysis of response rate of no RBC Transfusion for 24 weeks by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
RBC Transfusion Free Rate				
Responder, n(%)	9 (20.0%)	2 (8.7%)	2 (15.4%)	1 (12.5%)
95% Exact CI	0.0958, 0.3460	0.0107, 0.2804	0.0192, 0.4545	0.0032, 0.5265
Proportion Difference - Stratified CMH Method (95% CI)	0.12 (-0.08, 0.32)		0.01 (-0.37, 0.38)	
p-value	0.23		0.98	
Proportion Difference - Unstratified CMH Method (95% CI)	0.11 (-0.06, 0.29)		0.03 (-0.32, 0.38)	
p-value	0.21		0.87	
Proportion Difference - Unstratified Exact Method (95% CI)	0.11 (-0.14, 0.35)		0.03 (-0.40, 0.44)	
p-value	0.31		1.00	
Unadjusted Inverse Relative Risk (95% CI)	0.43 (0.10, 1.85)		0.81 (0.09, 7.58)	
p-value [1]	0.26		0.86	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	0.38 (0.08, 1.93)		0.79 (0.06, 10.38)	
p-value [1]	0.24		0.85	
Unadjusted Absolute Risk Difference (95% CI)	0.11 (-0.05, 0.28)		0.03 (-0.27, 0.33)	
Adjusted Inverse Relative Risk (95% CI) [2]	0.42 (0.11, 1.61)		NE	
p-value [2]	0.20		NE	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.5708: Analysis of response rate of no RBC Transfusion for 24 weeks by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	Post-PV Myelofibrosis MMB (N=8)	Post-PV Myelofibrosis BAT (N=8)	p-value
RBC Transfusion Free Rate			
Responder, n(%)	1 (12.5%)	1 (12.5%)	
95% Exact CI	0.0032, 0.5265	0.0032, 0.5265	
Proportion Difference - Stratified CMH Method (95% CI)	0.13 (-0.40, 0.66)		
p-value	0.62		
Proportion Difference - Unstratified CMH Method (95% CI)	0.00 (-0.39, 0.39)		
p-value	1.00		
Proportion Difference - Unstratified Exact Method (95% CI)	0.00 (-0.51, 0.51)		
p-value	1.00		
Unadjusted Inverse Relative Risk (95% CI)	1.00 (0.07, 13.37)		
p-value [1]	1.00		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.82
Unadjusted Inverse Odds Ratio (95% CI)	1.00 (0.05, 19.36)		
p-value [1]	1.00		
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.32, 0.32)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.5708: Analysis of response rate of no RBC Transfusion for 24 weeks by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-responder, n(%)	36 (80.0%)	21 (91.3%)	11 (84.6%)	7 (87.5%)
RBC Transfusion within 24 weeks	35 (77.8%)	21 (91.3%)	11 (84.6%)	5 (62.5%)
Discontinued prior to week 24	1 (2.2%)	0	0	2 (25.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.5708: Analysis of response rate of no RBC Transfusion for 24 weeks by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	Post-PV Myelofibrosis MMB (N=8)	Post-PV Myelofibrosis BAT (N=8)	p-value
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.91
Non-responder, n(%)	7 (87.5%)	7 (87.5%)	
RBC Transfusion within 24 weeks	6 (75.0%)	7 (87.5%)	
Discontinued prior to week 24	1 (12.5%)	0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC = Red Blood Cell.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.5704: Analysis of response rate of no RBC Transfusion for 24 weeks by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
RBC Transfusion Free Rate					
Responder, n(%)	7 (24.1%)	2 (28.6%)	5 (13.5%)	2 (6.3%)	
95% Exact CI	0.1030, 0.4354	0.0367, 0.7096	0.0454, 0.2877	0.0077, 0.2081	
Proportion Difference - Stratified CMH Method (95% CI)	0.02 (-0.39, 0.42)		0.08 (-0.08, 0.25)		
p-value	0.93		0.31		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.04 (-0.45, 0.36)		0.07 (-0.08, 0.22)		
p-value	0.83		0.34		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.04 (-0.46, 0.36)		0.07 (-0.16, 0.30)		
p-value	1.00		0.44		
Unadjusted Inverse Relative Risk (95% CI)	1.18 (0.31, 4.51)		0.46 (0.10, 2.22)		
p-value [1]	0.80		0.34		
Unadjusted interaction test for Treatment*Region [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	1.26 (0.20, 7.97)		0.43 (0.08, 2.37)		
p-value [1]	0.81		0.33		
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.41, 0.32)		0.07 (-0.07, 0.21)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Region [3]					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.5704: Analysis of response rate of no RBC Transfusion for 24 weeks by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Non-responder, n(%)	22 (75.9%)	5 (71.4%)	32 (86.5%)	30 (93.8%)	
RBC Transfusion within 24 weeks	20 (69.0%)	4 (57.1%)	32 (86.5%)	29 (90.6%)	
Discontinued prior to week 24	2 (6.9%)	1 (14.3%)	0	1 (3.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.5703: Analysis of response rate of no RBC Transfusion for 24 weeks by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
RBC Transfusion Free Rate					
Responder, n(%)	10 (19.2%)	1 (5.6%)	2 (14.3%)	3 (14.3%)	
95% Exact CI	0.0963, 0.3253	0.0014, 0.2729	0.0178, 0.4281	0.0305, 0.3634	
Proportion Difference - Stratified CMH Method (95% CI)	0.13 (-0.08, 0.34)		0.09 (-0.17, 0.36)		
p-value	0.22		0.49		
Proportion Difference - Unstratified CMH Method (95% CI)	0.14 (-0.03, 0.31)		0.00 (-0.26, 0.26)		
p-value	0.11		1.00		
Proportion Difference - Unstratified Exact Method (95% CI)	0.14 (-0.13, 0.40)		0.00 (-0.34, 0.34)		
p-value	0.27		1.00		
Unadjusted Inverse Relative Risk (95% CI)	0.29 (0.04, 2.10)		1.00 (0.19, 5.24)		
p-value [1]	0.22		1.00		
Unadjusted interaction test for Treatment*Gender [3]					0.30
Unadjusted Inverse Odds Ratio (95% CI)	0.25 (0.03, 2.08)		1.00 (0.14, 6.91)		
p-value [1]	0.20		1.00		
Unadjusted Absolute Risk Difference (95% CI)	0.14 (-0.01, 0.29)		0.00 (-0.24, 0.24)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.30 (0.05, 1.88)		0.46 (0.09, 2.32)		
p-value [2]	0.20		0.34		
Adjusted interaction test for Treatment*Gender [3]					0.57

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.5703: Analysis of response rate of no RBC Transfusion for 24 weeks by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Non-responder, n(%)	42 (80.8%)	17 (94.4%)	12 (85.7%)	18 (85.7%)	
RBC Transfusion within 24 weeks	41 (78.8%)	16 (88.9%)	11 (78.6%)	17 (81.0%)	
Discontinued prior to week 24	1 (1.9%)	1 (5.6%)	1 (7.1%)	1 (4.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-sg-norbc-24-rt-gba.sas V.03.05 Output file: t-norbc-24-rt-gba-sex.pdf 24AUG2023:16:48

Table 2.5710: Analysis of response rate of no RBC Transfusion for 24 weeks by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
RBC Transfusion Free Rate					
Responder, n(%)	5 (17.9%)	3 (12.5%)	7 (18.4%)	1 (6.7%)	
95% Exact CI	0.0606, 0.3689	0.0266, 0.3236	0.0774, 0.3433	0.0017, 0.3195	
Proportion Difference - Stratified CMH Method (95% CI)	0.09 (-0.14, 0.32)		0.14 (-0.14, 0.42)		
p-value	0.45		0.31		
Proportion Difference - Unstratified CMH Method (95% CI)	0.05 (-0.15, 0.26)		0.12 (-0.08, 0.32)		
p-value	0.61		0.25		
Proportion Difference - Unstratified Exact Method (95% CI)	0.05 (-0.22, 0.32)		0.12 (-0.18, 0.40)		
p-value	0.71		0.42		
Unadjusted Inverse Relative Risk (95% CI)	0.70 (0.19, 2.63)		0.36 (0.05, 2.70)		
p-value [1]	0.60		0.32		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.66 (0.14, 3.09)		0.32 (0.04, 2.82)		
p-value [1]	0.60		0.30		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.14, 0.25)		0.12 (-0.06, 0.29)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.5710: Analysis of response rate of no RBC Transfusion for 24 weeks by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Non-responder, n(%)	23 (82.1%)	21 (87.5%)	31 (81.6%)	14 (93.3%)	
RBC Transfusion within 24 weeks	22 (78.6%)	20 (83.3%)	30 (78.9%)	13 (86.7%)	
Discontinued prior to week 24	1 (3.6%)	1 (4.2%)	1 (2.6%)	1 (6.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.5709: Analysis of response rate of no RBC Transfusion for 24 weeks by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
RBC Transfusion Free Rate					
Responder, n(%)	8 (19.0%)	2 (10.0%)	4 (16.7%)	2 (10.5%)	
95% Exact CI	0.0860, 0.3412	0.0123, 0.3170	0.0474, 0.3738	0.0130, 0.3314	
Proportion Difference - Stratified CMH Method (95% CI)	0.13 (-0.05, 0.31)		0.07 (-0.15, 0.29)		
p-value	0.16		0.51		
Proportion Difference - Unstratified CMH Method (95% CI)	0.09 (-0.10, 0.28)		0.06 (-0.16, 0.28)		
p-value	0.35		0.58		
Proportion Difference - Unstratified Exact Method (95% CI)	0.09 (-0.18, 0.35)		0.06 (-0.24, 0.35)		
p-value	0.48		0.68		
Unadjusted Inverse Relative Risk (95% CI)	0.53 (0.12, 2.25)		0.63 (0.13, 3.09)		
p-value [1]	0.39		0.57		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.87
Unadjusted Inverse Odds Ratio (95% CI)	0.47 (0.09, 2.46)		0.59 (0.10, 3.62)		
p-value [1]	0.37		0.57		
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.09, 0.27)		0.06 (-0.14, 0.26)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.41 (0.12, 1.44)		0.57 (0.13, 2.45)		
p-value [2]	0.16		0.45		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.5709: Analysis of response rate of no RBC Transfusion for 24 weeks by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Adjusted interaction test for Treatment*Baseline TSS Group [3]					0.83
Non-responder, n(%)	34 (81.0%)	18 (90.0%)	20 (83.3%)	17 (89.5%)	
RBC Transfusion within 24 weeks	33 (78.6%)	17 (85.0%)	19 (79.2%)	16 (84.2%)	
Discontinued prior to week 24	1 (2.4%)	1 (5.0%)	1 (4.2%)	1 (5.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.5802: Analysis of response rate of no RBC Transfusion and no Hgb<8 [g/dL] for 24 weeks by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
No RBC Transfusion and no Hgb<8 [g/dL] Rate					
Responder, n(%)	5 (20.8%)	1 (11.1%)	7 (16.7%)	2 (6.7%)	
95% Exact CI	0.0713, 0.4215	0.0028, 0.4825	0.0697, 0.3136	0.0082, 0.2207	
Proportion Difference - Stratified CMH Method (95% CI)	0.04 (-0.30, 0.39)		0.13 (-0.04, 0.30)		
p-value	0.80		0.12		
Proportion Difference - Unstratified CMH Method (95% CI)	0.10 (-0.20, 0.40)		0.10 (-0.05, 0.25)		
p-value	0.53		0.20		
Proportion Difference - Unstratified Exact Method (95% CI)	0.10 (-0.29, 0.46)		0.10 (-0.14, 0.33)		
p-value	1.00		0.29		
Unadjusted Inverse Relative Risk (95% CI)	0.53 (0.07, 3.96)		0.40 (0.09, 1.79)		
p-value [1]	0.54		0.23		
Unadjusted interaction test for Treatment*Age Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.48 (0.05, 4.74)		0.36 (0.07, 1.86)		
p-value [1]	0.53		0.22		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.16, 0.36)		0.10 (-0.04, 0.24)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Age Group [3]					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.5802: Analysis of response rate of no RBC Transfusion and no Hgb<8 [g/dL] for 24 weeks by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Non-responder, n(%)	19 (79.2%)	8 (88.9%)	35 (83.3%)	28 (93.3%)	
RBC Transfusion or Hgb<8 [g/dL] within 24 weeks	19 (79.2%)	7 (77.8%)	33 (78.6%)	27 (90.0%)	
Discontinued prior to week 24	0	1 (11.1%)	2 (4.8%)	1 (3.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.5807: Analysis of response rate of no RBC Transfusion and no Hgb<8 [g/dL] for 24 weeks by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8g/dL		HGB >=8g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
No RBC Transfusion and no Hgb<8 [g/dL] Rate					
Responder, n(%)	1 (3.7%)	0	11 (28.2%)	3 (9.1%)	
95% Exact CI	0.0009, 0.1897	0.0000, 0.4593	0.1500, 0.4487	0.0192, 0.2433	
Proportion Difference - Stratified CMH Method (95% CI)	0.04 (-0.30, 0.39)		0.20 (0.01, 0.39)		
p-value	0.80		0.044		
Proportion Difference - Unstratified CMH Method (95% CI)	0.04 (-0.20, 0.28)		0.19 (0.01, 0.37)		
p-value	0.76		0.036		
Proportion Difference - Unstratified Exact Method (95% CI)	0.04 (-0.41, 0.48)		0.19 (-0.04, 0.41)		
p-value	1.00		0.071		
Unadjusted Inverse Relative Risk (95% CI)	1.33 (0.06, 29.35)		0.32 (0.10, 1.06)		
p-value [1]	0.86		0.062		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE
Unadjusted Inverse Odds Ratio (95% CI)	1.36 (0.05, 37.35)		0.25 (0.06, 1.01)		
p-value [1]	0.86		0.051		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.23, 0.19)		0.19 (0.02, 0.36)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.31 (0.10, 0.99)		
p-value [2]	NE		0.048		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.5807: Analysis of response rate of no RBC Transfusion and no Hgb<8 [g/dL] for 24 weeks by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8g/dL		HGB >=8g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE
Non-responder, n(%)	26 (96.3%)	6 (100.0%)	28 (71.8%)	30 (90.9%)	
RBC Transfusion or Hgb<8 [g/dL] within 24 weeks	25 (92.6%)	6 (100.0%)	27 (69.2%)	28 (84.8%)	
Discontinued prior to week 24	1 (3.7%)	0	1 (2.6%)	2 (6.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.5806: Analysis of response rate of no RBC Transfusion and no Hgb<8 [g/dL] for 24 weeks by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
No RBC Transfusion and no Hgb<8 [g/dL] Rate					
Responder, n(%)	8 (16.3%)	3 (9.7%)	4 (23.5%)	0	
95% Exact CI	0.0732, 0.2966	0.0204, 0.2575	0.0681, 0.4990	0.0000, 0.3694	
Proportion Difference - Stratified CMH Method (95% CI)	0.12 (-0.05, 0.30)		0.22 (-0.13, 0.57)		
p-value	0.16		0.21		
Proportion Difference - Unstratified CMH Method (95% CI)	0.07 (-0.09, 0.22)		0.24 (-0.04, 0.51)		
p-value	0.40		0.090		
Proportion Difference - Unstratified Exact Method (95% CI)	0.07 (-0.16, 0.29)		0.24 (-0.17, 0.60)		
p-value	0.52		0.27		
Unadjusted Inverse Relative Risk (95% CI)	0.59 (0.17, 2.07)		0.22 (0.01, 3.69)		
p-value [1]	0.41		0.29		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NE
Unadjusted Inverse Odds Ratio (95% CI)	0.55 (0.13, 2.25)		0.18 (0.01, 3.71)		
p-value [1]	0.41		0.26		
Unadjusted Absolute Risk Difference (95% CI)	0.07 (-0.08, 0.21)		0.19 (-0.06, 0.44)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.39 (0.13, 1.17)		NE		
p-value [2]	0.093		NE		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.5806: Analysis of response rate of no RBC Transfusion and no Hgb<8 [g/dL] for 24 weeks by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NE
Non-responder, n(%)	41 (83.7%)	28 (90.3%)	13 (76.5%)	8 (100.0%)	
RBC Transfusion or Hgb<8 [g/dL] within 24 weeks	40 (81.6%)	27 (87.1%)	12 (70.6%)	7 (87.5%)	
Discontinued prior to week 24	1 (2.0%)	1 (3.2%)	1 (5.9%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.5805: Analysis of response rate of no RBC Transfusion and no Hgb<8 [g/dL] for 24 weeks by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
No RBC Transfusion and no Hgb<8 [g/dL] Rate				
Responder, n(%)	2 (40.0%)	0	6 (13.6%)	3 (12.5%)
95% Exact CI	0.0527, 0.8534	0.0000, 0.4096	0.0517, 0.2735	0.0266, 0.3236
Proportion Difference - Stratified CMH Method (95% CI)	0.00 (-0.65, 0.65)		0.07 (-0.14, 0.28)	
p-value	1.00		0.54	
Proportion Difference - Unstratified CMH Method (95% CI)	0.40 (-0.12, 0.92)		0.01 (-0.17, 0.19)	
p-value	0.13		0.90	
Proportion Difference - Unstratified Exact Method (95% CI)	0.40 (-0.17, 0.85)		0.01 (-0.24, 0.26)	
p-value	0.15		1.00	
Unadjusted Inverse Relative Risk (95% CI)	0.15 (0.01, 2.58)		0.92 (0.25, 3.34)	
p-value [1]	0.19		0.90	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	0.09 (0.00, 2.51)		0.90 (0.20, 3.99)	
p-value [1]	0.16		0.89	
Unadjusted Absolute Risk Difference (95% CI)	0.35 (-0.07, 0.78)		0.01 (-0.16, 0.18)	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
CMH = Cochran-Mantel-Haenszel.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.5805: Analysis of response rate of no RBC Transfusion and no Hgb<8 [g/dL] for 24 weeks by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=17)	High Risk BAT (N=8)	p-value
No RBC Transfusion and no Hgb<8 [g/dL] Rate			
Responder, n(%)	4 (23.5%)	0	
95% Exact CI	0.0681, 0.4990	0.0000, 0.3694	
Proportion Difference - Stratified CMH Method (95% CI)	0.22 (-0.13, 0.57)		
p-value	0.21		
Proportion Difference - Unstratified CMH Method (95% CI)	0.24 (-0.04, 0.51)		
p-value	0.090		
Proportion Difference - Unstratified Exact Method (95% CI)	0.24 (-0.17, 0.60)		
p-value	0.27		
Unadjusted Inverse Relative Risk (95% CI)	0.22 (0.01, 3.69)		
p-value [1]	0.29		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	0.18 (0.01, 3.71)		
p-value [1]	0.26		
Unadjusted Absolute Risk Difference (95% CI)	0.19 (-0.06, 0.44)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
CMH = Cochran-Mantel-Haenszel.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.5805: Analysis of response rate of no RBC Transfusion and no Hgb<8 [g/dL] for 24 weeks by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Non-responder, n(%)	3 (60.0%)	7 (100.0%)	38 (86.4%)	21 (87.5%)
RBC Transfusion or Hgb<8 [g/dL] within 24 weeks	3 (60.0%)	7 (100.0%)	37 (84.1%)	20 (83.3%)
Discontinued prior to week 24	0	0	1 (2.3%)	1 (4.2%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
CMH = Cochran-Mantel-Haenszel.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.5805: Analysis of response rate of no RBC Transfusion and no Hgb<8 [g/dL] for 24 weeks by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=17)	High Risk BAT (N=8)	p-value
Non-responder, n(%)	13 (76.5%)	8 (100.0%)	
RBC Transfusion or Hgb<8 [g/dL] within 24 weeks	12 (70.6%)	7 (87.5%)	
Discontinued prior to week 24	1 (5.9%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
CMH = Cochran-Mantel-Haenszel.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.5808: Analysis of response rate of no RBC Transfusion and no Hgb<8 [g/dL] for 24 weeks by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
No RBC Transfusion and no Hgb<8 [g/dL] Rate				
Responder, n(%)	9 (20.0%)	1 (4.3%)	2 (15.4%)	1 (12.5%)
95% Exact CI	0.0958, 0.3460	0.0011, 0.2195	0.0192, 0.4545	0.0032, 0.5265
Proportion Difference - Stratified CMH Method (95% CI)	0.16 (-0.02, 0.35)		0.01 (-0.37, 0.38)	
p-value	0.082		0.98	
Proportion Difference - Unstratified CMH Method (95% CI)	0.16 (0.00, 0.31)		0.03 (-0.32, 0.38)	
p-value	0.050		0.87	
Proportion Difference - Unstratified Exact Method (95% CI)	0.16 (-0.10, 0.39)		0.03 (-0.40, 0.44)	
p-value	0.15		1.00	
Unadjusted Inverse Relative Risk (95% CI)	0.22 (0.03, 1.61)		0.81 (0.09, 7.58)	
p-value [1]	0.14		0.86	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	0.18 (0.02, 1.53)		0.79 (0.06, 10.38)	
p-value [1]	0.12		0.85	
Unadjusted Absolute Risk Difference (95% CI)	0.16 (0.01, 0.30)		0.03 (-0.27, 0.33)	
Adjusted Inverse Relative Risk (95% CI) [2]	0.21 (0.03, 1.36)		NE	
p-value [2]	0.10		NE	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.5808: Analysis of response rate of no RBC Transfusion and no Hgb<8 [g/dL] for 24 weeks by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	Post-PV Myelofibrosis MMB (N=8)	Post-PV Myelofibrosis BAT (N=8)	p-value
No RBC Transfusion and no Hgb<8 [g/dL] Rate			
Responder, n(%)	1 (12.5%)	1 (12.5%)	
95% Exact CI	0.0032, 0.5265	0.0032, 0.5265	
Proportion Difference - Stratified CMH Method (95% CI)	0.13 (-0.40, 0.66)		
p-value	0.62		
Proportion Difference - Unstratified CMH Method (95% CI)	0.00 (-0.39, 0.39)		
p-value	1.00		
Proportion Difference - Unstratified Exact Method (95% CI)	0.00 (-0.51, 0.51)		
p-value	1.00		
Unadjusted Inverse Relative Risk (95% CI)	1.00 (0.07, 13.37)		
p-value [1]	1.00		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.58
Unadjusted Inverse Odds Ratio (95% CI)	1.00 (0.05, 19.36)		
p-value [1]	1.00		
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.32, 0.32)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.67

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.5808: Analysis of response rate of no RBC Transfusion and no Hgb<8 [g/dL] for 24 weeks by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
Non-responder, n(%)	36 (80.0%)	22 (95.7%)	11 (84.6%)	7 (87.5%)
RBC Transfusion or Hgb<8 [g/dL] within 24 weeks	35 (77.8%)	22 (95.7%)	11 (84.6%)	5 (62.5%)
Discontinued prior to week 24	1 (2.2%)	0	0	2 (25.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.5808: Analysis of response rate of no RBC Transfusion and no Hgb<8 [g/dL] for 24 weeks by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
(Continued)	MMB (N=8)	BAT (N=8)	p-value
Non-responder, n(%)	7 (87.5%)	7 (87.5%)	
RBC Transfusion or Hgb<8 [g/dL] within 24 weeks	6 (75.0%)	7 (87.5%)	
Discontinued prior to week 24	1 (12.5%)	0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.5804: Analysis of response rate of no RBC Transfusion and no Hgb<8 [g/dL] for 24 weeks by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
No RBC Transfusion and no Hgb<8 [g/dL] Rate					
Responder, n(%)	7 (24.1%)	2 (28.6%)	5 (13.5%)	1 (3.1%)	
95% Exact CI	0.1030, 0.4354	0.0367, 0.7096	0.0454, 0.2877	0.0008, 0.1622	
Proportion Difference - Stratified CMH Method (95% CI)	0.02 (-0.39, 0.42)		0.11 (-0.05, 0.27)		
p-value	0.93		0.17		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.04 (-0.45, 0.36)		0.10 (-0.03, 0.24)		
p-value	0.83		0.14		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.04 (-0.46, 0.36)		0.10 (-0.13, 0.33)		
p-value	1.00		0.21		
Unadjusted Inverse Relative Risk (95% CI)	1.18 (0.31, 4.51)		0.23 (0.03, 1.88)		
p-value [1]	0.80		0.17		
Unadjusted interaction test for Treatment*Region [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	1.26 (0.20, 7.97)		0.21 (0.02, 1.87)		
p-value [1]	0.81		0.16		
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.41, 0.32)		0.10 (-0.02, 0.23)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Region [3]					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
CMH = Cochran-Mantel-Haenszel.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.5804: Analysis of response rate of no RBC Transfusion and no Hgb<8 [g/dL] for 24 weeks by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Non-responder, n(%)	22 (75.9%)	5 (71.4%)	32 (86.5%)	31 (96.9%)	
RBC Transfusion or Hgb<8 [g/dL] within 24 weeks	20 (69.0%)	4 (57.1%)	32 (86.5%)	30 (93.8%)	
Discontinued prior to week 24	2 (6.9%)	1 (14.3%)	0	1 (3.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
CMH = Cochran-Mantel-Haenszel.
RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.5803: Analysis of response rate of no RBC Transfusion and no Hgb<8 [g/dL] for 24 weeks by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
No RBC Transfusion and no Hgb<8 [g/dL] Rate					
Responder, n(%)	10 (19.2%)	0	2 (14.3%)	3 (14.3%)	
95% Exact CI	0.0963, 0.3253	0.0000, 0.1853	0.0178, 0.4281	0.0305, 0.3634	
Proportion Difference - Stratified CMH Method (95% CI)	0.19 (0.00, 0.38)		0.09 (-0.17, 0.36)		
p-value	0.055		0.49		
Proportion Difference - Unstratified CMH Method (95% CI)	0.19 (0.06, 0.33)		0.00 (-0.26, 0.26)		
p-value	0.005		1.00		
Proportion Difference - Unstratified Exact Method (95% CI)	0.19 (-0.07, 0.45)		0.00 (-0.34, 0.34)		
p-value	0.054		1.00		
Unadjusted Inverse Relative Risk (95% CI)	0.13 (0.01, 2.16)		1.00 (0.19, 5.24)		
p-value [1]	0.16		1.00		
Unadjusted interaction test for Treatment*Gender [3]					NE
Unadjusted Inverse Odds Ratio (95% CI)	0.11 (0.01, 1.97)		1.00 (0.14, 6.91)		
p-value [1]	0.13		1.00		
Unadjusted Absolute Risk Difference (95% CI)	0.17 (0.04, 0.30)		0.00 (-0.24, 0.24)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.46 (0.09, 2.32)		
p-value [2]	NE		0.34		
Adjusted interaction test for Treatment*Gender [3]					NE

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.5803: Analysis of response rate of no RBC Transfusion and no Hgb<8 [g/dL] for 24 weeks by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Non-responder, n(%)	42 (80.8%)	18 (100.0%)	12 (85.7%)	18 (85.7%)	
RBC Transfusion or Hgb<8 [g/dL] within 24 weeks	41 (78.8%)	17 (94.4%)	11 (78.6%)	17 (81.0%)	
Discontinued prior to week 24	1 (1.9%)	1 (5.6%)	1 (7.1%)	1 (4.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.5810: Analysis of response rate of no RBC Transfusion and no Hgb<8 [g/dL] for 24 weeks by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
No RBC Transfusion and no Hgb<8 [g/dL] Rate					
Responder, n(%)	5 (17.9%)	2 (8.3%)	7 (18.4%)	1 (6.7%)	
95% Exact CI	0.0606, 0.3689	0.0103, 0.2700	0.0774, 0.3433	0.0017, 0.3195	
Proportion Difference - Stratified CMH Method (95% CI)	0.12 (-0.11, 0.34)		0.14 (-0.14, 0.42)		
p-value	0.32		0.31		
Proportion Difference - Unstratified CMH Method (95% CI)	0.10 (-0.10, 0.29)		0.12 (-0.08, 0.32)		
p-value	0.33		0.25		
Proportion Difference - Unstratified Exact Method (95% CI)	0.10 (-0.18, 0.36)		0.12 (-0.18, 0.40)		
p-value	0.43		0.42		
Unadjusted Inverse Relative Risk (95% CI)	0.47 (0.10, 2.19)		0.36 (0.05, 2.70)		
p-value [1]	0.33		0.32		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.42 (0.07, 2.38)		0.32 (0.04, 2.82)		
p-value [1]	0.33		0.30		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.08, 0.28)		0.12 (-0.06, 0.29)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.5810: Analysis of response rate of no RBC Transfusion and no Hgb<8 [g/dL] for 24 weeks by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Non-responder, n(%)	23 (82.1%)	22 (91.7%)	31 (81.6%)	14 (93.3%)	
RBC Transfusion or Hgb<8 [g/dL] within 24 weeks	22 (78.6%)	21 (87.5%)	30 (78.9%)	13 (86.7%)	
Discontinued prior to week 24	1 (3.6%)	1 (4.2%)	1 (2.6%)	1 (6.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.5809: Analysis of response rate of no RBC Transfusion and no Hgb<8 [g/dL] for 24 weeks by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
No RBC Transfusion and no Hgb<8 [g/dL] Rate					
Responder, n(%)	8 (19.0%)	1 (5.0%)	4 (16.7%)	2 (10.5%)	
95% Exact CI	0.0860, 0.3412	0.0013, 0.2487	0.0474, 0.3738	0.0130, 0.3314	
Proportion Difference - Stratified CMH Method (95% CI)	0.17 (0.00, 0.35)		0.07 (-0.15, 0.29)		
p-value	0.055		0.51		
Proportion Difference - Unstratified CMH Method (95% CI)	0.14 (-0.03, 0.31)		0.06 (-0.16, 0.28)		
p-value	0.10		0.58		
Proportion Difference - Unstratified Exact Method (95% CI)	0.14 (-0.13, 0.40)		0.06 (-0.24, 0.35)		
p-value	0.25		0.68		
Unadjusted Inverse Relative Risk (95% CI)	0.26 (0.04, 1.96)		0.63 (0.13, 3.09)		
p-value [1]	0.19		0.57		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.22 (0.03, 1.93)		0.59 (0.10, 3.62)		
p-value [1]	0.17		0.57		
Unadjusted Absolute Risk Difference (95% CI)	0.14 (-0.01, 0.29)		0.06 (-0.14, 0.26)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.5809: Analysis of response rate of no RBC Transfusion and no Hgb<8 [g/dL] for 24 weeks by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Non-responder, n(%)	34 (81.0%)	19 (95.0%)	20 (83.3%)	17 (89.5%)	
RBC Transfusion or Hgb<8 [g/dL] within 24 weeks	33 (78.6%)	18 (90.0%)	19 (79.2%)	16 (84.2%)	
Discontinued prior to week 24	1 (2.4%)	1 (5.0%)	1 (4.2%)	1 (5.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
CMH = Cochran-Mantel-Haenszel. RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.3002: Analysis of RBC Transfusion Independent Response Rate at Week 24 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
RBC Transfusion Independent Rate at Week 24					
Responder, n(%)	8 (33.3%)	1 (11.1%)	14 (33.3%)	4 (13.3%)	
95% Exact CI	0.1563, 0.5532	0.0028, 0.4825	0.1957, 0.4955	0.0376, 0.3072	
Proportion Difference - Stratified CMH Method (95% CI)	0.19 (-0.18, 0.55)		0.22 (0.02, 0.41)		
p-value	0.31		0.031		
Proportion Difference - Unstratified CMH Method (95% CI)	0.22 (-0.09, 0.54)		0.20 (0.01, 0.39)		
p-value	0.17		0.043		
Proportion Difference - Unstratified Exact Method (95% CI)	0.22 (-0.16, 0.60)		0.20 (-0.04, 0.42)		
p-value	0.38		0.060		
Unadjusted Inverse Relative Risk (95% CI)	0.33 (0.05, 2.30)		0.40 (0.15, 1.10)		
p-value [1]	0.27		0.075		
Unadjusted interaction test for Treatment*Age Group [3]					0.86
Unadjusted Inverse Odds Ratio (95% CI)	0.25 (0.03, 2.36)		0.31 (0.09, 1.06)		
p-value [1]	0.23		0.061		
Unadjusted Absolute Risk Difference (95% CI)	0.22 (-0.06, 0.50)		0.20 (0.01, 0.39)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.39 (0.08, 1.93)		0.37 (0.14, 0.94)		
p-value [2]	0.25		0.037		
Adjusted interaction test for Treatment*Age Group [3]					0.93

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.3002: Analysis of RBC Transfusion Independent Response Rate at Week 24 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Non-Responder, n(%)	16 (66.7%)	8 (88.9%)	28 (66.7%)	26 (86.7%)	
Transfusion (except bleeding) in the last 12 weeks	8 (33.3%)	5 (55.6%)	18 (42.9%)	20 (66.7%)	
Any Hgb assessment < 8g/dL in the last 12 weeks	7 (29.2%)	3 (33.3%)	14 (33.3%)	15 (50.0%)	
Last Participation date < Day 162 in RT phase	8 (33.3%)	3 (33.3%)	10 (23.8%)	4 (13.3%)	
Other	2 (8.3%)	1 (11.1%)	7 (16.7%)	2 (6.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tf-ti-rr-by.sas V.03.05 Output file: t-rbcti24-gba-age.pdf 24AUG2023:16:57

Table 2.3008: Analysis of RBC Transfusion Independent Response Rate at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
RBC Transfusion Independent Rate at Week 24				
Responder, n(%)	15 (33.3%)	2 (8.7%)	5 (38.5%)	2 (25.0%)
95% Exact CI	0.2000, 0.4895	0.0107, 0.2804	0.1386, 0.6842	0.0319, 0.6509
Proportion Difference - Stratified CMH Method (95% CI)	0.24 (0.03, 0.44)		0.06 (-0.38, 0.50)	
p-value	0.023		0.80	
Proportion Difference - Unstratified CMH Method (95% CI)	0.25 (0.06, 0.44)		0.13 (-0.30, 0.57)	
p-value	0.011		0.54	
Proportion Difference - Unstratified Exact Method (95% CI)	0.25 (-0.01, 0.47)		0.13 (-0.31, 0.53)	
p-value	0.037		0.66	
Unadjusted Inverse Relative Risk (95% CI)	0.26 (0.07, 1.04)		0.65 (0.16, 2.59)	
p-value [1]	0.058		0.54	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	0.19 (0.04, 0.92)		0.53 (0.08, 3.76)	
p-value [1]	0.039		0.53	
Unadjusted Absolute Risk Difference (95% CI)	0.25 (0.07, 0.43)		0.13 (-0.27, 0.53)	
Adjusted Inverse Relative Risk (95% CI) [2]	0.27 (0.07, 1.01)		0.82 (0.20, 3.40)	
p-value [2]	0.052		0.78	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.3008: Analysis of RBC Transfusion Independent Response Rate at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=8)	BAT (N=8)	p-value
RBC Transfusion Independent Rate at Week 24			
Responder, n(%)	2 (25.0%)	1 (12.5%)	
95% Exact CI	0.0319, 0.6509	0.0032, 0.5265	
Proportion Difference - Stratified CMH Method (95% CI)	0.24 (-0.31, 0.80)		
p-value	0.39		
Proportion Difference - Unstratified CMH Method (95% CI)	0.13 (-0.31, 0.56)		
p-value	0.57		
Proportion Difference - Unstratified Exact Method (95% CI)	0.13 (-0.40, 0.60)		
p-value	1.00		
Unadjusted Inverse Relative Risk (95% CI)	0.50 (0.06, 4.47)		
p-value [1]	0.54		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.67
Unadjusted Inverse Odds Ratio (95% CI)	0.43 (0.03, 5.99)		
p-value [1]	0.53		
Unadjusted Absolute Risk Difference (95% CI)	0.13 (-0.25, 0.50)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.65

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.3008: Analysis of RBC Transfusion Independent Response Rate at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
Non-Responder, n(%)	30 (66.7%)	21 (91.3%)	8 (61.5%)	6 (75.0%)
Transfusion (except bleeding) in the last 12 weeks	18 (40.0%)	16 (69.6%)	4 (30.8%)	4 (50.0%)
Any Hgb assessment < 8g/dL in the last 12 weeks	15 (33.3%)	11 (47.8%)	3 (23.1%)	3 (37.5%)
Last Participation date < Day 162 in RT phase	12 (26.7%)	4 (17.4%)	4 (30.8%)	2 (25.0%)
Other	8 (17.8%)	3 (13.0%)	1 (7.7%)	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.3008: Analysis of RBC Transfusion Independent Response Rate at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=8)	BAT (N=8)	p-value
Non-Responder, n(%)	6 (75.0%)	7 (87.5%)	
Transfusion (except bleeding) in the last 12 weeks	4 (50.0%)	5 (62.5%)	
Any Hgb assessment < 8g/dL in the last 12 weeks	3 (37.5%)	4 (50.0%)	
Last Participation date < Day 162 in RT phase	2 (25.0%)	1 (12.5%)	
Other	0	0	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.3007: Analysis of RBC Transfusion Independent Response Rate at Week 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
RBC Transfusion Independent Rate at Week 24					
Responder, n(%)	8 (29.6%)	0	14 (35.9%)	5 (15.2%)	
95% Exact CI	0.1375, 0.5018	0.0000, 0.4593	0.2120, 0.5282	0.0511, 0.3190	
Proportion Difference - Stratified CMH Method (95% CI)	0.28 (-0.09, 0.65)		0.20 (0.00, 0.40)		
p-value	0.13		0.052		
Proportion Difference - Unstratified CMH Method (95% CI)	0.30 (0.01, 0.58)		0.21 (0.01, 0.41)		
p-value	0.043		0.041		
Proportion Difference - Unstratified Exact Method (95% CI)	0.30 (-0.16, 0.72)		0.21 (-0.03, 0.42)		
p-value	0.30		0.062		
Unadjusted Inverse Relative Risk (95% CI)	0.24 (0.02, 3.61)		0.42 (0.17, 1.05)		
p-value [1]	0.30		0.063		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE
Unadjusted Inverse Odds Ratio (95% CI)	0.18 (0.01, 3.50)		0.32 (0.10, 1.01)		
p-value [1]	0.26		0.052		
Unadjusted Absolute Risk Difference (95% CI)	0.23 (-0.02, 0.49)		0.21 (0.01, 0.40)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.44 (0.19, 1.03)		
p-value [2]	NE		0.059		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tf-ti-rr-by.sas V.03.05 Output file: t-rbcti24-gba-hgb.pdf 24AUG2023:16:58

Table 2.3007: Analysis of RBC Transfusion Independent Response Rate at Week 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Non-Responder, n(%)	19 (70.4%)	6 (100.0%)	25 (64.1%)	28 (84.8%)	
Transfusion (except bleeding) in the last 12 weeks	11 (40.7%)	4 (66.7%)	15 (38.5%)	21 (63.6%)	
Any Hgb assessment < 8g/dL in the last 12 weeks	11 (40.7%)	3 (50.0%)	10 (25.6%)	15 (45.5%)	
Last Participation date < Day 162 in RT phase	8 (29.6%)	2 (33.3%)	10 (25.6%)	5 (15.2%)	
Other	4 (14.8%)	1 (16.7%)	5 (12.8%)	2 (6.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.3006: Analysis of RBC Transfusion Independent Response Rate at Week 24 by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
RBC Transfusion Independent Rate at Week 24					
Responder, n(%)	18 (36.7%)	5 (16.1%)	4 (23.5%)	0	
95% Exact CI	0.2342, 0.5171	0.0545, 0.3373	0.0681, 0.4990	0.0000, 0.3694	
Proportion Difference - Stratified CMH Method (95% CI)	0.23 (0.04, 0.43)		0.22 (-0.13, 0.57)		
p-value	0.016		0.21		
Proportion Difference - Unstratified CMH Method (95% CI)	0.21 (0.01, 0.40)		0.24 (-0.04, 0.51)		
p-value	0.035		0.090		
Proportion Difference - Unstratified Exact Method (95% CI)	0.21 (-0.02, 0.42)		0.24 (-0.17, 0.60)		
p-value	0.075		0.27		
Unadjusted Inverse Relative Risk (95% CI)	0.44 (0.18, 1.06)		0.22 (0.01, 3.69)		
p-value [1]	0.068		0.29		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NE
Unadjusted Inverse Odds Ratio (95% CI)	0.33 (0.11, 1.01)		0.18 (0.01, 3.71)		
p-value [1]	0.053		0.26		
Unadjusted Absolute Risk Difference (95% CI)	0.21 (0.02, 0.39)		0.19 (-0.06, 0.44)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.39 (0.17, 0.88)		NE		
p-value [2]	0.024		NE		
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NE

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tf-ti-rr-by.sas V.03.05 Output file: t-rbcti24-gba-ip2.pdf 24AUG2023:16:58

Table 2.3006: Analysis of RBC Transfusion Independent Response Rate at Week 24 by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Non-Responder, n(%)	31 (63.3%)	26 (83.9%)	13 (76.5%)	8 (100.0%)	
Transfusion (except bleeding) in the last 12 weeks	19 (38.8%)	18 (58.1%)	7 (41.2%)	7 (87.5%)	
Any Hgb assessment < 8g/dL in the last 12 weeks	15 (30.6%)	12 (38.7%)	6 (35.3%)	6 (75.0%)	
Last Participation date < Day 162 in RT phase	12 (24.5%)	6 (19.4%)	6 (35.3%)	1 (12.5%)	
Other	5 (10.2%)	2 (6.5%)	4 (23.5%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.3005: Analysis of RBC Transfusion Independent Response Rate at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
RBC Transfusion Independent Rate at Week 24				
Responder, n(%)	2 (40.0%)	0	16 (36.4%)	5 (20.8%)
95% Exact CI	0.0527, 0.8534	0.0000, 0.4096	0.2241, 0.5223	0.0713, 0.4215
Proportion Difference - Stratified CMH Method (95% CI)	0.00 (-0.65, 0.65)		0.18 (-0.06, 0.42)	
p-value	1.00		0.14	
Proportion Difference - Unstratified CMH Method (95% CI)	0.40 (-0.12, 0.92)		0.16 (-0.07, 0.38)	
p-value	0.13		0.17	
Proportion Difference - Unstratified Exact Method (95% CI)	0.40 (-0.17, 0.85)		0.16 (-0.09, 0.39)	
p-value	0.15		0.27	
Unadjusted Inverse Relative Risk (95% CI)	0.15 (0.01, 2.58)		0.57 (0.24, 1.37)	
p-value [1]	0.19		0.21	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	0.09 (0.00, 2.51)		0.46 (0.14, 1.47)	
p-value [1]	0.16		0.19	
Unadjusted Absolute Risk Difference (95% CI)	0.35 (-0.07, 0.78)		0.16 (-0.06, 0.37)	
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.52 (0.22, 1.23)	
p-value [2]	NE		0.14	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.3005: Analysis of RBC Transfusion Independent Response Rate at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N=17)	BAT (N=8)	p-value
RBC Transfusion Independent Rate at Week 24			
Responder, n(%)	4 (23.5%)	0	
95% Exact CI	0.0681, 0.4990	0.0000, 0.3694	
Proportion Difference - Stratified CMH Method (95% CI)	0.22 (-0.13, 0.57)		
p-value	0.21		
Proportion Difference - Unstratified CMH Method (95% CI)	0.24 (-0.04, 0.51)		
p-value	0.090		
Proportion Difference - Unstratified Exact Method (95% CI)	0.24 (-0.17, 0.60)		
p-value	0.27		
Unadjusted Inverse Relative Risk (95% CI)	0.22 (0.01, 3.69)		
p-value [1]	0.29		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NE
Unadjusted Inverse Odds Ratio (95% CI)	0.18 (0.01, 3.71)		
p-value [1]	0.26		
Unadjusted Absolute Risk Difference (95% CI)	0.19 (-0.06, 0.44)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NE

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.3005: Analysis of RBC Transfusion Independent Response Rate at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Non-Responder, n(%)	3 (60.0%)	7 (100.0%)	28 (63.6%)	19 (79.2%)
Transfusion (except bleeding) in the last 12 weeks	2 (40.0%)	5 (71.4%)	17 (38.6%)	13 (54.2%)
Any Hgb assessment < 8g/dL in the last 12 weeks	2 (40.0%)	3 (42.9%)	13 (29.5%)	9 (37.5%)
Last Participation date < Day 162 in RT phase	1 (20.0%)	1 (14.3%)	11 (25.0%)	5 (20.8%)
Other	1 (20.0%)	2 (28.6%)	4 (9.1%)	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.3005: Analysis of RBC Transfusion Independent Response Rate at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N=17)	BAT (N=8)	p-value
Non-Responder, n(%)	13 (76.5%)	8 (100.0%)	
Transfusion (except bleeding) in the last 12 weeks	7 (41.2%)	7 (87.5%)	
Any Hgb assessment < 8g/dL in the last 12 weeks	6 (35.3%)	6 (75.0%)	
Last Participation date < Day 162 in RT phase	6 (35.3%)	1 (12.5%)	
Other	4 (23.5%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.3004: Analysis of RBC Transfusion Independent Response Rate at Week 24 by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
RBC Transfusion Independent Rate at Week 24					
Responder, n(%)	11 (37.9%)	2 (28.6%)	11 (29.7%)	3 (9.4%)	
95% Exact CI	0.2069, 0.5774	0.0367, 0.7096	0.1587, 0.4698	0.0198, 0.2502	
Proportion Difference - Stratified CMH Method (95% CI)	0.14 (-0.27, 0.56)		0.19 (0.01, 0.37)		
p-value	0.49		0.036		
Proportion Difference - Unstratified CMH Method (95% CI)	0.09 (-0.32, 0.51)		0.20 (0.02, 0.39)		
p-value	0.66		0.031		
Proportion Difference - Unstratified Exact Method (95% CI)	0.09 (-0.33, 0.49)		0.20 (-0.03, 0.42)		
p-value	1.00		0.042		
Unadjusted Inverse Relative Risk (95% CI)	0.75 (0.21, 2.66)		0.32 (0.10, 1.03)		
p-value [1]	0.66		0.056		
Unadjusted interaction test for Treatment*Region [3]					0.39
Unadjusted Inverse Odds Ratio (95% CI)	0.65 (0.11, 3.97)		0.24 (0.06, 0.97)		
p-value [1]	0.65		0.046		
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.28, 0.47)		0.20 (0.02, 0.38)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.65 (0.24, 1.77)		NE		
p-value [2]	0.40		NE		
Adjusted interaction test for Treatment*Region [3]					0.31

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.3004: Analysis of RBC Transfusion Independent Response Rate at Week 24 by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Non-Responder, n(%)	18 (62.1%)	5 (71.4%)	26 (70.3%)	29 (90.6%)	
Transfusion (except bleeding) in the last 12 weeks	12 (41.4%)	4 (57.1%)	14 (37.8%)	21 (65.6%)	
Any Hgb assessment < 8g/dL in the last 12 weeks	11 (37.9%)	3 (42.9%)	10 (27.0%)	15 (46.9%)	
Last Participation date < Day 162 in RT phase	6 (20.7%)	1 (14.3%)	12 (32.4%)	6 (18.8%)	
Other	7 (24.1%)	2 (28.6%)	2 (5.4%)	1 (3.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.3003: Analysis of RBC Transfusion Independent Response Rate at Week 24 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
RBC Transfusion Independent Rate at Week 24					
Responder, n(%)	15 (28.8%)	1 (5.6%)	7 (50.0%)	4 (19.0%)	
95% Exact CI	0.1713, 0.4308	0.0014, 0.2729	0.2304, 0.7696	0.0545, 0.4191	
Proportion Difference - Stratified CMH Method (95% CI)	0.22 (0.01, 0.43)		0.31 (0.02, 0.61)		
p-value	0.042		0.038		
Proportion Difference - Unstratified CMH Method (95% CI)	0.23 (0.05, 0.41)		0.31 (-0.01, 0.63)		
p-value	0.011		0.061		
Proportion Difference - Unstratified Exact Method (95% CI)	0.23 (-0.03, 0.49)		0.31 (-0.04, 0.61)		
p-value	0.053		0.073		
Unadjusted Inverse Relative Risk (95% CI)	0.19 (0.03, 1.36)		0.38 (0.14, 1.06)		
p-value [1]	0.098		0.065		
Unadjusted interaction test for Treatment*Gender [3]					0.49
Unadjusted Inverse Odds Ratio (95% CI)	0.15 (0.02, 1.19)		0.24 (0.05, 1.07)		
p-value [1]	0.072		0.061		
Unadjusted Absolute Risk Difference (95% CI)	0.23 (0.07, 0.40)		0.31 (0.00, 0.62)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.20 (0.03, 1.25)		0.35 (0.11, 1.09)		
p-value [2]	0.086		0.070		
Adjusted interaction test for Treatment*Gender [3]					0.68

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tf-ti-rr-by.sas V.03.05 Output file: t-rbcti24-gba-sex.pdf 24AUG2023:16:58

Table 2.3003: Analysis of RBC Transfusion Independent Response Rate at Week 24 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Non-Responder, n(%)	37 (71.2%)	17 (94.4%)	7 (50.0%)	17 (81.0%)	
Transfusion (except bleeding) in the last 12 weeks	23 (44.2%)	12 (66.7%)	3 (21.4%)	13 (61.9%)	
Any Hgb assessment < 8g/dL in the last 12 weeks	18 (34.6%)	7 (38.9%)	3 (21.4%)	11 (52.4%)	
Last Participation date < Day 162 in RT phase	14 (26.9%)	4 (22.2%)	4 (28.6%)	3 (14.3%)	
Other	8 (15.4%)	2 (11.1%)	1 (7.1%)	1 (4.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.3010: Analysis of RBC Transfusion Independent Response Rate at Week 24 by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median (2329.91 cm^3)		>=Median (2329.91 cm^3)		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
RBC Transfusion Independent Rate at Week 24					
Responder, n(%)	13 (46.4%)	3 (12.5%)	9 (23.7%)	2 (13.3%)	
95% Exact CI	0.2751, 0.6613	0.0266, 0.3236	0.1144, 0.4024	0.0166, 0.4046	
Proportion Difference - Stratified CMH Method (95% CI)	0.37 (0.13, 0.61)		0.09 (-0.21, 0.40)		
p-value	0.002		0.55		
Proportion Difference - Unstratified CMH Method (95% CI)	0.34 (0.10, 0.57)		0.10 (-0.13, 0.34)		
p-value	0.005		0.39		
Proportion Difference - Unstratified Exact Method (95% CI)	0.34 (0.06, 0.58)		0.10 (-0.19, 0.39)		
p-value	0.015		0.48		
Unadjusted Inverse Relative Risk (95% CI)	0.27 (0.09, 0.83)		0.56 (0.14, 2.31)		
p-value [1]	0.023		0.42		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.48
Unadjusted Inverse Odds Ratio (95% CI)	0.16 (0.04, 0.68)		0.50 (0.09, 2.62)		
p-value [1]	0.013		0.41		
Unadjusted Absolute Risk Difference (95% CI)	0.34 (0.11, 0.57)		0.10 (-0.12, 0.32)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.24 (0.09, 0.65)		0.59 (0.16, 2.26)		
p-value [2]	0.005		0.44		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.41

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tf-ti-rr-by.sas V.03.05 Output file: t-rbcti24-gba-spv.pdf 24AUG2023:16:58

Table 2.3010: Analysis of RBC Transfusion Independent Response Rate at Week 24 by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median (2329.91 cm^3)		>=Median (2329.91 cm^3)		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Non-Responder, n(%)	15 (53.6%)	21 (87.5%)	29 (76.3%)	13 (86.7%)	
Transfusion (except bleeding) in the last 12 weeks	10 (35.7%)	19 (79.2%)	16 (42.1%)	6 (40.0%)	
Any Hgb assessment < 8g/dL in the last 12 weeks	9 (32.1%)	13 (54.2%)	12 (31.6%)	5 (33.3%)	
Last Participation date < Day 162 in RT phase	5 (17.9%)	2 (8.3%)	13 (34.2%)	5 (33.3%)	
Other	4 (14.3%)	2 (8.3%)	5 (13.2%)	1 (6.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.3009: Analysis of RBC Transfusion Independent Response Rate at Week 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
RBC Transfusion Independent Rate at Week 24					
Responder, n(%)	18 (42.9%)	2 (10.0%)	4 (16.7%)	3 (15.8%)	
95% Exact CI	0.2772, 0.5904	0.0123, 0.3170	0.0474, 0.3738	0.0338, 0.3958	
Proportion Difference - Stratified CMH Method (95% CI)	0.36 (0.16, 0.56)		0.02 (-0.23, 0.26)		
p-value	<0.001		0.89		
Proportion Difference - Unstratified CMH Method (95% CI)	0.33 (0.12, 0.54)		0.01 (-0.23, 0.24)		
p-value	0.002		0.94		
Proportion Difference - Unstratified Exact Method (95% CI)	0.33 (0.06, 0.56)		0.01 (-0.28, 0.30)		
p-value	0.010		1.00		
Unadjusted Inverse Relative Risk (95% CI)	0.23 (0.06, 0.91)		0.95 (0.24, 3.73)		
p-value [1]	0.036		0.94		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.19
Unadjusted Inverse Odds Ratio (95% CI)	0.15 (0.03, 0.72)		0.94 (0.18, 4.81)		
p-value [1]	0.018		0.94		
Unadjusted Absolute Risk Difference (95% CI)	0.33 (0.13, 0.53)		0.01 (-0.21, 0.23)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.21 (0.06, 0.73)		0.90 (0.24, 3.43)		
p-value [2]	0.014		0.88		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					0.18

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tf-ti-rr-by.sas V.03.05 Output file: t-rbcti24-gba-tss.pdf 24AUG2023:16:58

Table 2.3009: Analysis of RBC Transfusion Independent Response Rate at Week 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Non-Responder, n(%)	24 (57.1%)	18 (90.0%)	20 (83.3%)	16 (84.2%)	
Transfusion (except bleeding) in the last 12 weeks	15 (35.7%)	13 (65.0%)	11 (45.8%)	12 (63.2%)	
Any Hgb assessment < 8g/dL in the last 12 weeks	12 (28.6%)	9 (45.0%)	9 (37.5%)	9 (47.4%)	
Last Participation date < Day 162 in RT phase	9 (21.4%)	3 (15.0%)	9 (37.5%)	4 (21.1%)	
Other	7 (16.7%)	2 (10.0%)	2 (8.3%)	1 (5.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.3802: Analysis of Time to RBC Transfusion Independent Response by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Subjects with Event					
RBC Transfusion Independent Response, n(%)	9 (37.5%)	1 (11.1%)	16 (38.1%)	6 (20.0%)	
Censor					
Subjects Censored, n(%)	15 (62.5%)	8 (88.9%)	26 (61.9%)	24 (80.0%)	
Kaplan-Meier Estimate of Time to RBC Transfusion Independent Response (Weeks)					
25-percentile (95% CI)	12.43 (12.14, 19.57)	NE (12.14, NE)	13.29 (12.14, 22.14)	NE (12.14, NE)	
Median (95% CI)	NE (12.43, NE)	NE (12.14, NE)	NE (15.43, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	4.14, 26.29	2.86, 24.57	4.00, 26.43	1.86, 25.29	
Stratified Log-Rank Test p-value	0.32		0.057		
Adjusted Inverse Hazard Ratio (95% CI)	0.42 (0.05, 3.43)		0.39 (0.14, 1.08)		
Unstratified Log-Rank Test p-value	0.27		0.060		
Unadjusted Inverse Hazard Ratio (95% CI)	0.34 (0.04, 2.68)		0.42 (0.16, 1.06)		
P-value for interaction test					0.85

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-ti-sub.sas V.03.05 Output file: t-tte-ti-age.pdf 24AUG2023:16:32

Table 2.3806: Analysis of Time to RBC Transfusion Independent Response by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Subjects with Event					
RBC Transfusion Independent Response, n(%)	20 (40.8%)	7 (22.6%)	5 (29.4%)	0	
Censor					
Subjects Censored, n(%)	29 (59.2%)	24 (77.4%)	12 (70.6%)	8 (100.0%)	
Kaplan-Meier Estimate of Time to RBC Transfusion Independent Response (Weeks)					
25-percentile (95% CI)	13.57 (12.14, 19.57)	23.86 (12.14, NE)	12.14 (12.14, NE)	NE (NE, NE)	
Median (95% CI)	NE (18.14, NE)	NE (NE, NE)	NE (12.14, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	4.14, 26.43	2.86, 25.00	4.00, 25.00	1.86, 25.29	
Stratified Log-Rank Test p-value	0.052		0.12		
Adjusted Inverse Hazard Ratio (95% CI)	0.39 (0.15, 1.01)		0.00 (0.00, NE)		
Unstratified Log-Rank Test p-value	0.11		0.081		
Unadjusted Inverse Hazard Ratio (95% CI)	0.50 (0.21, 1.19)		0.00 (0.00, NE)		
P-value for interaction test					0.99

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-ti-sub.sas V.03.05 Output file: t-tte-ti-dipss2.pdf 24AUG2023:16:32

Table 2.3805: Analysis of Time to RBC Transfusion Independent Response by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Subjects with Event				
RBC Transfusion Independent Response, n(%)	2 (40.0%)	1 (14.3%)	18 (40.9%)	6 (25.0%)
Censor				
Subjects Censored, n(%)	3 (60.0%)	6 (85.7%)	26 (59.1%)	18 (75.0%)
Kaplan-Meier Estimate of Time to RBC Transfusion Independent Response (Weeks)				
25-percentile (95% CI)	12.14 (12.14, NE)	NE (14.43, NE)	15.43 (12.14, 19.57)	21.86 (12.14, NE)
Median (95% CI)	NE (12.14, NE)	NE (14.43, NE)	NE (19.29, NE)	NE (21.86, NE)
75-percentile (95% CI)	NE (12.14, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Min, Max	9.29, 23.86	2.86, 24.14	4.14, 26.43	7.00, 25.00
Stratified Log-Rank Test p-value	0.41		0.14	
Adjusted Inverse Hazard Ratio (95% CI)	>999.99 (<0.01, NE)		0.46 (0.15, 1.34)	
Unstratified Log-Rank Test p-value	0.23		0.23	
Unadjusted Inverse Hazard Ratio (95% CI)	0.24 (0.02, 2.67)		0.58 (0.23, 1.46)	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-ti-sub.sas V.03.05 Output file: t-tte-ti-dipss3.pdf 24AUG2023:16:32

Table 2.3805: Analysis of Time to RBC Transfusion Independent Response by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=17)	High Risk BAT (N=8)	p-value
Subjects with Event			
RBC Transfusion Independent Response, n(%)	5 (29.4%)	0	
Censor			
Subjects Censored, n(%)	12 (70.6%)	8 (100.0%)	
Kaplan-Meier Estimate of Time to RBC Transfusion Independent Response (Weeks)			
25-percentile (95% CI)	12.14 (12.14, NE)	NE (NE, NE)	
Median (95% CI)	NE (12.14, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	
Min, Max	4.00, 25.00	1.86, 25.29	
Stratified Log-Rank Test p-value	0.12		
Adjusted Inverse Hazard Ratio (95% CI)	0.00 (0.00, NE)		
Unstratified Log-Rank Test p-value	0.081		
Unadjusted Inverse Hazard Ratio (95% CI)	0.00 (0.00, NE)		
P-value for interaction test			0.98

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-ti-sub.sas V.03.05 Output file: t-tte-ti-dipss3.pdf 24AUG2023:16:32

Table 2.3804: Analysis of Time to RBC Transfusion Independent Response by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Subjects with Event					
RBC Transfusion Independent Response, n(%)	12 (41.4%)	2 (28.6%)	13 (35.1%)	5 (15.6%)	
Censor					
Subjects Censored, n(%)	17 (58.6%)	5 (71.4%)	24 (64.9%)	27 (84.4%)	
Kaplan-Meier Estimate of Time to RBC Transfusion Independent Response (Weeks)					
25-percentile (95% CI)	12.14 (12.14, 20.14)	12.14 (12.14, NE)	15.43 (12.14, 22.43)	NE (14.43, NE)	
Median (95% CI)	NE (12.14, NE)	NE (12.14, NE)	NE (18.14, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (12.14, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	4.14, 25.00	1.86, 25.29	4.00, 26.43	2.86, 25.14	
Stratified Log-Rank Test p-value	0.31		0.026		
Adjusted Inverse Hazard Ratio (95% CI)	0.65 (0.14, 3.01)		0.28 (0.09, 0.85)		
Unstratified Log-Rank Test p-value	0.58		0.041		
Unadjusted Inverse Hazard Ratio (95% CI)	0.70 (0.16, 3.11)		0.36 (0.13, 1.00)		
P-value for interaction test					0.29

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-ti-sub.sas V.03.05 Output file: t-tte-ti-geo.pdf 24AUG2023:16:32

Table 2.3807: Analysis of Time to RBC Transfusion Independent Response by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Subjects with Event					
RBC Transfusion Independent Response, n(%)	9 (33.3%)	0	16 (41.0%)	7 (21.2%)	
Censor					
Subjects Censored, n(%)	18 (66.7%)	6 (100.0%)	23 (59.0%)	26 (78.8%)	
Kaplan-Meier Estimate of Time to RBC Transfusion Independent Response (Weeks)					
25-percentile (95% CI)	15.43 (12.14, NE)	NE (NE, NE)	12.14 (12.14, 19.29)	NE (12.14, NE)	
Median (95% CI)	NE (17.57, NE)	NE (NE, NE)	NE (12.43, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	4.00, 25.00	2.86, 25.29	4.14, 26.43	1.86, 25.00	
Stratified Log-Rank Test p-value	0.14		0.033		
Adjusted Inverse Hazard Ratio (95% CI)	0.00 (0.00, NE)		0.36 (0.14, 0.92)		
Unstratified Log-Rank Test p-value	0.16		0.046		
Unadjusted Inverse Hazard Ratio (95% CI)	0.00 (0.00, NE)		0.41 (0.17, 1.01)		
P-value for interaction test					0.99

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-ti-sub.sas V.03.05 Output file: t-tte-ti-hgb.pdf 24AUG2023:16:32

Table 2.3808: Analysis of Time to RBC Transfusion Independent Response by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-ET Myelofibrosis		Post-PV Myelofibrosis	
	MMB (N=13)	BAT (N=8)	MMB (N=8)	BAT (N=8)
Subjects with Event				
RBC Transfusion Independent Response, n(%)	5 (38.5%)	2 (25.0%)	3 (37.5%)	1 (12.5%)
Censor				
Subjects Censored, n(%)	8 (61.5%)	6 (75.0%)	5 (62.5%)	7 (87.5%)
Kaplan-Meier Estimate of Time to RBC Transfusion Independent Response (Weeks)				
25-percentile (95% CI)	12.29 (12.14, NE)	23.86 (12.14, NE)	17.29 (12.14, NE)	NE (12.14, NE)
Median (95% CI)	22.14 (12.29, NE)	NE (12.14, NE)	NE (12.14, NE)	NE (12.14, NE)
75-percentile (95% CI)	NE (22.14, NE)	NE (23.86, NE)	NE (22.43, NE)	NE (NE, NE)
Min, Max	4.00, 25.00	1.86, 25.00	12.14, 25.29	7.71, 24.57
Stratified Log-Rank Test p-value	0.50		0.18	
Adjusted Inverse Hazard Ratio (95% CI)	0.66 (0.10, 4.50)		<0.01 (<0.01, NE)	
Unstratified Log-Rank Test p-value	0.49		0.32	
Unadjusted Inverse Hazard Ratio (95% CI)	0.56 (0.11, 2.98)		0.34 (0.04, 3.28)	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-ti-sub.sas V.03.05 Output file: t-tte-ti-mf.pdf 24AUG2023:16:32

Table 2.3808: Analysis of Time to RBC Transfusion Independent Response by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	Primary Myelofibrosis MMB (N=45)	Primary Myelofibrosis BAT (N=23)	p-value
Subjects with Event			
RBC Transfusion Independent Response, n(%)	17 (37.8%)	4 (17.4%)	
Censor			
Subjects Censored, n(%)	28 (62.2%)	19 (82.6%)	
Kaplan-Meier Estimate of Time to RBC Transfusion Independent Response (Weeks)			
25-percentile (95% CI)	12.86 (12.14, 18.14)	NE (12.14, NE)	
Median (95% CI)	NE (17.57, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	
Min, Max	4.14, 26.43	2.86, 25.29	
Stratified Log-Rank Test p-value	0.034		
Adjusted Inverse Hazard Ratio (95% CI)	0.32 (0.11, 0.99)		
Unstratified Log-Rank Test p-value	0.065		
Unadjusted Inverse Hazard Ratio (95% CI)	0.37 (0.12, 1.10)		
P-value for interaction test			0.53

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-ti-sub.sas V.03.05 Output file: t-tte-ti-mf.pdf 24AUG2023:16:32

Table 2.3803: Analysis of Time to RBC Transfusion Independent Response by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Subjects with Event					
RBC Transfusion Independent Response, n(%)	17 (32.7%)	3 (16.7%)	8 (57.1%)	4 (19.0%)	
Censor					
Subjects Censored, n(%)	35 (67.3%)	15 (83.3%)	6 (42.9%)	17 (81.0%)	
Kaplan-Meier Estimate of Time to RBC Transfusion Independent Response (Weeks)					
25-percentile (95% CI)	15.43 (12.14, 22.14)	NE (14.43, NE)	12.29 (12.14, 18.14)	NE (12.14, NE)	
Median (95% CI)	NE (20.14, NE)	NE (21.86, NE)	18.14 (12.14, NE)	NE (NE, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (13.57, NE)	NE (NE, NE)	
Min, Max	4.00, 26.43	1.86, 25.29	6.86, 24.86	7.71, 25.00	
Stratified Log-Rank Test p-value	0.082		0.020		
Adjusted Inverse Hazard Ratio (95% CI)	0.34 (0.10, 1.22)		0.22 (0.05, 0.89)		
Unstratified Log-Rank Test p-value	0.22		0.011		
Unadjusted Inverse Hazard Ratio (95% CI)	0.46 (0.13, 1.58)		0.24 (0.07, 0.82)		
P-value for interaction test					0.32

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-ti-sub.sas V.03.05 Output file: t-tte-ti-sex.pdf 24AUG2023:16:32

Table 2.3810: Analysis of Time to RBC Transfusion Independent Response by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Subjects with Event					
RBC Transfusion Independent Response, n(%)	15 (53.6%)	4 (16.7%)	10 (26.3%)	3 (20.0%)	
Censor					
Subjects Censored, n(%)	13 (46.4%)	20 (83.3%)	28 (73.7%)	12 (80.0%)	
Kaplan-Meier Estimate of Time to RBC Transfusion Independent Response (Weeks)					
25-percentile (95% CI)	12.29 (12.14, 15.43)	NE (12.14, NE)	17.57 (12.14, NE)	23.86 (12.14, NE)	
Median (95% CI)	22.14 (12.43, NE)	NE (NE, NE)	NE (20.14, NE)	NE (14.43, NE)	
75-percentile (95% CI)	NE (22.43, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	6.86, 25.29	1.86, 25.29	4.00, 26.43	2.86, 25.00	
Stratified Log-Rank Test p-value	0.005		0.68		
Adjusted Inverse Hazard Ratio (95% CI)	0.22 (0.07, 0.71)		0.63 (0.15, 2.60)		
Unstratified Log-Rank Test p-value	0.007		0.70		
Unadjusted Inverse Hazard Ratio (95% CI)	0.25 (0.08, 0.76)		0.76 (0.21, 2.75)		
P-value for interaction test					0.26

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-ti-sub.sas V.03.05 Output file: t-tte-ti-svb.pdf 24AUG2023:16:32

Table 2.3809: Analysis of Time to RBC Transfusion Independent Response by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Subjects with Event					
RBC Transfusion Independent Response, n(%)	19 (45.2%)	4 (20.0%)	6 (25.0%)	3 (15.8%)	
Censor					
Subjects Censored, n(%)	23 (54.8%)	16 (80.0%)	18 (75.0%)	16 (84.2%)	
Kaplan-Meier Estimate of Time to RBC Transfusion Independent Response (Weeks)					
25-percentile (95% CI)	12.29 (12.14, 19.29)	NE (12.14, NE)	15.00 (12.14, NE)	NE (12.14, NE)	
Median (95% CI)	22.43 (15.43, NE)	NE (21.86, NE)	NE (12.43, NE)	NE (23.86, NE)	
75-percentile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	
Min, Max	4.14, 26.43	1.86, 25.29	4.00, 26.29	2.86, 25.14	
Stratified Log-Rank Test p-value	0.012		0.44		
Adjusted Inverse Hazard Ratio (95% CI)	0.22 (0.07, 0.72)		0.58 (0.14, 2.33)		
Unstratified Log-Rank Test p-value	0.046		0.46		
Unadjusted Inverse Hazard Ratio (95% CI)	0.35 (0.12, 1.03)		0.60 (0.15, 2.40)		
P-value for interaction test					0.45

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
RBC transfusion independent response is defined as the absence of RBC transfusions and no hemoglobin level below 8 g/dL in the prior 12 weeks.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment and baseline TD (yes,no).
Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no) and treatment by subgroup interaction. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.3902: Analysis of RBC Transfusion Dependence Rate at Week 24 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Not-Dependent, n(%)	9 (37.5%)	3 (33.3%)	18 (42.9%)	8 (26.7%)	
Transfusion Requiring, n(%)	1 (4.2%)	2 (22.2%)	4 (9.5%)	4 (13.3%)	
Transfusion Independent, n(%)	8 (33.3%)	1 (11.1%)	14 (33.3%)	4 (13.3%)	
Dependent, n(%)	15 (62.5%)	6 (66.7%)	24 (57.1%)	22 (73.3%)	
95% Exact CI	0.4059, 0.8120	0.2993, 0.9251	0.4096, 0.7228	0.5411, 0.8772	
Proportion Difference - Stratified CMH Method (95% CI)	0.08 (-0.29, 0.45)		-0.17 (-0.40, 0.07)		
p-value	0.67		0.16		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.04 (-0.43, 0.34)		-0.16 (-0.38, 0.06)		
p-value	0.83		0.15		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.04 (-0.42, 0.34)		-0.16 (-0.39, 0.08)		
p-value	1.00		0.21		
Unadjusted Relative Risk (95% CI)	0.94 (0.54, 1.64)		0.78 (0.55, 1.09)		
p-value [1]	0.82		0.15		
Unadjusted interaction test for Treatment*Age Group [3]					0.57
Unadjusted Odds Ratio (95% CI)	0.83 (0.17, 4.18)		0.48 (0.18, 1.34)		
p-value [1]	0.82		0.16		
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.41, 0.32)		-0.16 (-0.38, 0.06)		
Adjusted Relative Risk (95% CI) [2]	1.13 (0.70, 1.80)		0.78 (0.55, 1.09)		
p-value [2]	0.62		0.14		
Adjusted interaction test for Treatment*Age Group [3]					0.33

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.3902: Analysis of RBC Transfusion Dependence Rate at Week 24 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
>=4 units transfused in the last 8 weeks	5 (20.8%)	3 (33.3%)	9 (21.4%)	12 (40.0%)	
Any Hgb assessment < 8g/dL in the last 8 weeks	6 (25.0%)	3 (33.3%)	13 (31.0%)	12 (40.0%)	
Last Participation date < Day 162 in RT phase	8 (33.3%)	3 (33.3%)	10 (23.8%)	4 (13.3%)	
Other	2 (8.3%)	1 (11.1%)	5 (11.9%)	7 (23.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.3908: Analysis of RBC Transfusion Dependence Rate at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
Not-Dependent, n(%)	18 (40.0%)	5 (21.7%)	5 (38.5%)	3 (37.5%)
Transfusion Requiring, n(%)	3 (6.7%)	3 (13.0%)	0	1 (12.5%)
Transfusion Independent, n(%)	15 (33.3%)	2 (8.7%)	5 (38.5%)	2 (25.0%)
Dependent, n(%)	27 (60.0%)	18 (78.3%)	8 (61.5%)	5 (62.5%)
95% Exact CI	0.4433, 0.7430	0.5630, 0.9254	0.3158, 0.8614	0.2449, 0.9148
Proportion Difference - Stratified CMH Method (95% CI)	-0.16 (-0.40, 0.09)		0.12 (-0.39, 0.63)	
p-value	0.21		0.65	
Proportion Difference - Unstratified CMH Method (95% CI)	-0.18 (-0.41, 0.05)		-0.01 (-0.46, 0.45)	
p-value	0.12		0.97	
Proportion Difference - Unstratified Exact Method (95% CI)	-0.18 (-0.41, 0.08)		-0.01 (-0.43, 0.43)	
p-value	0.18		1.00	
Unadjusted Relative Risk (95% CI)	0.77 (0.56, 1.06)		0.98 (0.50, 1.96)	
p-value [1]	0.11		0.96	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Odds Ratio (95% CI)	0.42 (0.13, 1.32)		0.96 (0.16, 5.90)	
p-value [1]	0.14		0.96	
Unadjusted Absolute Risk Difference (95% CI)	-0.18 (-0.40, 0.04)		-0.01 (-0.44, 0.42)	
Adjusted Relative Risk (95% CI) [2]	0.80 (0.58, 1.09)		NE	
p-value [2]	0.16		NE	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.3908: Analysis of RBC Transfusion Dependence Rate at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=8)	BAT (N=8)	p-value
Not-Dependent, n(%)	4 (50.0%)	3 (37.5%)	
Transfusion Requiring, n(%)	2 (25.0%)	2 (25.0%)	
Transfusion Independent, n(%)	2 (25.0%)	1 (12.5%)	
Dependent, n(%)	4 (50.0%)	5 (62.5%)	
95% Exact CI	0.1570, 0.8430	0.2449, 0.9148	
Proportion Difference - Stratified CMH Method (95% CI)	-0.10 (-0.73, 0.53)		
p-value	0.76		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.13 (-0.64, 0.39)		
p-value	0.64		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.13 (-0.60, 0.40)		
p-value	1.00		
Unadjusted Relative Risk (95% CI)	0.80 (0.33, 1.92)		
p-value [1]	0.62		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.81
Unadjusted Odds Ratio (95% CI)	0.60 (0.08, 4.40)		
p-value [1]	0.62		
Unadjusted Absolute Risk Difference (95% CI)	-0.13 (-0.61, 0.36)		
Adjusted Relative Risk (95% CI) [2]	0.84 (0.31, 2.23)		
p-value [2]	0.72		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.71

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.3908: Analysis of RBC Transfusion Dependence Rate at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
>=4 units transfused in the last 8 weeks	10 (22.2%)	10 (43.5%)	2 (15.4%)	3 (37.5%)
Any Hgb assessment < 8g/dL in the last 8 weeks	14 (31.1%)	9 (39.1%)	3 (23.1%)	3 (37.5%)
Last Participation date < Day 162 in RT phase	12 (26.7%)	4 (17.4%)	4 (30.8%)	2 (25.0%)
Other	6 (13.3%)	5 (21.7%)	1 (7.7%)	1 (12.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.3908: Analysis of RBC Transfusion Dependence Rate at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=8)	BAT (N=8)	p-value
>=4 units transfused in the last 8 weeks	2 (25.0%)	2 (25.0%)	
Any Hgb assessment < 8g/dL in the last 8 weeks	2 (25.0%)	3 (37.5%)	
Last Participation date < Day 162 in RT phase	2 (25.0%)	1 (12.5%)	
Other	0	2 (25.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.3907: Analysis of RBC Transfusion Dependence Rate at Week 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Not-Dependent, n(%)	9 (33.3%)	1 (16.7%)	18 (46.2%)	10 (30.3%)	
Transfusion Requiring, n(%)	1 (3.7%)	1 (16.7%)	4 (10.3%)	5 (15.2%)	
Transfusion Independent, n(%)	8 (29.6%)	0	14 (35.9%)	5 (15.2%)	
Dependent, n(%)	18 (66.7%)	5 (83.3%)	21 (53.8%)	23 (69.7%)	
95% Exact CI	0.4604, 0.8348	0.3588, 0.9958	0.3718, 0.6991	0.5129, 0.8441	
Proportion Difference - Stratified CMH Method (95% CI)	-0.15 (-0.60, 0.30)		-0.12 (-0.36, 0.11)		
p-value	0.51		0.31		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.17 (-0.57, 0.24)		-0.16 (-0.38, 0.07)		
p-value	0.42		0.17		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.17 (-0.64, 0.29)		-0.16 (-0.38, 0.07)		
p-value	0.64		0.23		
Unadjusted Relative Risk (95% CI)	0.80 (0.51, 1.25)		0.77 (0.53, 1.12)		
p-value [1]	0.33		0.17		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.91
Unadjusted Odds Ratio (95% CI)	0.40 (0.04, 3.96)		0.51 (0.19, 1.34)		
p-value [1]	0.43		0.17		
Unadjusted Absolute Risk Difference (95% CI)	-0.17 (-0.51, 0.18)		-0.16 (-0.38, 0.06)		
Adjusted Relative Risk (95% CI) [2]	0.82 (0.53, 1.26)		0.82 (0.57, 1.18)		
p-value [2]	0.35		0.28		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.95

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.3907: Analysis of RBC Transfusion Dependence Rate at Week 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
>=4 units transfused in the last 8 weeks	5 (18.5%)	2 (33.3%)	9 (23.1%)	13 (39.4%)	
Any Hgb assessment < 8g/dL in the last 8 weeks	9 (33.3%)	3 (50.0%)	10 (25.6%)	12 (36.4%)	
Last Participation date < Day 162 in RT phase	8 (29.6%)	2 (33.3%)	10 (25.6%)	5 (15.2%)	
Other	4 (14.8%)	2 (33.3%)	3 (7.7%)	6 (18.2%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.3906: Analysis of RBC Transfusion Dependence Rate at Week 24 by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Not-Dependent, n(%)	23 (46.9%)	10 (32.3%)	4 (23.5%)	1 (12.5%)	
Transfusion Requiring, n(%)	5 (10.2%)	5 (16.1%)	0	1 (12.5%)	
Transfusion Independent, n(%)	18 (36.7%)	5 (16.1%)	4 (23.5%)	0	
Dependent, n(%)	26 (53.1%)	21 (67.7%)	13 (76.5%)	7 (87.5%)	
95% Exact CI	0.3827, 0.6747	0.4863, 0.8332	0.5010, 0.9319	0.4735, 0.9968	
Proportion Difference - Stratified CMH Method (95% CI)	-0.11 (-0.35, 0.13)		-0.07 (-0.42, 0.28)		
p-value	0.37		0.68		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.15 (-0.37, 0.07)		-0.11 (-0.46, 0.24)		
p-value	0.19		0.53		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.15 (-0.36, 0.08)		-0.11 (-0.50, 0.29)		
p-value	0.25		1.00		
Unadjusted Relative Risk (95% CI)	0.78 (0.55, 1.12)		0.87 (0.60, 1.27)		
p-value [1]	0.18		0.48		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					0.68
Unadjusted Odds Ratio (95% CI)	0.54 (0.21, 1.38)		0.46 (0.04, 5.00)		
p-value [1]	0.20		0.53		
Unadjusted Absolute Risk Difference (95% CI)	-0.15 (-0.36, 0.07)		-0.11 (-0.42, 0.19)		
Adjusted Relative Risk (95% CI) [2]	0.84 (0.59, 1.20)		0.92 (0.61, 1.38)		
p-value [2]	0.33		0.67		
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					0.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tf-td-rr-by.sas V.03.05 Output file: t-rbctd24-gba-ip2.pdf 24AUG2023:16:39

Table 2.3906: Analysis of RBC Transfusion Dependence Rate at Week 24 by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
>=4 units transfused in the last 8 weeks	10 (20.4%)	11 (35.5%)	4 (23.5%)	4 (50.0%)	
Any Hgb assessment < 8g/dL in the last 8 weeks	13 (26.5%)	9 (29.0%)	6 (35.3%)	6 (75.0%)	
Last Participation date < Day 162 in RT phase	12 (24.5%)	6 (19.4%)	6 (35.3%)	1 (12.5%)	
Other	3 (6.1%)	6 (19.4%)	4 (23.5%)	2 (25.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.3905: Analysis of RBC Transfusion Dependence Rate at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Not-Dependent, n(%)	2 (40.0%)	2 (28.6%)	21 (47.7%)	8 (33.3%)
Transfusion Requiring, n(%)	0	2 (28.6%)	5 (11.4%)	3 (12.5%)
Transfusion Independent, n(%)	2 (40.0%)	0	16 (36.4%)	5 (20.8%)
Dependent, n(%)	3 (60.0%)	5 (71.4%)	23 (52.3%)	16 (66.7%)
95% Exact CI	0.1466, 0.9473	0.2904, 0.9633	0.3669, 0.6754	0.4468, 0.8437
Proportion Difference - Stratified CMH Method (95% CI)	0.67 (-0.15, 1.48)		-0.08 (-0.37, 0.20)	
p-value	0.11		0.57	
Proportion Difference - Unstratified CMH Method (95% CI)	-0.11 (-0.72, 0.49)		-0.14 (-0.39, 0.10)	
p-value	0.71		0.25	
Proportion Difference - Unstratified Exact Method (95% CI)	-0.11 (-0.64, 0.45)		-0.14 (-0.38, 0.11)	
p-value	1.00		0.31	
Unadjusted Relative Risk (95% CI)	0.84 (0.36, 1.98)		0.78 (0.53, 1.17)	
p-value [1]	0.69		0.23	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Unadjusted Odds Ratio (95% CI)	0.60 (0.05, 6.80)		0.55 (0.19, 1.54)	
p-value [1]	0.68		0.25	
Unadjusted Absolute Risk Difference (95% CI)	-0.11 (-0.66, 0.43)		-0.14 (-0.38, 0.10)	
Adjusted Relative Risk (95% CI) [2]	NE		0.87 (0.57, 1.33)	
p-value [2]	NE		0.52	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.3905: Analysis of RBC Transfusion Dependence Rate at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N=17)	BAT (N=8)	p-value
Not-Dependent, n(%)	4 (23.5%)	1 (12.5%)	
Transfusion Requiring, n(%)	0	1 (12.5%)	
Transfusion Independent, n(%)	4 (23.5%)	0	
Dependent, n(%)	13 (76.5%)	7 (87.5%)	
95% Exact CI	0.5010, 0.9319	0.4735, 0.9968	
Proportion Difference - Stratified CMH Method (95% CI)	-0.07 (-0.42, 0.28)		
p-value	0.68		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.11 (-0.46, 0.24)		
p-value	0.53		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.11 (-0.50, 0.29)		
p-value	1.00		
Unadjusted Relative Risk (95% CI)	0.87 (0.60, 1.27)		
p-value [1]	0.48		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			0.93
Unadjusted Odds Ratio (95% CI)	0.46 (0.04, 5.00)		
p-value [1]	0.53		
Unadjusted Absolute Risk Difference (95% CI)	-0.11 (-0.42, 0.19)		
Adjusted Relative Risk (95% CI) [2]	0.92 (0.61, 1.38)		
p-value [2]	0.67		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			0.90

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.3905: Analysis of RBC Transfusion Dependence Rate at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
>=4 units transfused in the last 8 weeks	2 (40.0%)	3 (42.9%)	8 (18.2%)	8 (33.3%)
Any Hgb assessment < 8g/dL in the last 8 weeks	2 (40.0%)	2 (28.6%)	11 (25.0%)	7 (29.2%)
Last Participation date < Day 162 in RT phase	1 (20.0%)	1 (14.3%)	11 (25.0%)	5 (20.8%)
Other	1 (20.0%)	2 (28.6%)	2 (4.5%)	4 (16.7%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.3905: Analysis of RBC Transfusion Dependence Rate at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N=17)	BAT (N=8)	p-value
>=4 units transfused in the last 8 weeks	4 (23.5%)	4 (50.0%)	
Any Hgb assessment < 8g/dL in the last 8 weeks	6 (35.3%)	6 (75.0%)	
Last Participation date < Day 162 in RT phase	6 (35.3%)	1 (12.5%)	
Other	4 (23.5%)	2 (25.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification. CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.3904: Analysis of RBC Transfusion Dependence Rate at Week 24 by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Not-Dependent, n(%)	12 (41.4%)	3 (42.9%)	15 (40.5%)	8 (25.0%)	
Transfusion Requiring, n(%)	1 (3.4%)	1 (14.3%)	4 (10.8%)	5 (15.6%)	
Transfusion Independent, n(%)	11 (37.9%)	2 (28.6%)	11 (29.7%)	3 (9.4%)	
Dependent, n(%)	17 (58.6%)	4 (57.1%)	22 (59.5%)	24 (75.0%)	
95% Exact CI	0.3894, 0.7648	0.1841, 0.9010	0.4210, 0.7525	0.5660, 0.8854	
Proportion Difference - Stratified CMH Method (95% CI)	-0.03 (-0.50, 0.45)		-0.12 (-0.34, 0.10)		
p-value	0.91		0.30		
Proportion Difference - Unstratified CMH Method (95% CI)	0.01 (-0.42, 0.45)		-0.16 (-0.38, 0.07)		
p-value	0.95		0.17		
Proportion Difference - Unstratified Exact Method (95% CI)	0.01 (-0.40, 0.43)		-0.16 (-0.38, 0.08)		
p-value	1.00		0.21		
Unadjusted Relative Risk (95% CI)	1.03 (0.50, 2.09)		0.79 (0.57, 1.11)		
p-value [1]	0.94		0.17		
Unadjusted interaction test for Treatment*Region [3]					0.50
Unadjusted Odds Ratio (95% CI)	1.06 (0.20, 5.64)		0.49 (0.17, 1.38)		
p-value [1]	0.94		0.18		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.39, 0.42)		-0.16 (-0.37, 0.06)		
Adjusted Relative Risk (95% CI) [2]	0.96 (0.48, 1.89)		0.84 (0.62, 1.14)		
p-value [2]	0.90		0.26		
Adjusted interaction test for Treatment*Region [3]					0.43

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tf-td-rr-by.sas V.03.05 Output file: t-rbctd24-gba-reg.pdf 24AUG2023:16:39

Table 2.3904: Analysis of RBC Transfusion Dependence Rate at Week 24 by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
>=4 units transfused in the last 8 weeks	5 (17.2%)	3 (42.9%)	9 (24.3%)	12 (37.5%)	
Any Hgb assessment < 8g/dL in the last 8 weeks	10 (34.5%)	3 (42.9%)	9 (24.3%)	12 (37.5%)	
Last Participation date < Day 162 in RT phase	6 (20.7%)	1 (14.3%)	12 (32.4%)	6 (18.8%)	
Other	5 (17.2%)	3 (42.9%)	2 (5.4%)	5 (15.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.3903: Analysis of RBC Transfusion Dependence Rate at Week 24 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Not-Dependent, n(%)	20 (38.5%)	4 (22.2%)	7 (50.0%)	7 (33.3%)	
Transfusion Requiring, n(%)	5 (9.6%)	3 (16.7%)	0	3 (14.3%)	
Transfusion Independent, n(%)	15 (28.8%)	1 (5.6%)	7 (50.0%)	4 (19.0%)	
Dependent, n(%)	32 (61.5%)	14 (77.8%)	7 (50.0%)	14 (66.7%)	
95% Exact CI	0.4702, 0.7470	0.5236, 0.9359	0.2304, 0.7696	0.4303, 0.8541	
Proportion Difference - Stratified CMH Method (95% CI)	-0.15 (-0.41, 0.12)		-0.11 (-0.46, 0.24)		
p-value	0.28		0.54		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.16 (-0.40, 0.08)		-0.17 (-0.51, 0.18)		
p-value	0.19		0.34		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.16 (-0.42, 0.11)		-0.17 (-0.49, 0.18)		
p-value	0.26		0.48		
Unadjusted Relative Risk (95% CI)	0.79 (0.57, 1.10)		0.75 (0.41, 1.37)		
p-value [1]	0.16		0.35		
Unadjusted interaction test for Treatment*Gender [3]					0.88
Unadjusted Odds Ratio (95% CI)	0.46 (0.13, 1.59)		0.50 (0.13, 2.00)		
p-value [1]	0.22		0.33		
Unadjusted Absolute Risk Difference (95% CI)	-0.16 (-0.40, 0.07)		-0.17 (-0.50, 0.16)		
Adjusted Relative Risk (95% CI) [2]	0.81 (0.59, 1.11)		0.83 (0.46, 1.51)		
p-value [2]	0.18		0.54		
Adjusted interaction test for Treatment*Gender [3]					0.90

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tf-td-rr-by.sas V.03.05 Output file: t-rbctd24-gba-sex.pdf 24AUG2023:16:39

Table 2.3903: Analysis of RBC Transfusion Dependence Rate at Week 24 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
>=4 units transfused in the last 8 weeks	11 (21.2%)	7 (38.9%)	3 (21.4%)	8 (38.1%)	
Any Hgb assessment < 8g/dL in the last 8 weeks	16 (30.8%)	7 (38.9%)	3 (21.4%)	8 (38.1%)	
Last Participation date < Day 162 in RT phase	14 (26.9%)	4 (22.2%)	4 (28.6%)	3 (14.3%)	
Other	6 (11.5%)	3 (16.7%)	1 (7.1%)	5 (23.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.3910: Analysis of RBC Transfusion Dependence Rate at Week 24 by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median (2329.91 cm^3)		>=Median (2329.91 cm^3)		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Not-Dependent, n(%)	14 (50.0%)	8 (33.3%)	13 (34.2%)	3 (20.0%)	
Transfusion Requiring, n(%)	1 (3.6%)	5 (20.8%)	4 (10.5%)	1 (6.7%)	
Transfusion Independent, n(%)	13 (46.4%)	3 (12.5%)	9 (23.7%)	2 (13.3%)	
Dependent, n(%)	14 (50.0%)	16 (66.7%)	25 (65.8%)	12 (80.0%)	
95% Exact CI	0.3065, 0.6935	0.4468, 0.8437	0.4865, 0.8037	0.5191, 0.9567	
Proportion Difference - Stratified CMH Method (95% CI)	-0.18 (-0.46, 0.11)		-0.14 (-0.46, 0.17)		
p-value	0.22		0.38		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.17 (-0.44, 0.10)		-0.14 (-0.41, 0.12)		
p-value	0.23		0.29		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.17 (-0.43, 0.11)		-0.14 (-0.43, 0.15)		
p-value	0.27		0.51		
Unadjusted Relative Risk (95% CI)	0.75 (0.47, 1.20)		0.82 (0.58, 1.16)		
p-value [1]	0.23		0.26		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.75
Unadjusted Odds Ratio (95% CI)	0.50 (0.16, 1.54)		0.48 (0.11, 2.01)		
p-value [1]	0.23		0.32		
Unadjusted Absolute Risk Difference (95% CI)	-0.17 (-0.43, 0.10)		-0.14 (-0.39, 0.11)		
Adjusted Relative Risk (95% CI) [2]	0.74 (0.47, 1.15)		0.83 (0.60, 1.14)		
p-value [2]	0.18		0.25		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.57

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tf-td-rr-by.sas V.03.05 Output file: t-rbctd24-gba-spv.pdf 24AUG2023:16:40

Table 2.3910: Analysis of RBC Transfusion Dependence Rate at Week 24 by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median (2329.91 cm^3)		>=Median (2329.91 cm^3)		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
>=4 units transfused in the last 8 weeks	4 (14.3%)	10 (41.7%)	10 (26.3%)	5 (33.3%)	
Any Hgb assessment < 8g/dL in the last 8 weeks	8 (28.6%)	12 (50.0%)	11 (28.9%)	3 (20.0%)	
Last Participation date < Day 162 in RT phase	5 (17.9%)	2 (8.3%)	13 (34.2%)	5 (33.3%)	
Other	2 (7.1%)	5 (20.8%)	5 (13.2%)	3 (20.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.3909: Analysis of RBC Transfusion Dependence Rate at Week 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Not-Dependent, n(%)	21 (50.0%)	7 (35.0%)	6 (25.0%)	4 (21.1%)	
Transfusion Requiring, n(%)	3 (7.1%)	5 (25.0%)	2 (8.3%)	1 (5.3%)	
Transfusion Independent, n(%)	18 (42.9%)	2 (10.0%)	4 (16.7%)	3 (15.8%)	
Dependent, n(%)	21 (50.0%)	13 (65.0%)	18 (75.0%)	15 (78.9%)	
95% Exact CI	0.3419, 0.6581	0.4078, 0.8461	0.5329, 0.9023	0.5443, 0.9395	
Proportion Difference - Stratified CMH Method (95% CI)	-0.16 (-0.43, 0.12)		-0.05 (-0.31, 0.21)		
p-value	0.27		0.72		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.15 (-0.41, 0.11)		-0.04 (-0.30, 0.22)		
p-value	0.27		0.77		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.15 (-0.41, 0.12)		-0.04 (-0.33, 0.25)		
p-value	0.29		1.00		
Unadjusted Relative Risk (95% CI)	0.77 (0.49, 1.20)		0.95 (0.68, 1.32)		
p-value [1]	0.24		0.76		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.46
Unadjusted Odds Ratio (95% CI)	0.54 (0.18, 1.62)		0.80 (0.19, 3.37)		
p-value [1]	0.27		0.76		
Unadjusted Absolute Risk Difference (95% CI)	-0.15 (-0.41, 0.11)		-0.04 (-0.29, 0.21)		
Adjusted Relative Risk (95% CI) [2]	0.76 (0.49, 1.19)		0.94 (0.69, 1.29)		
p-value [2]	0.23		0.70		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					0.46

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.3909: Analysis of RBC Transfusion Dependence Rate at Week 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
>=4 units transfused in the last 8 weeks	6 (14.3%)	6 (30.0%)	8 (33.3%)	9 (47.4%)	
Any Hgb assessment < 8g/dL in the last 8 weeks	12 (28.6%)	8 (40.0%)	7 (29.2%)	7 (36.8%)	
Last Participation date < Day 162 in RT phase	9 (21.4%)	3 (15.0%)	9 (37.5%)	4 (21.1%)	
Other	6 (14.3%)	6 (30.0%)	1 (4.2%)	2 (10.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel, RBC = Red Blood Cell.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Data Extracted: CRF data: 25JUN2019

Table 2.2802: Analysis of Time to First RBC Unit Transfused by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Subjects with Event					
First RBC Unit Transfused, n(%)	19 (79.2%)	7 (77.8%)	34 (81.0%)	26 (86.7%)	
Censor					
Subjects Censored, n(%)	5 (20.8%)	2 (22.2%)	8 (19.0%)	4 (13.3%)	
Kaplan-Meier Estimate of Time to First RBC Unit Transfused (Weeks)					
25-percentile (95% CI)	0.86 (0.29, 1.86)	2.00 (0.43, 4.29)	0.57 (0.29, 1.29)	0.86 (0.29, 1.43)	
Median (95% CI)	3.14 (0.86, 6.14)	4.29 (0.43, NE)	2.00 (1.14, 2.71)	2.00 (1.43, 4.00)	
75-percentile (95% CI)	9.57 (4.14, NE)	6.57 (2.57, NE)	6.29 (2.43, NE)	4.86 (2.14, 12.00)	
Min, Max	0.29, 24.86	0.43, 24.86	0.29, 25.14	0.29, 24.29	
Stratified Log-Rank Test p-value	0.84		0.19		
Adjusted Hazard Ratio (95% CI)	1.22 (0.48, 3.12)		0.64 (0.37, 1.13)		
Unstratified Log-Rank Test p-value	0.85		0.76		
Unadjusted Hazard Ratio (95% CI)	1.09 (0.46, 2.60)		0.93 (0.55, 1.55)		
P-value for interaction test					0.40

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-rbc-tran-sub.sas V.03.05 Output file: t-tte-rbc-tran-age.pdf 24AUG2023:16:32

Table 2.2806: Analysis of Time to First RBC Unit Transfused by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Subjects with Event					
First RBC Unit Transfused, n(%)	41 (83.7%)	26 (83.9%)	12 (70.6%)	7 (87.5%)	
Censor					
Subjects Censored, n(%)	8 (16.3%)	5 (16.1%)	5 (29.4%)	1 (12.5%)	
Kaplan-Meier Estimate of Time to First RBC Unit Transfused (Weeks)					
25-percentile (95% CI)	0.57 (0.29, 1.29)	1.29 (0.43, 2.00)	1.00 (0.43, 2.00)	0.57 (0.29, 1.43)	
Median (95% CI)	2.00 (1.14, 3.43)	2.71 (1.71, 4.57)	2.00 (0.71, 6.29)	1.43 (0.29, NE)	
75-percentile (95% CI)	6.14 (3.43, NE)	6.14 (4.00, NE)	NE (2.00, NE)	5.86 (0.86, NE)	
Min, Max	0.29, 25.14	0.29, 24.86	0.43, 24.86	0.29, 9.86	
Stratified Log-Rank Test p-value	0.49		0.21		
Adjusted Hazard Ratio (95% CI)	0.82 (0.48, 1.40)		0.48 (0.16, 1.44)		
Unstratified Log-Rank Test p-value	0.72		0.18		
Unadjusted Hazard Ratio (95% CI)	1.09 (0.67, 1.80)		0.52 (0.20, 1.36)		
P-value for interaction test					0.19

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-rbc-tran-sub.sas V.03.05 Output file: t-tte-rbc-tran-dipss2.pdf 24AUG2023:16:32

Table 2.2805: Analysis of Time to First RBC Unit Transfused by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Subjects with Event				
First RBC Unit Transfused, n(%)	3 (60.0%)	7 (100.0%)	38 (86.4%)	19 (79.2%)
Censor				
Subjects Censored, n(%)	2 (40.0%)	0	6 (13.6%)	5 (20.8%)
Kaplan-Meier Estimate of Time to First RBC Unit Transfused (Weeks)				
25-percentile (95% CI)	4.14 (2.00, NE)	0.43 (0.29, 2.57)	0.57 (0.29, 1.00)	1.36 (0.43, 2.00)
Median (95% CI)	9.00 (2.00, NE)	2.57 (0.29, 4.29)	1.86 (0.86, 2.71)	2.71 (1.43, 6.14)
75-percentile (95% CI)	NE (2.00, NE)	4.29 (2.00, NE)	6.07 (2.43, NE)	9.29 (4.57, NE)
Min, Max	2.00, 23.86	0.29, 4.57	0.29, 25.14	0.43, 24.86
Stratified Log-Rank Test p-value	0.53		0.94	
Adjusted Hazard Ratio (95% CI)	0.52 (0.08, 3.20)		0.97 (0.51, 1.85)	
Unstratified Log-Rank Test p-value	0.040		0.25	
Unadjusted Hazard Ratio (95% CI)	0.22 (0.04, 1.08)		1.38 (0.79, 2.40)	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-rbc-tran-sub.sas V.03.05 Output file: t-tte-rbc-tran-dipss3.pdf 24AUG2023:16:32

Table 2.2805: Analysis of Time to First RBC Unit Transfused by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	High Risk MMB (N=17)	High Risk BAT (N=8)	p-value
Subjects with Event			
First RBC Unit Transfused, n(%)	12 (70.6%)	7 (87.5%)	
Censor			
Subjects Censored, n(%)	5 (29.4%)	1 (12.5%)	
Kaplan-Meier Estimate of Time to First RBC Unit Transfused (Weeks)			
25-percentile (95% CI)	1.00 (0.43, 2.00)	0.57 (0.29, 1.43)	
Median (95% CI)	2.00 (0.71, 6.29)	1.43 (0.29, NE)	
75-percentile (95% CI)	NE (2.00, NE)	5.86 (0.86, NE)	
Min, Max	0.43, 24.86	0.29, 9.86	
Stratified Log-Rank Test p-value	0.21		
Adjusted Hazard Ratio (95% CI)	0.48 (0.16, 1.44)		
Unstratified Log-Rank Test p-value	0.18		
Unadjusted Hazard Ratio (95% CI)	0.52 (0.20, 1.36)		
P-value for interaction test			0.27

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-rbc-tran-sub.sas V.03.05 Output file: t-tte-rbc-tran-dipss3.pdf 24AUG2023:16:32

Table 2.2804: Analysis of Time to First RBC Unit Transfused by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Subjects with Event					
First RBC Unit Transfused, n(%)	20 (69.0%)	4 (57.1%)	33 (89.2%)	29 (90.6%)	
Censor					
Subjects Censored, n(%)	9 (31.0%)	3 (42.9%)	4 (10.8%)	3 (9.4%)	
Kaplan-Meier Estimate of Time to First RBC Unit Transfused (Weeks)					
25-percentile (95% CI)	0.86 (0.29, 1.43)	1.43 (0.29, 4.29)	0.57 (0.29, 1.43)	0.86 (0.43, 1.71)	
Median (95% CI)	2.71 (1.00, 7.14)	4.29 (0.29, NE)	2.00 (1.00, 2.71)	2.00 (1.29, 4.57)	
75-percentile (95% CI)	NE (4.14, NE)	NE (2.57, NE)	5.86 (2.14, NE)	5.50 (2.71, 12.00)	
Min, Max	0.29, 24.14	0.29, 24.14	0.29, 25.14	0.29, 24.86	
Stratified Log-Rank Test p-value	0.81		0.62		
Adjusted Hazard Ratio (95% CI)	0.89 (0.29, 2.72)		0.83 (0.48, 1.42)		
Unstratified Log-Rank Test p-value	0.67		0.95		
Unadjusted Hazard Ratio (95% CI)	1.26 (0.43, 3.70)		1.01 (0.61, 1.68)		
P-value for interaction test					0.77

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-rbc-tran-sub.sas V.03.05 Output file: t-tte-rbc-tran-geo.pdf 24AUG2023:16:32

Table 2.2807: Analysis of Time to First RBC Unit Transfused by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Subjects with Event					
First RBC Unit Transfused, n(%)	25 (92.6%)	6 (100.0%)	28 (71.8%)	27 (81.8%)	
Censor					
Subjects Censored, n(%)	2 (7.4%)	0	11 (28.2%)	6 (18.2%)	
Kaplan-Meier Estimate of Time to First RBC Unit Transfused (Weeks)					
25-percentile (95% CI)	0.57 (0.29, 1.14)	0.43 (0.29, 1.43)	0.86 (0.29, 1.86)	1.43 (0.43, 2.00)	
Median (95% CI)	1.43 (0.71, 2.29)	1.36 (0.29, NE)	4.14 (1.43, 7.14)	2.71 (1.71, 4.86)	
75-percentile (95% CI)	2.71 (1.86, 9.00)	2.00 (0.43, NE)	25.14 (6.00, NE)	6.57 (4.00, NE)	
Min, Max	0.29, 23.57	0.29, 4.29	0.29, 25.14	0.29, 24.86	
Stratified Log-Rank Test p-value	0.23		0.20		
Adjusted Hazard Ratio (95% CI)	0.66 (0.26, 1.68)		0.66 (0.37, 1.18)		
Unstratified Log-Rank Test p-value	0.44		0.38		
Unadjusted Hazard Ratio (95% CI)	0.70 (0.28, 1.73)		0.79 (0.46, 1.35)		
P-value for interaction test					0.88

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.2808: Analysis of Time to First RBC Unit Transfused by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-ET Myelofibrosis		Post-PV Myelofibrosis	
	MMB (N=13)	BAT (N=8)	MMB (N=8)	BAT (N=8)
Subjects with Event				
First RBC Unit Transfused, n(%)	11 (84.6%)	5 (62.5%)	6 (75.0%)	7 (87.5%)
Censor				
Subjects Censored, n(%)	2 (15.4%)	3 (37.5%)	2 (25.0%)	1 (12.5%)
Kaplan-Meier Estimate of Time to First RBC Unit Transfused (Weeks)				
25-percentile (95% CI)	0.43 (0.29, 0.57)	2.21 (1.43, 6.57)	1.79 (0.29, 2.71)	1.64 (0.71, 4.57)
Median (95% CI)	0.57 (0.29, 2.14)	2.71 (1.43, NE)	2.57 (0.29, NE)	3.36 (0.71, 9.86)
75-percentile (95% CI)	2.14 (0.57, NE)	NE (2.71, NE)	NE (2.14, NE)	8.00 (2.00, NE)
Min, Max	0.29, 24.29	1.43, 24.14	0.29, 24.14	0.71, 24.86
Stratified Log-Rank Test p-value	0.14		0.44	
Adjusted Hazard Ratio (95% CI)	2.37 (0.68, 8.29)		0.37 (0.09, 1.57)	
Unstratified Log-Rank Test p-value	0.097		0.60	
Unadjusted Hazard Ratio (95% CI)	2.40 (0.83, 6.97)		0.74 (0.25, 2.25)	
P-value for interaction test				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-rbc-tran-sub.sas V.03.05 Output file: t-tte-rbc-tran-mf.pdf 24AUG2023:16:33

Table 2.2808: Analysis of Time to First RBC Unit Transfused by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	Primary Myelofibrosis MMB (N=45)	Primary Myelofibrosis BAT (N=23)	p-value
Subjects with Event			
First RBC Unit Transfused, n(%)	36 (80.0%)	21 (91.3%)	
Censor			
Subjects Censored, n(%)	9 (20.0%)	2 (8.7%)	
Kaplan-Meier Estimate of Time to First RBC Unit Transfused (Weeks)			
25-percentile (95% CI)	1.00 (0.43, 1.43)	0.71 (0.29, 1.43)	
Median (95% CI)	2.00 (1.29, 5.86)	1.86 (0.86, 4.00)	
75-percentile (95% CI)	7.14 (4.14, NE)	4.57 (2.00, 12.00)	
Min, Max	0.29, 25.14	0.29, 24.29	
Stratified Log-Rank Test p-value	0.12		
Adjusted Hazard Ratio (95% CI)	0.61 (0.35, 1.07)		
Unstratified Log-Rank Test p-value	0.19		
Unadjusted Hazard Ratio (95% CI)	0.69 (0.40, 1.20)		
P-value for interaction test			0.088

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-rbc-tran-sub.sas V.03.05 Output file: t-tte-rbc-tran-mf.pdf 24AUG2023:16:33

Table 2.2803: Analysis of Time to First RBC Unit Transfused by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Subjects with Event					
First RBC Unit Transfused, n(%)	42 (80.8%)	16 (88.9%)	11 (78.6%)	17 (81.0%)	
Censor					
Subjects Censored, n(%)	10 (19.2%)	2 (11.1%)	3 (21.4%)	4 (19.0%)	
Kaplan-Meier Estimate of Time to First RBC Unit Transfused (Weeks)					
25-percentile (95% CI)	0.79 (0.43, 1.43)	1.43 (0.29, 1.86)	0.57 (0.29, 1.29)	0.86 (0.29, 2.00)	
Median (95% CI)	2.00 (1.43, 4.14)	2.00 (1.43, 4.57)	1.71 (0.29, 6.00)	2.57 (0.86, 6.14)	
75-percentile (95% CI)	7.14 (4.14, NE)	4.57 (2.00, 12.00)	6.00 (1.29, NE)	6.57 (2.71, NE)	
Min, Max	0.29, 25.14	0.29, 24.29	0.29, 24.00	0.29, 24.86	
Stratified Log-Rank Test p-value	0.35		0.25		
Adjusted Hazard Ratio (95% CI)	0.72 (0.40, 1.31)		0.56 (0.23, 1.37)		
Unstratified Log-Rank Test p-value	0.46		0.75		
Unadjusted Hazard Ratio (95% CI)	0.80 (0.45, 1.42)		1.15 (0.54, 2.45)		
P-value for interaction test					0.98

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.2810: Analysis of Time to First RBC Unit Transfused by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Subjects with Event					
First RBC Unit Transfused, n(%)	22 (78.6%)	20 (83.3%)	31 (81.6%)	13 (86.7%)	
Censor					
Subjects Censored, n(%)	6 (21.4%)	4 (16.7%)	7 (18.4%)	2 (13.3%)	
Kaplan-Meier Estimate of Time to First RBC Unit Transfused (Weeks)					
25-percentile (95% CI)	0.50 (0.29, 1.29)	1.14 (0.29, 2.00)	1.00 (0.43, 1.43)	0.86 (0.43, 1.71)	
Median (95% CI)	2.07 (0.57, 3.43)	2.57 (1.43, 4.86)	2.00 (1.14, 5.86)	1.86 (0.71, 4.57)	
75-percentile (95% CI)	6.21 (2.14, NE)	6.14 (2.71, NE)	9.00 (4.14, NE)	6.14 (1.86, NE)	
Min, Max	0.29, 24.29	0.29, 24.86	0.29, 25.14	0.43, 24.14	
Stratified Log-Rank Test p-value	0.51		0.25		
Adjusted Hazard Ratio (95% CI)	0.80 (0.42, 1.52)		0.61 (0.30, 1.26)		
Unstratified Log-Rank Test p-value	0.95		0.64		
Unadjusted Hazard Ratio (95% CI)	1.02 (0.56, 1.88)		0.86 (0.45, 1.64)		
P-value for interaction test					0.65

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no) and baseline TSS (<18,>=18).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment, baseline TD (yes,no) and baseline TSS (<18,>=18). Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no), baseline TSS (<18,>=18) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-tte-rbc-tran-sub.sas V.03.05 Output file: t-tte-rbc-tran-svb.pdf 24AUG2023:16:33

Table 2.2809: Analysis of Time to First RBC Unit Transfused by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Subjects with Event					
First RBC Unit Transfused, n(%)	33 (78.6%)	17 (85.0%)	20 (83.3%)	16 (84.2%)	
Censor					
Subjects Censored, n(%)	9 (21.4%)	3 (15.0%)	4 (16.7%)	3 (15.8%)	
Kaplan-Meier Estimate of Time to First RBC Unit Transfused (Weeks)					
25-percentile (95% CI)	0.71 (0.29, 1.29)	1.57 (0.71, 2.00)	0.57 (0.29, 1.43)	0.43 (0.29, 1.43)	
Median (95% CI)	2.21 (1.14, 5.86)	2.00 (1.43, 4.29)	1.93 (0.57, 2.71)	2.57 (0.43, 6.14)	
75-percentile (95% CI)	9.00 (4.14, NE)	4.57 (2.14, NE)	6.00 (2.00, NE)	6.57 (2.57, NE)	
Min, Max	0.29, 24.86	0.71, 24.86	0.29, 25.14	0.29, 24.14	
Stratified Log-Rank Test p-value	0.32		0.59		
Adjusted Hazard Ratio (95% CI)	0.71 (0.38, 1.32)		0.78 (0.38, 1.59)		
Unstratified Log-Rank Test p-value	0.66		0.94		
Unadjusted Hazard Ratio (95% CI)	0.88 (0.49, 1.58)		1.03 (0.53, 2.02)		
P-value for interaction test					0.87

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratified two-sided p-value is from a log-rank test comparing treatment stratified by baseline TD (yes,no).
Adjusted hazard ratio and 95% CI are from a Cox proportional hazards model with covariates of treatment and baseline TD (yes,no).
Unstratified two-sided p-value is from a log-rank test comparing treatment.
Unadjusted hazard ratio and 95% CI are from a Cox proportional hazards model with a covariate of treatment.
P-value for interaction test is from a Cox proportional hazards model with covariates of treatment, subgroup, baseline TD (yes,no) and treatment by subgroup interaction. NE = Not estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.7802: Analysis of Patient Global Impression of Change at Week 24 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	BAT (N = 9)	MMB (N = 42)	BAT (N = 30)	p-value
Week 24 at Randomized Treatment Phase, n(%)					
Improvement, n(%)	10 (41.7%)	1 (11.1%)	25 (59.5%)	9 (30.0%)	
Very much improved	0	0	6 (14.3%)	0	
Much improved	5 (20.8%)	0	14 (33.3%)	2 (6.7%)	
Minimally improved	5 (20.8%)	1 (11.1%)	5 (11.9%)	7 (23.3%)	
95% Exact CI	0.2211, 0.6336	0.0028, 0.4825	0.4328, 0.7437	0.1473, 0.4940	
Proportion Difference - Stratified CMH Method (95% CI)	0.24 (-0.13, 0.60)		0.29 (0.04, 0.53)		
p-value	0.21		0.021		
Proportion Difference - Unstratified CMH Method (95% CI)	0.31 (-0.01, 0.62)		0.30 (0.07, 0.52)		
p-value	0.061		0.010		
Proportion Difference - Unstratified Exact Method (95% CI)	0.31 (-0.08, 0.64)		0.30 (0.06, 0.51)		
p-value	0.21		0.017		
Unadjusted Inverse Relative Risk (95% CI)	0.27 (0.04, 1.80)		0.50 (0.28, 0.92)		
p-value [1]	0.17		0.025		
Unadjusted interaction test for Treatment*Age Group [3]					0.46
Unadjusted Inverse Odds Ratio (95% CI)	0.18 (0.02, 1.63)		0.29 (0.11, 0.79)		
p-value [1]	0.13		0.015		
Unadjusted Absolute Risk Difference (95% CI)	0.31 (0.02, 0.59)		0.30 (0.07, 0.52)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.34 (0.07, 1.76)		0.51 (0.28, 0.93)		
p-value [2]	0.20		0.029		
Adjusted interaction test for Treatment*Age Group [3]					0.58

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7802: Analysis of Patient Global Impression of Change at Week 24 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	BAT (N = 9)	MMB (N = 42)	BAT (N = 30)	p-value
Worsening, n(%)	1 (4.2%)	2 (22.2%)	2 (4.8%)	6 (20.0%)	
Minimally worse	1 (4.2%)	1 (11.1%)	2 (4.8%)	3 (10.0%)	
Much worse	0	1 (11.1%)	0	2 (6.7%)	
Very much worse	0	0	0	1 (3.3%)	
95% Exact CI	0.0011, 0.2112	0.0281, 0.6001	0.0058, 0.1616	0.0771, 0.3857	
Proportion Difference - Stratified CMH Method (95% CI)	-0.08 (-0.45, 0.28)		-0.13 (-0.31, 0.06)		
p-value	0.65		0.17		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.18 (-0.50, 0.13)		-0.15 (-0.32, 0.01)		
p-value	0.26		0.070		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.18 (-0.54, 0.21)		-0.15 (-0.38, 0.08)		
p-value	0.17		0.060		
Unadjusted Relative Risk (95% CI)	0.19 (0.02, 1.82)		0.24 (0.05, 1.10)		
p-value [1]	0.15		0.066		
Unadjusted interaction test for Treatment*Age Group [3]					NA
Unadjusted Odds Ratio (95% CI)	0.15 (0.01, 1.94)		0.20 (0.04, 1.07)		
p-value [1]	0.15		0.060		
Unadjusted Absolute Risk Difference (95% CI)	-0.18 (-0.46, 0.10)		-0.15 (-0.31, 0.00)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Age Group [3]					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7802: Analysis of Patient Global Impression of Change at Week 24 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	BAT (N = 9)	MMB (N = 42)	BAT (N = 30)	p-value
Missing Assessment	12 (50.0%)	4 (44.4%)	12 (28.6%)	7 (23.3%)	
No change	1 (4.2%)	2 (22.2%)	3 (7.1%)	8 (26.7%)	
Return Rate (%)	50%	56%	71%	77%	
Number of Subjects in Risk	16	5	32	25	
Return Rate in Risk (%)	75%	100%	94%	92%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7804: Analysis of Patient Global Impression of Change at Week 24 by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N = 29)	BAT (N = 7)	MMB (N = 37)	BAT (N = 32)	p-value
Week 24 at Randomized Treatment Phase, n(%)					
Improvement, n(%)	18 (62.1%)	1 (14.3%)	17 (45.9%)	9 (28.1%)	
Very much improved	5 (17.2%)	0	1 (2.7%)	0	
Much improved	10 (34.5%)	1 (14.3%)	9 (24.3%)	1 (3.1%)	
Minimally improved	3 (10.3%)	0	7 (18.9%)	8 (25.0%)	
95% Exact CI	0.4226, 0.7931	0.0036, 0.5787	0.2949, 0.6308	0.1375, 0.4675	
Proportion Difference - Stratified CMH Method (95% CI)	0.54 (0.11, 0.98)		0.14 (-0.08, 0.36)		
p-value	0.014		0.22		
Proportion Difference - Unstratified CMH Method (95% CI)	0.48 (0.12, 0.84)		0.18 (-0.05, 0.41)		
p-value	0.009		0.13		
Proportion Difference - Unstratified Exact Method (95% CI)	0.48 (0.06, 0.82)		0.18 (-0.06, 0.40)		
p-value	0.037		0.14		
Unadjusted Inverse Relative Risk (95% CI)	0.23 (0.04, 1.44)		0.61 (0.32, 1.18)		
p-value [1]	0.12		0.14		
Unadjusted interaction test for Treatment*Region [3]					0.22
Unadjusted Inverse Odds Ratio (95% CI)	0.10 (0.01, 0.96)		0.46 (0.17, 1.26)		
p-value [1]	0.046		0.13		
Unadjusted Absolute Risk Difference (95% CI)	0.48 (0.16, 0.79)		0.18 (-0.05, 0.40)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.20 (0.04, 1.11)		NE		
p-value [2]	0.066		NE		
Adjusted interaction test for Treatment*Region [3]					0.32

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.7804: Analysis of Patient Global Impression of Change at Week 24 by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N = 29)	BAT (N = 7)	MMB (N = 37)	BAT (N = 32)	p-value
Worsening, n(%)	0	2 (28.6%)	3 (8.1%)	6 (18.8%)	
Minimally worse	0	0	3 (8.1%)	4 (12.5%)	
Much worse	0	2 (28.6%)	0	1 (3.1%)	
Very much worse	0	0	0	1 (3.1%)	
95% Exact CI	0.0000, 0.1194	0.0367, 0.7096	0.0170, 0.2191	0.0721, 0.3644	
Proportion Difference - Stratified CMH Method (95% CI)	-0.29 (-0.66, 0.08)		-0.09 (-0.27, 0.09)		
p-value	0.12		0.32		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.29 (-0.66, 0.09)		-0.11 (-0.28, 0.06)		
p-value	0.13		0.22		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.29 (-0.71, 0.13)		-0.11 (-0.33, 0.13)		
p-value	0.033		0.29		
Unadjusted Relative Risk (95% CI)	0.05 (0.00, 1.00)		0.43 (0.12, 1.59)		
p-value [1]	0.050		0.21		
Unadjusted interaction test for Treatment*Region [3]					NA
Unadjusted Odds Ratio (95% CI)	0.04 (0.00, 0.89)		0.38 (0.09, 1.67)		
p-value [1]	0.042		0.20		
Unadjusted Absolute Risk Difference (95% CI)	-0.30 (-0.62, 0.03)		-0.11 (-0.27, 0.05)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Region [3]					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.7804: Analysis of Patient Global Impression of Change at Week 24 by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N = 29)	BAT (N = 7)	MMB (N = 37)	BAT (N = 32)	p-value
Missing Assessment	10 (34.5%)	3 (42.9%)	14 (37.8%)	8 (25.0%)	
No change	1 (3.4%)	1 (14.3%)	3 (8.1%)	9 (28.1%)	
Return Rate (%)	66%	57%	62%	75%	
Number of Subjects in Risk	23	5	25	25	
Return Rate in Risk (%)	83%	80%	92%	96%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.7807: Analysis of Patient Global Impression of Change at Week 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 27)	BAT (N = 6)	MMB (N = 39)	BAT (N = 33)	p-value
Week 24 at Randomized Treatment Phase, n(%)					
Improvement, n(%)	13 (48.1%)	0	22 (56.4%)	10 (30.3%)	
Very much improved	2 (7.4%)	0	4 (10.3%)	0	
Much improved	8 (29.6%)	0	11 (28.2%)	2 (6.1%)	
Minimally improved	3 (11.1%)	0	7 (17.9%)	8 (24.2%)	
95% Exact CI	0.2867, 0.6805	0.0000, 0.4593	0.3962, 0.7219	0.1559, 0.4871	
Proportion Difference - Stratified CMH Method (95% CI)	0.49 (0.11, 0.87)		0.21 (-0.02, 0.44)		
p-value	0.012		0.076		
Proportion Difference - Unstratified CMH Method (95% CI)	0.48 (0.19, 0.78)		0.26 (0.04, 0.49)		
p-value	0.001		0.023		
Proportion Difference - Unstratified Exact Method (95% CI)	0.48 (0.03, 0.83)		0.26 (0.03, 0.47)		
p-value	0.060		0.034		
Unadjusted Inverse Relative Risk (95% CI)	0.15 (0.01, 2.20)		0.54 (0.30, 0.97)		
p-value [1]	0.17		0.038		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE
Unadjusted Inverse Odds Ratio (95% CI)	0.08 (0.00, 1.61)		0.34 (0.13, 0.89)		
p-value [1]	0.100		0.028		
Unadjusted Absolute Risk Difference (95% CI)	0.41 (0.14, 0.68)		0.26 (0.04, 0.48)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.61 (0.35, 1.06)		
p-value [2]	NE		0.080		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-chg-pgic.sas V.03.05 Output file: t-subgrp-chg-pgic-rt-gba-hgb.pdf 24AUG2023:16:59

Table 2.7807: Analysis of Patient Global Impression of Change at Week 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 27)	BAT (N = 6)	MMB (N = 39)	BAT (N = 33)	p-value
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.7807: Analysis of Patient Global Impression of Change at Week 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 27)	BAT (N = 6)	MMB (N = 39)	BAT (N = 33)	p-value
Worsening, n(%)	0	0	3 (7.7%)	8 (24.2%)	
Minimally worse	0	0	3 (7.7%)	4 (12.1%)	
Much worse	0	0	0	3 (9.1%)	
Very much worse	0	0	0	1 (3.0%)	
95% Exact CI	0.0000, 0.1277	0.0000, 0.4593	0.0162, 0.2087	0.1109, 0.4226	
Proportion Difference - Stratified CMH Method (95% CI)	0.00 (-0.33, 0.33)		-0.13 (-0.31, 0.05)		
p-value	1.00		0.16		
Proportion Difference - Unstratified CMH Method (95% CI)	0.00 (-0.23, 0.23)		-0.17 (-0.34, 0.01)		
p-value	1.00		0.064		
Proportion Difference - Unstratified Exact Method (95% CI)	NE		-0.17 (-0.39, 0.07)		
p-value	NE		0.097		
Unadjusted Relative Risk (95% CI)	NA		0.32 (0.09, 1.10)		
p-value [1]	NA		0.070		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE
Unadjusted Odds Ratio (95% CI)	NA		0.26 (0.06, 1.08)		
p-value [1]	NA		0.064		
Unadjusted Absolute Risk Difference (95% CI)	NA		-0.17 (-0.33, 0.00)		
Adjusted Relative Risk (95% CI) [2]	NA		NE		
p-value [2]	NA		NE		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.7807: Analysis of Patient Global Impression of Change at Week 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 27)	BAT (N = 6)	MMB (N = 39)	BAT (N = 33)	p-value
Missing Assessment	11 (40.7%)	4 (66.7%)	13 (33.3%)	7 (21.2%)	
No change	3 (11.1%)	2 (33.3%)	1 (2.6%)	8 (24.2%)	
Return Rate (%)	59%	33%	67%	79%	
Number of Subjects in Risk	19	3	29	27	
Return Rate in Risk (%)	84%	67%	90%	96%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.7806: Analysis of Patient Global Impression of Change at Week 24 by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 49)	BAT (N = 31)	MMB (N = 17)	BAT (N = 8)	p-value
Week 24 at Randomized Treatment Phase, n(%)					
Improvement, n(%)	28 (57.1%)	9 (29.0%)	7 (41.2%)	1 (12.5%)	
Very much improved	4 (8.2%)	0	2 (11.8%)	0	
Much improved	15 (30.6%)	1 (3.2%)	4 (23.5%)	1 (12.5%)	
Minimally improved	9 (18.4%)	8 (25.8%)	1 (5.9%)	0	
95% Exact CI	0.4221, 0.7118	0.1422, 0.4804	0.1844, 0.6708	0.0032, 0.5265	
Proportion Difference - Stratified CMH Method (95% CI)	0.26 (0.03, 0.49)		0.32 (-0.09, 0.73)		
p-value	0.025		0.12		
Proportion Difference - Unstratified CMH Method (95% CI)	0.28 (0.07, 0.50)		0.29 (-0.08, 0.65)		
p-value	0.010		0.13		
Proportion Difference - Unstratified Exact Method (95% CI)	0.28 (0.06, 0.48)		0.29 (-0.13, 0.65)		
p-value	0.021		0.21		
Unadjusted Inverse Relative Risk (95% CI)	0.51 (0.28, 0.93)		0.30 (0.04, 2.07)		
p-value [1]	0.027		0.22		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					0.56
Unadjusted Inverse Odds Ratio (95% CI)	0.31 (0.12, 0.80)		0.20 (0.02, 2.05)		
p-value [1]	0.016		0.18		
Unadjusted Absolute Risk Difference (95% CI)	0.28 (0.07, 0.49)		0.29 (-0.04, 0.61)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.53 (0.29, 0.94)		0.28 (0.04, 1.79)		
p-value [2]	0.031		0.18		
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					0.55

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7806: Analysis of Patient Global Impression of Change at Week 24 by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 49)	BAT (N = 31)	MMB (N = 17)	BAT (N = 8)	p-value
Worsening, n(%)	2 (4.1%)	5 (16.1%)	1 (5.9%)	3 (37.5%)	
Minimally worse	2 (4.1%)	3 (9.7%)	1 (5.9%)	1 (12.5%)	
Much worse	0	2 (6.5%)	0	1 (12.5%)	
Very much worse	0	0	0	1 (12.5%)	
95% Exact CI	0.0050, 0.1398	0.0545, 0.3373	0.0015, 0.2869	0.0852, 0.7551	
Proportion Difference - Stratified CMH Method (95% CI)	-0.10 (-0.27, 0.06)		-0.33 (-0.73, 0.07)		
p-value	0.20		0.11		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.12 (-0.27, 0.03)		-0.32 (-0.70, 0.07)		
p-value	0.11		0.11		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.12 (-0.34, 0.10)		-0.32 (-0.68, 0.11)		
p-value	0.10		0.081		
Unadjusted Relative Risk (95% CI)	0.25 (0.05, 1.22)		0.16 (0.02, 1.28)		
p-value [1]	0.088		0.084		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Unadjusted Odds Ratio (95% CI)	0.22 (0.04, 1.22)		0.10 (0.01, 1.24)		
p-value [1]	0.084		0.073		
Unadjusted Absolute Risk Difference (95% CI)	-0.12 (-0.26, 0.02)		-0.32 (-0.67, 0.04)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7806: Analysis of Patient Global Impression of Change at Week 24 by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 49)	BAT (N = 31)	MMB (N = 17)	BAT (N = 8)	p-value
Missing Assessment	17 (34.7%)	8 (25.8%)	7 (41.2%)	3 (37.5%)	
No change	2 (4.1%)	9 (29.0%)	2 (11.8%)	1 (12.5%)	
Return Rate (%)	65%	74%	59%	63%	
Number of Subjects in Risk	37	24	11	6	
Return Rate in Risk (%)	86%	96%	91%	83%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7805: Analysis of Patient Global Impression of Change at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 5)	BAT (N = 7)	MMB (N = 44)	BAT (N = 24)
Week 24 at Randomized Treatment Phase, n(%)				
Improvement, n(%)	4 (80.0%)	2 (28.6%)	24 (54.5%)	7 (29.2%)
Very much improved	0	0	4 (9.1%)	0
Much improved	2 (40.0%)	0	13 (29.5%)	1 (4.2%)
Minimally improved	2 (40.0%)	2 (28.6%)	7 (15.9%)	6 (25.0%)
95% Exact CI	0.2836, 0.9949	0.0367, 0.7096	0.3885, 0.6961	0.1262, 0.5109
Proportion Difference - Stratified CMH Method (95% CI)	0.33 (-0.62, 1.28)		0.23 (-0.03, 0.50)	
p-value	0.49		0.082	
Proportion Difference - Unstratified CMH Method (95% CI)	0.51 (-0.05, 1.08)		0.25 (0.01, 0.49)	
p-value	0.074		0.038	
Proportion Difference - Unstratified Exact Method (95% CI)	0.51 (-0.10, 0.88)		0.25 (0.00, 0.48)	
p-value	0.24		0.074	
Unadjusted Inverse Relative Risk (95% CI)	0.36 (0.10, 1.25)		0.53 (0.27, 1.05)	
p-value [1]	0.11		0.071	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	0.10 (0.01, 1.54)		0.34 (0.12, 0.99)	
p-value [1]	0.099		0.048	
Unadjusted Absolute Risk Difference (95% CI)	0.51 (0.03, 1.00)		0.25 (0.02, 0.49)	
Adjusted Inverse Relative Risk (95% CI) [2]	0.50 (0.08, 2.99)		0.56 (0.30, 1.06)	
p-value [2]	0.45		0.074	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7805: Analysis of Patient Global Impression of Change at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 17)	BAT (N = 8)	p-value
Week 24 at Randomized Treatment Phase, n(%)			
Improvement, n(%)	7 (41.2%)	1 (12.5%)	
Very much improved	2 (11.8%)	0	
Much improved	4 (23.5%)	1 (12.5%)	
Minimally improved	1 (5.9%)	0	
95% Exact CI	0.1844, 0.6708	0.0032, 0.5265	
Proportion Difference - Stratified CMH Method (95% CI)	0.32 (-0.09, 0.73)		
p-value	0.12		
Proportion Difference - Unstratified CMH Method (95% CI)	0.29 (-0.08, 0.65)		
p-value	0.13		
Proportion Difference - Unstratified Exact Method (95% CI)	0.29 (-0.13, 0.65)		
p-value	0.21		
Unadjusted Inverse Relative Risk (95% CI)	0.30 (0.04, 2.07)		
p-value [1]	0.22		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			0.75
Unadjusted Inverse Odds Ratio (95% CI)	0.20 (0.02, 2.05)		
p-value [1]	0.18		
Unadjusted Absolute Risk Difference (95% CI)	0.29 (-0.04, 0.61)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.28 (0.04, 1.79)		
p-value [2]	0.18		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			0.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7805: Analysis of Patient Global Impression of Change at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 5)	BAT (N = 7)	MMB (N = 44)	BAT (N = 24)
Worsening, n(%)	0	2 (28.6%)	2 (4.5%)	3 (12.5%)
Minimally worse	0	1 (14.3%)	2 (4.5%)	2 (8.3%)
Much worse	0	1 (14.3%)	0	1 (4.2%)
Very much worse	0	0	0	0
95% Exact CI	0.0000, 0.5218	0.0367, 0.7096	0.0056, 0.1547	0.0266, 0.3236
Proportion Difference - Stratified CMH Method (95% CI)	0.00 (-0.65, 0.65)		-0.07 (-0.27, 0.14)	
p-value	1.00		0.51	
Proportion Difference - Unstratified CMH Method (95% CI)	-0.29 (-0.74, 0.17)		-0.08 (-0.24, 0.08)	
p-value	0.22		0.32	
Proportion Difference - Unstratified Exact Method (95% CI)	-0.29 (-0.74, 0.30)		-0.08 (-0.32, 0.17)	
p-value	0.47		0.34	
Unadjusted Relative Risk (95% CI)	0.27 (0.02, 4.59)		0.36 (0.07, 2.03)	
p-value [1]	0.36		0.25	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Unadjusted Odds Ratio (95% CI)	0.20 (0.01, 5.20)		0.33 (0.05, 2.15)	
p-value [1]	0.33		0.25	
Unadjusted Absolute Risk Difference (95% CI)	-0.23 (-0.62, 0.16)		-0.08 (-0.23, 0.07)	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7805: Analysis of Patient Global Impression of Change at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 17)	BAT (N = 8)	p-value
Worsening, n(%)	1 (5.9%)	3 (37.5%)	
Minimally worse	1 (5.9%)	1 (12.5%)	
Much worse	0	1 (12.5%)	
Very much worse	0	1 (12.5%)	
95% Exact CI	0.0015, 0.2869	0.0852, 0.7551	
Proportion Difference - Stratified CMH Method (95% CI)	-0.33 (-0.73, 0.07)		
p-value	0.11		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.32 (-0.70, 0.07)		
p-value	0.11		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.32 (-0.68, 0.11)		
p-value	0.081		
Unadjusted Relative Risk (95% CI)	0.16 (0.02, 1.28)		
p-value [1]	0.084		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Unadjusted Odds Ratio (95% CI)	0.10 (0.01, 1.24)		
p-value [1]	0.073		
Unadjusted Absolute Risk Difference (95% CI)	-0.32 (-0.67, 0.04)		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7805: Analysis of Patient Global Impression of Change at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 5)	BAT (N = 7)	MMB (N = 44)	BAT (N = 24)
Missing Assessment	1 (20.0%)	3 (42.9%)	16 (36.4%)	5 (20.8%)
No change	0	0	2 (4.5%)	9 (37.5%)
Return Rate (%)	80%	57%	64%	79%
Number of Subjects in Risk	4	5	33	19
Return Rate in Risk (%)	100%	80%	85%	100%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7805: Analysis of Patient Global Impression of Change at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 17)	BAT (N = 8)	p-value
Missing Assessment	7 (41.2%)	3 (37.5%)	
No change	2 (11.8%)	1 (12.5%)	
Return Rate (%)	59%	63%	
Number of Subjects in Risk	11	6	
Return Rate in Risk (%)	91%	83%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7808: Analysis of Patient Global Impression of Change at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 45)	BAT (N = 23)	MMB (N = 13)	BAT (N = 8)
Week 24 at Randomized Treatment Phase, n(%)				
Improvement, n(%)	25 (55.6%)	5 (21.7%)	6 (46.2%)	2 (25.0%)
Very much improved	2 (4.4%)	0	1 (7.7%)	0
Much improved	16 (35.6%)	1 (4.3%)	2 (15.4%)	1 (12.5%)
Minimally improved	7 (15.6%)	4 (17.4%)	3 (23.1%)	1 (12.5%)
95% Exact CI	0.4000, 0.7036	0.0746, 0.4370	0.1922, 0.7487	0.0319, 0.6509
Proportion Difference - Stratified CMH Method (95% CI)	0.30 (0.06, 0.54)		0.21 (-0.27, 0.68)	
p-value	0.014		0.39	
Proportion Difference - Unstratified CMH Method (95% CI)	0.34 (0.11, 0.57)		0.21 (-0.22, 0.65)	
p-value	0.004		0.34	
Proportion Difference - Unstratified Exact Method (95% CI)	0.34 (0.08, 0.55)		0.21 (-0.24, 0.60)	
p-value	0.010		0.40	
Unadjusted Inverse Relative Risk (95% CI)	0.39 (0.17, 0.89)		0.54 (0.14, 2.06)	
p-value [1]	0.025		0.37	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	0.22 (0.07, 0.70)		0.39 (0.06, 2.70)	
p-value [1]	0.011		0.34	
Unadjusted Absolute Risk Difference (95% CI)	0.34 (0.12, 0.56)		0.21 (-0.19, 0.62)	
Adjusted Inverse Relative Risk (95% CI) [2]	0.43 (0.19, 0.94)		NE	
p-value [2]	0.035		NE	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.7808: Analysis of Patient Global Impression of Change at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 8)	BAT (N = 8)	p-value
Week 24 at Randomized Treatment Phase, n(%)			
Improvement, n(%)	4 (50.0%)	3 (37.5%)	
Very much improved	3 (37.5%)	0	
Much improved	1 (12.5%)	0	
Minimally improved	0	3 (37.5%)	
95% Exact CI	0.1570, 0.8430	0.0852, 0.7551	
Proportion Difference - Stratified CMH Method (95% CI)	0.29 (-0.31, 0.88)		
p-value	0.35		
Proportion Difference - Unstratified CMH Method (95% CI)	0.13 (-0.39, 0.64)		
p-value	0.64		
Proportion Difference - Unstratified Exact Method (95% CI)	0.13 (-0.40, 0.60)		
p-value	1.00		
Unadjusted Inverse Relative Risk (95% CI)	0.75 (0.24, 2.33)		
p-value [1]	0.62		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.68
Unadjusted Inverse Odds Ratio (95% CI)	0.60 (0.08, 4.40)		
p-value [1]	0.62		
Unadjusted Absolute Risk Difference (95% CI)	0.13 (-0.36, 0.61)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			0.75

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-chg-pgic.sas V.03.05 Output file: t-subgrp-chg-pgic-rt-gba-mf.pdf 24AUG2023:16:59

Table 2.7808: Analysis of Patient Global Impression of Change at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 45)	BAT (N = 23)	MMB (N = 13)	BAT (N = 8)
Worsening, n(%)	3 (6.7%)	5 (21.7%)	0	1 (12.5%)
Minimally worse	3 (6.7%)	3 (13.0%)	0	0
Much worse	0	2 (8.7%)	0	1 (12.5%)
Very much worse	0	0	0	0
95% Exact CI	0.0140, 0.1827	0.0746, 0.4370	0.0000, 0.2471	0.0032, 0.5265
Proportion Difference - Stratified CMH Method (95% CI)	-0.13 (-0.34, 0.07)		-0.15 (-0.55, 0.26)	
p-value	0.21		0.48	
Proportion Difference - Unstratified CMH Method (95% CI)	-0.15 (-0.34, 0.04)		-0.13 (-0.42, 0.17)	
p-value	0.12		0.41	
Proportion Difference - Unstratified Exact Method (95% CI)	-0.15 (-0.39, 0.10)		-0.13 (-0.53, 0.31)	
p-value	0.11		0.38	
Unadjusted Relative Risk (95% CI)	0.31 (0.08, 1.17)		0.21 (0.01, 4.71)	
p-value [1]	0.084		0.33	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Odds Ratio (95% CI)	0.26 (0.06, 1.19)		0.19 (0.01, 5.14)	
p-value [1]	0.083		0.32	
Unadjusted Absolute Risk Difference (95% CI)	-0.15 (-0.33, 0.03)		-0.13 (-0.39, 0.13)	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.7808: Analysis of Patient Global Impression of Change at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 8)	BAT (N = 8)	p-value
Worsening, n(%)	0	2 (25.0%)	
Minimally worse	0	1 (12.5%)	
Much worse	0	0	
Very much worse	0	1 (12.5%)	
95% Exact CI	0.0000, 0.3694	0.0319, 0.6509	
Proportion Difference - Stratified CMH Method (95% CI)	-0.36 (-0.92, 0.19)		
p-value	0.20		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.25 (-0.62, 0.12)		
p-value	0.19		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.25 (-0.70, 0.29)		
p-value	0.47		
Unadjusted Relative Risk (95% CI)	0.20 (0.01, 3.61)		
p-value [1]	0.28		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Unadjusted Odds Ratio (95% CI)	0.15 (0.01, 3.77)		
p-value [1]	0.25		
Unadjusted Absolute Risk Difference (95% CI)	-0.22 (-0.55, 0.11)		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.7808: Analysis of Patient Global Impression of Change at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 45)	BAT (N = 23)	MMB (N = 13)	BAT (N = 8)
Missing Assessment	14 (31.1%)	7 (30.4%)	7 (53.8%)	3 (37.5%)
No change	3 (6.7%)	6 (26.1%)	0	2 (25.0%)
Return Rate (%)	69%	70%	46%	63%
Number of Subjects in Risk	33	18	9	5
Return Rate in Risk (%)	94%	89%	67%	100%

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.7808: Analysis of Patient Global Impression of Change at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 8)	BAT (N = 8)	p-value
Missing Assessment	3 (37.5%)	1 (12.5%)	
No change	1 (12.5%)	2 (25.0%)	
Return Rate (%)	63%	88%	
Number of Subjects in Risk	6	7	
Return Rate in Risk (%)	83%	100%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.7803: Analysis of Patient Global Impression of Change at Week 24 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 52)	BAT (N = 18)	MMB (N = 14)	BAT (N = 21)	p-value
Week 24 at Randomized Treatment Phase, n(%)					
Improvement, n(%)	27 (51.9%)	3 (16.7%)	8 (57.1%)	7 (33.3%)	
Very much improved	4 (7.7%)	0	2 (14.3%)	0	
Much improved	15 (28.8%)	0	4 (28.6%)	2 (9.5%)	
Minimally improved	8 (15.4%)	3 (16.7%)	2 (14.3%)	5 (23.8%)	
95% Exact CI	0.3763, 0.6599	0.0358, 0.4142	0.2886, 0.8234	0.1459, 0.5697	
Proportion Difference - Stratified CMH Method (95% CI)	0.34 (0.11, 0.57)		0.12 (-0.21, 0.46)		
p-value	0.004		0.47		
Proportion Difference - Unstratified CMH Method (95% CI)	0.35 (0.12, 0.58)		0.24 (-0.10, 0.58)		
p-value	0.003		0.17		
Proportion Difference - Unstratified Exact Method (95% CI)	0.35 (0.08, 0.59)		0.24 (-0.11, 0.55)		
p-value	0.012		0.19		
Unadjusted Inverse Relative Risk (95% CI)	0.32 (0.11, 0.93)		0.58 (0.27, 1.24)		
p-value [1]	0.037		0.16		
Unadjusted interaction test for Treatment*Gender [3]					0.34
Unadjusted Inverse Odds Ratio (95% CI)	0.19 (0.05, 0.72)		0.38 (0.09, 1.51)		
p-value [1]	0.015		0.17		
Unadjusted Absolute Risk Difference (95% CI)	0.35 (0.13, 0.57)		0.24 (-0.09, 0.57)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.33 (0.12, 0.91)		0.75 (0.36, 1.56)		
p-value [2]	0.032		0.44		
Adjusted interaction test for Treatment*Gender [3]					0.33

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7803: Analysis of Patient Global Impression of Change at Week 24 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 52)	BAT (N = 18)	MMB (N = 14)	BAT (N = 21)	p-value
Worsening, n(%)	1 (1.9%)	3 (16.7%)	2 (14.3%)	5 (23.8%)	
Minimally worse	1 (1.9%)	3 (16.7%)	2 (14.3%)	1 (4.8%)	
Much worse	0	0	0	3 (14.3%)	
Very much worse	0	0	0	1 (4.8%)	
95% Exact CI	0.0005, 0.1026	0.0358, 0.4142	0.0178, 0.4281	0.0822, 0.4717	
Proportion Difference - Stratified CMH Method (95% CI)	-0.14 (-0.35, 0.07)		-0.10 (-0.40, 0.21)		
p-value	0.19		0.53		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.15 (-0.34, 0.04)		-0.10 (-0.37, 0.18)		
p-value	0.13		0.50		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.15 (-0.40, 0.13)		-0.10 (-0.43, 0.25)		
p-value	0.050		0.68		
Unadjusted Relative Risk (95% CI)	0.12 (0.01, 1.04)		0.60 (0.13, 2.67)		
p-value [1]	0.054		0.50		
Unadjusted interaction test for Treatment*Gender [3]					NA
Unadjusted Odds Ratio (95% CI)	0.10 (0.01, 1.01)		0.53 (0.09, 3.23)		
p-value [1]	0.051		0.49		
Unadjusted Absolute Risk Difference (95% CI)	-0.15 (-0.32, 0.03)		-0.10 (-0.35, 0.16)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Gender [3]					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7803: Analysis of Patient Global Impression of Change at Week 24 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 52)	BAT (N = 18)	MMB (N = 14)	BAT (N = 21)	p-value
Missing Assessment	20 (38.5%)	8 (44.4%)	4 (28.6%)	3 (14.3%)	
No change	4 (7.7%)	4 (22.2%)	0	6 (28.6%)	
Return Rate (%)	62%	56%	71%	86%	
Number of Subjects in Risk	38	12	10	18	
Return Rate in Risk (%)	84%	83%	100%	100%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7810: Analysis of Patient Global Impression of Change at Week 24 by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N = 28)	BAT (N = 24)	MMB (N = 38)	BAT (N = 15)	p-value
Week 24 at Randomized Treatment Phase, n(%)					
Improvement, n(%)	17 (60.7%)	9 (37.5%)	18 (47.4%)	1 (6.7%)	
Very much improved	4 (14.3%)	0	2 (5.3%)	0	
Much improved	9 (32.1%)	2 (8.3%)	10 (26.3%)	0	
Minimally improved	4 (14.3%)	7 (29.2%)	6 (15.8%)	1 (6.7%)	
95% Exact CI	0.4058, 0.7850	0.1880, 0.5941	0.3098, 0.6418	0.0017, 0.3195	
Proportion Difference - Stratified CMH Method (95% CI)	0.27 (-0.02, 0.56)		0.31 (0.01, 0.62)		
p-value	0.068		0.042		
Proportion Difference - Unstratified CMH Method (95% CI)	0.23 (-0.04, 0.50)		0.41 (0.19, 0.63)		
p-value	0.093		< 0.001		
Proportion Difference - Unstratified Exact Method (95% CI)	0.23 (-0.05, 0.48)		0.41 (0.12, 0.68)		
p-value	0.16		0.009		
Unadjusted Inverse Relative Risk (95% CI)	0.62 (0.34, 1.12)		0.14 (0.02, 0.96)		
p-value [1]	0.11		0.046		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.046
Unadjusted Inverse Odds Ratio (95% CI)	0.39 (0.13, 1.19)		0.08 (0.01, 0.67)		
p-value [1]	0.098		0.020		
Unadjusted Absolute Risk Difference (95% CI)	0.23 (-0.03, 0.50)		0.41 (0.20, 0.61)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.57 (0.32, 1.02)		NE		
p-value [2]	0.059		NE		

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.7810: Analysis of Patient Global Impression of Change at Week 24 by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N = 28)	BAT (N = 24)	MMB (N = 38)	BAT (N = 15)	p-value
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					0.083

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.7810: Analysis of Patient Global Impression of Change at Week 24 by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N = 28)	BAT (N = 24)	MMB (N = 38)	BAT (N = 15)	p-value
Worsening, n(%)	1 (3.6%)	3 (12.5%)	2 (5.3%)	5 (33.3%)	
Minimally worse	1 (3.6%)	1 (4.2%)	2 (5.3%)	3 (20.0%)	
Much worse	0	2 (8.3%)	0	1 (6.7%)	
Very much worse	0	0	0	1 (6.7%)	
95% Exact CI	0.0009, 0.1835	0.0266, 0.3236	0.0064, 0.1775	0.1182, 0.6162	
Proportion Difference - Stratified CMH Method (95% CI)	-0.09 (-0.29, 0.11)		-0.25 (-0.59, 0.09)		
p-value	0.38		0.15		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.09 (-0.25, 0.08)		-0.28 (-0.54, -0.02)		
p-value	0.29		0.035		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.09 (-0.35, 0.18)		-0.28 (-0.55, 0.02)		
p-value	0.32		0.015		
Unadjusted Relative Risk (95% CI)	0.29 (0.03, 2.57)		0.16 (0.03, 0.73)		
p-value [1]	0.26		0.018		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Odds Ratio (95% CI)	0.26 (0.03, 2.68)		0.11 (0.02, 0.66)		
p-value [1]	0.26		0.016		
Unadjusted Absolute Risk Difference (95% CI)	-0.09 (-0.24, 0.06)		-0.28 (-0.53, -0.03)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.7810: Analysis of Patient Global Impression of Change at Week 24 by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N = 28)	BAT (N = 24)	MMB (N = 38)	BAT (N = 15)	p-value
Missing Assessment	10 (35.7%)	5 (20.8%)	14 (36.8%)	6 (40.0%)	
No change	0	7 (29.2%)	4 (10.5%)	3 (20.0%)	
Return Rate (%)	64%	79%	63%	60%	
Number of Subjects in Risk	23	20	25	10	
Return Rate in Risk (%)	78%	95%	96%	90%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.
Data Extracted: CRF data: 25JUN2019

Table 2.7809: Analysis of Patient Global Impression of Change at Week 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 42)	BAT (N = 20)	MMB (N = 24)	BAT (N = 19)	p-value
Week 24 at Randomized Treatment Phase, n(%)					
Improvement, n(%)	25 (59.5%)	8 (40.0%)	10 (41.7%)	2 (10.5%)	
Very much improved	3 (7.1%)	0	3 (12.5%)	0	
Much improved	14 (33.3%)	1 (5.0%)	5 (20.8%)	1 (5.3%)	
Minimally improved	8 (19.0%)	7 (35.0%)	2 (8.3%)	1 (5.3%)	
95% Exact CI	0.4328, 0.7437	0.1912, 0.6395	0.2211, 0.6336	0.0130, 0.3314	
Proportion Difference - Stratified CMH Method (95% CI)	0.21 (-0.05, 0.48)		0.30 (0.04, 0.56)		
p-value	0.11		0.025		
Proportion Difference - Unstratified CMH Method (95% CI)	0.20 (-0.07, 0.46)		0.31 (0.06, 0.56)		
p-value	0.15		0.016		
Proportion Difference - Unstratified Exact Method (95% CI)	0.20 (-0.08, 0.45)		0.31 (0.02, 0.57)		
p-value	0.18		0.039		
Unadjusted Inverse Relative Risk (95% CI)	0.67 (0.37, 1.21)		0.25 (0.06, 1.02)		
p-value [1]	0.19		0.053		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					0.15
Unadjusted Inverse Odds Ratio (95% CI)	0.45 (0.15, 1.34)		0.16 (0.03, 0.88)		
p-value [1]	0.15		0.035		
Unadjusted Absolute Risk Difference (95% CI)	0.20 (-0.07, 0.46)		0.31 (0.07, 0.55)		
Adjusted Inverse Relative Risk (95% CI) [2]	0.65 (0.36, 1.16)		0.26 (0.07, 1.05)		
p-value [2]	0.14		0.059		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					0.14

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7809: Analysis of Patient Global Impression of Change at Week 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 42)	BAT (N = 20)	MMB (N = 24)	BAT (N = 19)	p-value
Worsening, n(%)	1 (2.4%)	1 (5.0%)	2 (8.3%)	7 (36.8%)	
Minimally worse	1 (2.4%)	1 (5.0%)	2 (8.3%)	3 (15.8%)	
Much worse	0	0	0	3 (15.8%)	
Very much worse	0	0	0	1 (5.3%)	
95% Exact CI	0.0006, 0.1257	0.0013, 0.2487	0.0103, 0.2700	0.1629, 0.6164	
Proportion Difference - Stratified CMH Method (95% CI)	-0.03 (-0.18, 0.12)		-0.29 (-0.56, -0.03)		
p-value	0.68		0.031		
Proportion Difference - Unstratified CMH Method (95% CI)	-0.03 (-0.15, 0.10)		-0.29 (-0.54, -0.03)		
p-value	0.69		0.028		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.03 (-0.29, 0.24)		-0.29 (-0.55, 0.02)		
p-value	0.54		0.030		
Unadjusted Relative Risk (95% CI)	0.48 (0.03, 7.23)		0.23 (0.05, 0.97)		
p-value [1]	0.59		0.045		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Unadjusted Odds Ratio (95% CI)	0.46 (0.03, 7.81)		0.16 (0.03, 0.87)		
p-value [1]	0.59		0.034		
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.13, 0.08)		-0.29 (-0.53, -0.04)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NA

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.7809: Analysis of Patient Global Impression of Change at Week 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 42)	BAT (N = 20)	MMB (N = 24)	BAT (N = 19)	p-value
Missing Assessment	13 (31.0%)	6 (30.0%)	11 (45.8%)	5 (26.3%)	
No change	3 (7.1%)	5 (25.0%)	1 (4.2%)	5 (26.3%)	
Return Rate (%)	69%	70%	54%	74%	
Number of Subjects in Risk	33	16	15	14	
Return Rate in Risk (%)	88%	88%	87%	100%	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8502: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	BAT (N = 9)	MMB (N = 42)	BAT (N = 30)	p-value
EQ-5D-5L VAS Response Rate at Week 4					
Responder, n(%)	5 (20.8%)	2 (22.2%)	7 (16.7%)	2 (6.7%)	
Non-Responder, n(%)	19 (79.2%)	7 (77.8%)	35 (83.3%)	28 (93.3%)	
Non-missing	12 (50.0%)	3 (33.3%)	21 (50.0%)	19 (63.3%)	
Missing	7 (29.2%)	4 (44.4%)	14 (33.3%)	9 (30.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-eq5d-gba.sas V.03.05 Output file: t-subgrp-eq5d-det-gba-age.pdf 24AUG2023:16:52

Table 2.8502: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	BAT (N = 9)	MMB (N = 42)	BAT (N = 30)	p-value
EQ-5D-5L VAS Response Rate at Week 8					
Responder, n(%)	6 (25.0%)	2 (22.2%)	6 (14.3%)	3 (10.0%)	
Non-Responder, n(%)	18 (75.0%)	7 (77.8%)	36 (85.7%)	27 (90.0%)	
Non-missing	11 (45.8%)	2 (22.2%)	21 (50.0%)	17 (56.7%)	
Missing	7 (29.2%)	5 (55.6%)	15 (35.7%)	10 (33.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8502: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	BAT (N = 9)	MMB (N = 42)	BAT (N = 30)	p-value
EQ-5D-5L VAS Response Rate at Week 12					
Responder, n(%)	4 (16.7%)	2 (22.2%)	7 (16.7%)	3 (10.0%)	
Non-Responder, n(%)	20 (83.3%)	7 (77.8%)	35 (83.3%)	27 (90.0%)	
Non-missing	9 (37.5%)	2 (22.2%)	17 (40.5%)	19 (63.3%)	
Missing	11 (45.8%)	5 (55.6%)	18 (42.9%)	8 (26.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8502: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	BAT (N = 9)	MMB (N = 42)	BAT (N = 30)	p-value
EQ-5D-5L VAS Response Rate at Week 16					
Responder, n(%)	3 (12.5%)	1 (11.1%)	5 (11.9%)	3 (10.0%)	
Non-Responder, n(%)	21 (87.5%)	8 (88.9%)	37 (88.1%)	27 (90.0%)	
Non-missing	9 (37.5%)	3 (33.3%)	19 (45.2%)	19 (63.3%)	
Missing	12 (50.0%)	5 (55.6%)	18 (42.9%)	8 (26.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-eq5d-gba.sas V.03.05 Output file: t-subgrp-eq5d-det-gba-age.pdf 24AUG2023:16:52

Table 2.8502: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	BAT (N = 9)	MMB (N = 42)	BAT (N = 30)	p-value
EQ-5D-5L VAS Response Rate at Week 20					
Responder, n(%)	3 (12.5%)	1 (11.1%)	4 (9.5%)	2 (6.7%)	
Non-Responder, n(%)	21 (87.5%)	8 (88.9%)	38 (90.5%)	28 (93.3%)	
Non-missing	7 (29.2%)	3 (33.3%)	18 (42.9%)	18 (60.0%)	
Missing	14 (58.3%)	5 (55.6%)	20 (47.6%)	10 (33.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8502: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	BAT (N = 9)	MMB (N = 42)	BAT (N = 30)	p-value
EQ-5D-5L VAS Response Rate at Week 24					
Responder, n(%)	2 (8.3%)	0	3 (7.1%)	2 (6.7%)	
Unadjusted Relative Risk (95% CI)	2.00 (0.11, 38.08)		1.07 (0.19, 6.02)		
p-value [1]	0.64		0.94		
Unadjusted interaction test for Treatment*Age Group [3]					NA
Unadjusted Odds Ratio (95% CI)	2.11 (0.09, 48.27)		1.08 (0.17, 6.88)		
p-value [1]	0.64		0.94		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.13, 0.23)		0.00 (-0.11, 0.12)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Age Group [3]					NA
Non-Responder, n(%)	22 (91.7%)	9 (100.0%)	39 (92.9%)	28 (93.3%)	
Non-missing	4 (16.7%)	4 (44.4%)	18 (42.9%)	17 (56.7%)	
Missing	18 (75.0%)	5 (55.6%)	21 (50.0%)	11 (36.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8506: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 49)	BAT (N = 31)	MMB (N = 17)	BAT (N = 8)	p-value
EQ-5D-5L VAS Response Rate at Week 4					
Responder, n(%)	9 (18.4%)	3 (9.7%)	3 (17.6%)	1 (12.5%)	
Non-Responder, n(%)	40 (81.6%)	28 (90.3%)	14 (82.4%)	7 (87.5%)	
Non-missing	25 (51.0%)	17 (54.8%)	8 (47.1%)	5 (62.5%)	
Missing	15 (30.6%)	11 (35.5%)	6 (35.3%)	2 (25.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8506: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 49)	BAT (N = 31)	MMB (N = 17)	BAT (N = 8)	p-value
EQ-5D-5L VAS Response Rate at Week 8					
Responder, n(%)	10 (20.4%)	3 (9.7%)	2 (11.8%)	2 (25.0%)	
Non-Responder, n(%)	39 (79.6%)	28 (90.3%)	15 (88.2%)	6 (75.0%)	
Non-missing	23 (46.9%)	15 (48.4%)	9 (52.9%)	4 (50.0%)	
Missing	16 (32.7%)	13 (41.9%)	6 (35.3%)	2 (25.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8506: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 49)	BAT (N = 31)	MMB (N = 17)	BAT (N = 8)	p-value
EQ-5D-5L VAS Response Rate at Week 12					
Responder, n(%)	8 (16.3%)	4 (12.9%)	3 (17.6%)	1 (12.5%)	
Non-Responder, n(%)	41 (83.7%)	27 (87.1%)	14 (82.4%)	7 (87.5%)	
Non-missing	19 (38.8%)	16 (51.6%)	7 (41.2%)	5 (62.5%)	
Missing	22 (44.9%)	11 (35.5%)	7 (41.2%)	2 (25.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-eq5d-gba.sas V.03.05 Output file: t-subgrp-eq5d-det-gba-dip2.pdf 24AUG2023:16:52

Table 2.8506: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 49)	BAT (N = 31)	MMB (N = 17)	BAT (N = 8)	p-value
EQ-5D-5L VAS Response Rate at Week 16					
Responder, n(%)	6 (12.2%)	3 (9.7%)	2 (11.8%)	1 (12.5%)	
Non-Responder, n(%)	43 (87.8%)	28 (90.3%)	15 (88.2%)	7 (87.5%)	
Non-missing	21 (42.9%)	17 (54.8%)	7 (41.2%)	5 (62.5%)	
Missing	22 (44.9%)	11 (35.5%)	8 (47.1%)	2 (25.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8506: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 49)	BAT (N = 31)	MMB (N = 17)	BAT (N = 8)	p-value
EQ-5D-5L VAS Response Rate at Week 20					
Responder, n(%)	6 (12.2%)	1 (3.2%)	1 (5.9%)	2 (25.0%)	
Non-Responder, n(%)	43 (87.8%)	30 (96.8%)	16 (94.1%)	6 (75.0%)	
Non-missing	19 (38.8%)	17 (54.8%)	6 (35.3%)	4 (50.0%)	
Missing	24 (49.0%)	13 (41.9%)	10 (58.8%)	2 (25.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8506: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 49)	BAT (N = 31)	MMB (N = 17)	BAT (N = 8)	p-value
EQ-5D-5L VAS Response Rate at Week 24					
Responder, n(%)	4 (8.2%)	1 (3.2%)	1 (5.9%)	1 (12.5%)	
Unadjusted Relative Risk (95% CI)	2.53 (0.30, 21.61)		0.47 (0.03, 6.60)		
p-value [1]	0.40		0.58		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Unadjusted Odds Ratio (95% CI)	2.67 (0.28, 25.04)		0.44 (0.02, 8.04)		
p-value [1]	0.39		0.58		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.05, 0.15)		-0.07 (-0.32, 0.19)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Non-Responder, n(%)	45 (91.8%)	30 (96.8%)	16 (94.1%)	7 (87.5%)	
Non-missing	16 (32.7%)	17 (54.8%)	6 (35.3%)	4 (50.0%)	
Missing	29 (59.2%)	13 (41.9%)	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8505: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 5)	BAT (N = 7)	MMB (N = 44)	BAT (N = 24)
EQ-5D-5L VAS Response Rate at Week 4				
Responder, n(%)	0	0	9 (20.5%)	3 (12.5%)
Non-Responder, n(%)	5 (100.0%)	7 (100.0%)	35 (79.5%)	21 (87.5%)
Non-missing	2 (40.0%)	3 (42.9%)	23 (52.3%)	14 (58.3%)
Missing	3 (60.0%)	4 (57.1%)	12 (27.3%)	7 (29.2%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8505: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 17)	BAT (N = 8)	p-value
EQ-5D-5L VAS Response Rate at Week 4			
Responder, n(%)	3 (17.6%)	1 (12.5%)	
Non-Responder, n(%)	14 (82.4%)	7 (87.5%)	
Non-missing	8 (47.1%)	5 (62.5%)	
Missing	6 (35.3%)	2 (25.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8505: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 5)	BAT (N = 7)	MMB (N = 44)	BAT (N = 24)
EQ-5D-5L VAS Response Rate at Week 8				
Responder, n(%)	1 (20.0%)	1 (14.3%)	9 (20.5%)	2 (8.3%)
Non-Responder, n(%)	4 (80.0%)	6 (85.7%)	35 (79.5%)	22 (91.7%)
Non-missing	1 (20.0%)	3 (42.9%)	22 (50.0%)	12 (50.0%)
Missing	3 (60.0%)	3 (42.9%)	13 (29.5%)	10 (41.7%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8505: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 17)	BAT (N = 8)	p-value
EQ-5D-5L VAS Response Rate at Week 8			
Responder, n(%)	2 (11.8%)	2 (25.0%)	
Non-Responder, n(%)	15 (88.2%)	6 (75.0%)	
Non-missing	9 (52.9%)	4 (50.0%)	
Missing	6 (35.3%)	2 (25.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8505: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 5)	BAT (N = 7)	MMB (N = 44)	BAT (N = 24)
EQ-5D-5L VAS Response Rate at Week 12				
Responder, n(%)	1 (20.0%)	0	7 (15.9%)	4 (16.7%)
Non-Responder, n(%)	4 (80.0%)	7 (100.0%)	37 (84.1%)	20 (83.3%)
Non-missing	0	4 (57.1%)	19 (43.2%)	12 (50.0%)
Missing	4 (80.0%)	3 (42.9%)	18 (40.9%)	8 (33.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8505: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 17)	BAT (N = 8)	p-value
EQ-5D-5L VAS Response Rate at Week 12			
Responder, n(%)	3 (17.6%)	1 (12.5%)	
Non-Responder, n(%)	14 (82.4%)	7 (87.5%)	
Non-missing	7 (41.2%)	5 (62.5%)	
Missing	7 (41.2%)	2 (25.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8505: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 5)	BAT (N = 7)	MMB (N = 44)	BAT (N = 24)
EQ-5D-5L VAS Response Rate at Week 16				
Responder, n(%)	1 (20.0%)	0	5 (11.4%)	3 (12.5%)
Non-Responder, n(%)	4 (80.0%)	7 (100.0%)	39 (88.6%)	21 (87.5%)
Non-missing	0	4 (57.1%)	21 (47.7%)	13 (54.2%)
Missing	4 (80.0%)	3 (42.9%)	18 (40.9%)	8 (33.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8505: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 17)	BAT (N = 8)	p-value
EQ-5D-5L VAS Response Rate at Week 16			
Responder, n(%)	2 (11.8%)	1 (12.5%)	
Non-Responder, n(%)	15 (88.2%)	7 (87.5%)	
Non-missing	7 (41.2%)	5 (62.5%)	
Missing	8 (47.1%)	2 (25.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8505: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 5)	BAT (N = 7)	MMB (N = 44)	BAT (N = 24)
EQ-5D-5L VAS Response Rate at Week 20				
Responder, n(%)	1 (20.0%)	0	5 (11.4%)	1 (4.2%)
Non-Responder, n(%)	4 (80.0%)	7 (100.0%)	39 (88.6%)	23 (95.8%)
Non-missing	0	3 (42.9%)	19 (43.2%)	14 (58.3%)
Missing	4 (80.0%)	4 (57.1%)	20 (45.5%)	9 (37.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8505: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 17)	BAT (N = 8)	p-value
EQ-5D-5L VAS Response Rate at Week 20			
Responder, n(%)	1 (5.9%)	2 (25.0%)	
Non-Responder, n(%)	16 (94.1%)	6 (75.0%)	
Non-missing	6 (35.3%)	4 (50.0%)	
Missing	10 (58.8%)	2 (25.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8505: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 5)	BAT (N = 7)	MMB (N = 44)	BAT (N = 24)
EQ-5D-5L VAS Response Rate at Week 24				
Responder, n(%)	1 (20.0%)	0	3 (6.8%)	1 (4.2%)
Unadjusted Relative Risk (95% CI)	4.00 (0.20, 82.01)		1.64 (0.18, 14.89)	
p-value [1]	0.37		0.66	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Unadjusted Odds Ratio (95% CI)	5.00 (0.17, 150.93)		1.68 (0.17, 17.13)	
p-value [1]	0.35		0.66	
Unadjusted Absolute Risk Difference (95% CI)	0.19 (-0.20, 0.57)		0.03 (-0.08, 0.14)	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Non-Responder, n(%)	4 (80.0%)	7 (100.0%)	41 (93.2%)	23 (95.8%)
Non-missing	0	3 (42.9%)	16 (36.4%)	14 (58.3%)
Missing	4 (80.0%)	4 (57.1%)	25 (56.8%)	9 (37.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8505: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 17)	BAT (N = 8)	p-value
EQ-5D-5L VAS Response Rate at Week 24			
Responder, n(%)	1 (5.9%)	1 (12.5%)	
Unadjusted Relative Risk (95% CI)	0.47 (0.03, 6.60)		
p-value [1]	0.58		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Unadjusted Odds Ratio (95% CI)	0.44 (0.02, 8.04)		
p-value [1]	0.58		
Unadjusted Absolute Risk Difference (95% CI)	-0.07 (-0.32, 0.19)		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	16 (94.1%)	7 (87.5%)	
Non-missing	6 (35.3%)	4 (50.0%)	
Missing	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8504: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N = 29)	BAT (N = 7)	MMB (N = 37)	BAT (N = 32)	p-value
EQ-5D-5L VAS Response Rate at Week 4					
Responder, n(%)	4 (13.8%)	0	8 (21.6%)	4 (12.5%)	
Non-Responder, n(%)	25 (86.2%)	7 (100.0%)	29 (78.4%)	28 (87.5%)	
Non-missing	12 (41.4%)	3 (42.9%)	21 (56.8%)	19 (59.4%)	
Missing	13 (44.8%)	4 (57.1%)	8 (21.6%)	9 (28.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-eq5d-gba.sas V.03.05 Output file: t-subgrp-eq5d-det-gba-geo.pdf 24AUG2023:16:52

Table 2.8504: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N = 29)	BAT (N = 7)	MMB (N = 37)	BAT (N = 32)	p-value
EQ-5D-5L VAS Response Rate at Week 8					
Responder, n(%)	3 (10.3%)	0	9 (24.3%)	5 (15.6%)	
Non-Responder, n(%)	26 (89.7%)	7 (100.0%)	28 (75.7%)	27 (84.4%)	
Non-missing	11 (37.9%)	2 (28.6%)	21 (56.8%)	17 (53.1%)	
Missing	15 (51.7%)	5 (71.4%)	7 (18.9%)	10 (31.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-eq5d-gba.sas V.03.05 Output file: t-subgrp-eq5d-det-gba-geo.pdf 24AUG2023:16:52

Table 2.8504: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N = 29)	BAT (N = 7)	MMB (N = 37)	BAT (N = 32)	p-value
EQ-5D-5L VAS Response Rate at Week 12					
Responder, n(%)	3 (10.3%)	0	8 (21.6%)	5 (15.6%)	
Non-Responder, n(%)	26 (89.7%)	7 (100.0%)	29 (78.4%)	27 (84.4%)	
Non-missing	8 (27.6%)	3 (42.9%)	18 (48.6%)	18 (56.3%)	
Missing	18 (62.1%)	4 (57.1%)	11 (29.7%)	9 (28.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8504: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N = 29)	BAT (N = 7)	MMB (N = 37)	BAT (N = 32)	p-value
EQ-5D-5L VAS Response Rate at Week 16					
Responder, n(%)	0	0	8 (21.6%)	4 (12.5%)	
Non-Responder, n(%)	29 (100.0%)	7 (100.0%)	29 (78.4%)	28 (87.5%)	
Non-missing	10 (34.5%)	3 (42.9%)	18 (48.6%)	19 (59.4%)	
Missing	19 (65.5%)	4 (57.1%)	11 (29.7%)	9 (28.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8504: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N = 29)	BAT (N = 7)	MMB (N = 37)	BAT (N = 32)	p-value
EQ-5D-5L VAS Response Rate at Week 20					
Responder, n(%)	0	0	7 (18.9%)	3 (9.4%)	
Non-Responder, n(%)	29 (100.0%)	7 (100.0%)	30 (81.1%)	29 (90.6%)	
Non-missing	11 (37.9%)	3 (42.9%)	14 (37.8%)	18 (56.3%)	
Missing	18 (62.1%)	4 (57.1%)	16 (43.2%)	11 (34.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8504: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N = 29)	BAT (N = 7)	MMB (N = 37)	BAT (N = 32)	p-value
EQ-5D-5L VAS Response Rate at Week 24					
Responder, n(%)	0	0	5 (13.5%)	2 (6.3%)	
Unadjusted Relative Risk (95% CI)	NA		2.16 (0.45, 10.39)		
p-value [1]	NA		0.34		
Unadjusted interaction test for Treatment*Region [3]					NA
Unadjusted Odds Ratio (95% CI)	NA		2.34 (0.42, 13.01)		
p-value [1]	NA		0.33		
Unadjusted Absolute Risk Difference (95% CI)	NA		0.07 (-0.07, 0.21)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Region [3]					NA
Non-Responder, n(%)	29 (100.0%)	7 (100.0%)	32 (86.5%)	30 (93.8%)	
Non-missing	9 (31.0%)	3 (42.9%)	13 (35.1%)	18 (56.3%)	
Missing	20 (69.0%)	4 (57.1%)	19 (51.4%)	12 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8507: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 27)	BAT (N = 6)	MMB (N = 39)	BAT (N = 33)	p-value
EQ-5D-5L VAS Response Rate at Week 4					
Responder, n(%)	5 (18.5%)	0	7 (17.9%)	4 (12.1%)	
Non-Responder, n(%)	22 (81.5%)	6 (100.0%)	32 (82.1%)	29 (87.9%)	
Non-missing	13 (48.1%)	2 (33.3%)	20 (51.3%)	20 (60.6%)	
Missing	9 (33.3%)	4 (66.7%)	12 (30.8%)	9 (27.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-eq5d-gba.sas V.03.05 Output file: t-subgrp-eq5d-det-gba-hgb.pdf 24AUG2023:16:52

Table 2.8507: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 27)	BAT (N = 6)	MMB (N = 39)	BAT (N = 33)	p-value
EQ-5D-5L VAS Response Rate at Week 8					
Responder, n(%)	4 (14.8%)	0	8 (20.5%)	5 (15.2%)	
Non-Responder, n(%)	23 (85.2%)	6 (100.0%)	31 (79.5%)	28 (84.8%)	
Non-missing	12 (44.4%)	2 (33.3%)	20 (51.3%)	17 (51.5%)	
Missing	11 (40.7%)	4 (66.7%)	11 (28.2%)	11 (33.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

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Table 2.8507: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 27)	BAT (N = 6)	MMB (N = 39)	BAT (N = 33)	p-value
EQ-5D-5L VAS Response Rate at Week 12					
Responder, n(%)	5 (18.5%)	0	6 (15.4%)	5 (15.2%)	
Non-Responder, n(%)	22 (81.5%)	6 (100.0%)	33 (84.6%)	28 (84.8%)	
Non-missing	9 (33.3%)	2 (33.3%)	17 (43.6%)	19 (57.6%)	
Missing	13 (48.1%)	4 (66.7%)	16 (41.0%)	9 (27.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-eq5d-gba.sas V.03.05 Output file: t-subgrp-eq5d-det-gba-hgb.pdf 24AUG2023:16:52

Table 2.8507: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 27)	BAT (N = 6)	MMB (N = 39)	BAT (N = 33)	p-value
EQ-5D-5L VAS Response Rate at Week 16					
Responder, n(%)	2 (7.4%)	1 (16.7%)	6 (15.4%)	3 (9.1%)	
Non-Responder, n(%)	25 (92.6%)	5 (83.3%)	33 (84.6%)	30 (90.9%)	
Non-missing	11 (40.7%)	1 (16.7%)	17 (43.6%)	21 (63.6%)	
Missing	14 (51.9%)	4 (66.7%)	16 (41.0%)	9 (27.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8507: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 27)	BAT (N = 6)	MMB (N = 39)	BAT (N = 33)	p-value
EQ-5D-5L VAS Response Rate at Week 20					
Responder, n(%)	3 (11.1%)	0	4 (10.3%)	3 (9.1%)	
Non-Responder, n(%)	24 (88.9%)	6 (100.0%)	35 (89.7%)	30 (90.9%)	
Non-missing	10 (37.0%)	2 (33.3%)	15 (38.5%)	19 (57.6%)	
Missing	14 (51.9%)	4 (66.7%)	20 (51.3%)	11 (33.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-eq5d-gba.sas V.03.05 Output file: t-subgrp-eq5d-det-gba-hgb.pdf 24AUG2023:16:52

Table 2.8507: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 27)	BAT (N = 6)	MMB (N = 39)	BAT (N = 33)	p-value
EQ-5D-5L VAS Response Rate at Week 24					
Responder, n(%)	0	0	5 (12.8%)	2 (6.1%)	
Unadjusted Relative Risk (95% CI)	NA		2.12 (0.44, 10.20)		
p-value [1]	NA		0.35		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Unadjusted Odds Ratio (95% CI)	NA		2.28 (0.41, 12.61)		
p-value [1]	NA		0.35		
Unadjusted Absolute Risk Difference (95% CI)	NA		0.07 (-0.07, 0.20)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Non-Responder, n(%)	27 (100.0%)	6 (100.0%)	34 (87.2%)	31 (93.9%)	
Non-missing	10 (37.0%)	2 (33.3%)	12 (30.8%)	19 (57.6%)	
Missing	17 (63.0%)	4 (66.7%)	22 (56.4%)	12 (36.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8508: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 45)	BAT (N = 23)	MMB (N = 13)	BAT (N = 8)
EQ-5D-5L VAS Response Rate at Week 4				
Responder, n(%)	8 (17.8%)	3 (13.0%)	3 (23.1%)	1 (12.5%)
Non-Responder, n(%)	37 (82.2%)	20 (87.0%)	10 (76.9%)	7 (87.5%)
Non-missing	22 (48.9%)	12 (52.2%)	7 (53.8%)	3 (37.5%)
Missing	15 (33.3%)	8 (34.8%)	3 (23.1%)	4 (50.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8508: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 8)	BAT (N = 8)	p-value
EQ-5D-5L VAS Response Rate at Week 4			
Responder, n(%)	1 (12.5%)	0	
Non-Responder, n(%)	7 (87.5%)	8 (100.0%)	
Non-missing	4 (50.0%)	7 (87.5%)	
Missing	3 (37.5%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8508: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 45)	BAT (N = 23)	MMB (N = 13)	BAT (N = 8)
EQ-5D-5L VAS Response Rate at Week 8				
Responder, n(%)	8 (17.8%)	2 (8.7%)	2 (15.4%)	2 (25.0%)
Non-Responder, n(%)	37 (82.2%)	21 (91.3%)	11 (84.6%)	6 (75.0%)
Non-missing	22 (48.9%)	12 (52.2%)	7 (53.8%)	2 (25.0%)
Missing	15 (33.3%)	9 (39.1%)	4 (30.8%)	4 (50.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8508: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 8)	BAT (N = 8)	p-value
EQ-5D-5L VAS Response Rate at Week 8			
Responder, n(%)	2 (25.0%)	1 (12.5%)	
Non-Responder, n(%)	6 (75.0%)	7 (87.5%)	
Non-missing	3 (37.5%)	5 (62.5%)	
Missing	3 (37.5%)	2 (25.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8508: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 45)	BAT (N = 23)	MMB (N = 13)	BAT (N = 8)
EQ-5D-5L VAS Response Rate at Week 12				
Responder, n(%)	8 (17.8%)	3 (13.0%)	1 (7.7%)	1 (12.5%)
Non-Responder, n(%)	37 (82.2%)	20 (87.0%)	12 (92.3%)	7 (87.5%)
Non-missing	18 (40.0%)	12 (52.2%)	5 (38.5%)	3 (37.5%)
Missing	19 (42.2%)	8 (34.8%)	7 (53.8%)	4 (50.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8508: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 8)	BAT (N = 8)	p-value
EQ-5D-5L VAS Response Rate at Week 12			
Responder, n(%)	2 (25.0%)	1 (12.5%)	
Non-Responder, n(%)	6 (75.0%)	7 (87.5%)	
Non-missing	3 (37.5%)	6 (75.0%)	
Missing	3 (37.5%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8508: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 45)	BAT (N = 23)	MMB (N = 13)	BAT (N = 8)
EQ-5D-5L VAS Response Rate at Week 16				
Responder, n(%)	6 (13.3%)	3 (13.0%)	1 (7.7%)	1 (12.5%)
Non-Responder, n(%)	39 (86.7%)	20 (87.0%)	12 (92.3%)	7 (87.5%)
Non-missing	19 (42.2%)	12 (52.2%)	5 (38.5%)	3 (37.5%)
Missing	20 (44.4%)	8 (34.8%)	7 (53.8%)	4 (50.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8508: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 8)	BAT (N = 8)	p-value
EQ-5D-5L VAS Response Rate at Week 16			
Responder, n(%)	1 (12.5%)	0	
Non-Responder, n(%)	7 (87.5%)	8 (100.0%)	
Non-missing	4 (50.0%)	7 (87.5%)	
Missing	3 (37.5%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8508: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 45)	BAT (N = 23)	MMB (N = 13)	BAT (N = 8)
EQ-5D-5L VAS Response Rate at Week 20				
Responder, n(%)	5 (11.1%)	1 (4.3%)	1 (7.7%)	2 (25.0%)
Non-Responder, n(%)	40 (88.9%)	22 (95.7%)	12 (92.3%)	6 (75.0%)
Non-missing	16 (35.6%)	12 (52.2%)	6 (46.2%)	2 (25.0%)
Missing	24 (53.3%)	10 (43.5%)	6 (46.2%)	4 (50.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8508: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 8)	BAT (N = 8)	p-value
EQ-5D-5L VAS Response Rate at Week 20			
Responder, n(%)	1 (12.5%)	0	
Non-Responder, n(%)	7 (87.5%)	8 (100.0%)	
Non-missing	3 (37.5%)	7 (87.5%)	
Missing	4 (50.0%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8508: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 45)	BAT (N = 23)	MMB (N = 13)	BAT (N = 8)
EQ-5D-5L VAS Response Rate at Week 24				
Responder, n(%)	5 (11.1%)	2 (8.7%)	0	0
Unadjusted Relative Risk (95% CI)	1.28 (0.27, 6.09)		NA	
p-value [1]	0.76		NA	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Odds Ratio (95% CI)	1.31 (0.23, 7.35)		NA	
p-value [1]	0.76		NA	
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.12, 0.17)		NA	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	40 (88.9%)	21 (91.3%)	13 (100.0%)	8 (100.0%)
Non-missing	14 (31.1%)	11 (47.8%)	5 (38.5%)	3 (37.5%)
Missing	26 (57.8%)	10 (43.5%)	8 (61.5%)	5 (62.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-eq5d-gba.sas V.03.05 Output file: t-subgrp-eq5d-det-gba-mf.pdf 24AUG2023:16:52

Table 2.8508: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 8)	BAT (N = 8)	p-value
EQ-5D-5L VAS Response Rate at Week 24			
Responder, n(%)	0	0	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Non-Responder, n(%)	8 (100.0%)	8 (100.0%)	
Non-missing	3 (37.5%)	7 (87.5%)	
Missing	5 (62.5%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8503: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 52)	BAT (N = 18)	MMB (N = 14)	BAT (N = 21)	p-value
EQ-5D-5L VAS Response Rate at Week 4					
Responder, n(%)	9 (17.3%)	3 (16.7%)	3 (21.4%)	1 (4.8%)	
Non-Responder, n(%)	43 (82.7%)	15 (83.3%)	11 (78.6%)	20 (95.2%)	
Non-missing	25 (48.1%)	8 (44.4%)	8 (57.1%)	14 (66.7%)	
Missing	18 (34.6%)	7 (38.9%)	3 (21.4%)	6 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8503: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 52)	BAT (N = 18)	MMB (N = 14)	BAT (N = 21)	p-value
EQ-5D-5L VAS Response Rate at Week 8					
Responder, n(%)	10 (19.2%)	2 (11.1%)	2 (14.3%)	3 (14.3%)	
Non-Responder, n(%)	42 (80.8%)	16 (88.9%)	12 (85.7%)	18 (85.7%)	
Non-missing	23 (44.2%)	8 (44.4%)	9 (64.3%)	11 (52.4%)	
Missing	19 (36.5%)	8 (44.4%)	3 (21.4%)	7 (33.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8503: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 52)	BAT (N = 18)	MMB (N = 14)	BAT (N = 21)	p-value
EQ-5D-5L VAS Response Rate at Week 12					
Responder, n(%)	10 (19.2%)	3 (16.7%)	1 (7.1%)	2 (9.5%)	
Non-Responder, n(%)	42 (80.8%)	15 (83.3%)	13 (92.9%)	19 (90.5%)	
Non-missing	19 (36.5%)	7 (38.9%)	7 (50.0%)	14 (66.7%)	
Missing	23 (44.2%)	8 (44.4%)	6 (42.9%)	5 (23.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8503: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 52)	BAT (N = 18)	MMB (N = 14)	BAT (N = 21)	p-value
EQ-5D-5L VAS Response Rate at Week 16					
Responder, n(%)	7 (13.5%)	3 (16.7%)	1 (7.1%)	1 (4.8%)	
Non-Responder, n(%)	45 (86.5%)	15 (83.3%)	13 (92.9%)	20 (95.2%)	
Non-missing	20 (38.5%)	7 (38.9%)	8 (57.1%)	15 (71.4%)	
Missing	25 (48.1%)	8 (44.4%)	5 (35.7%)	5 (23.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-eq5d-gba.sas V.03.05 Output file: t-subgrp-eq5d-det-gba-sex.pdf 24AUG2023:16:52

Table 2.8503: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 52)	BAT (N = 18)	MMB (N = 14)	BAT (N = 21)	p-value
EQ-5D-5L VAS Response Rate at Week 20					
Responder, n(%)	6 (11.5%)	2 (11.1%)	1 (7.1%)	1 (4.8%)	
Non-Responder, n(%)	46 (88.5%)	16 (88.9%)	13 (92.9%)	20 (95.2%)	
Non-missing	18 (34.6%)	7 (38.9%)	7 (50.0%)	14 (66.7%)	
Missing	28 (53.8%)	9 (50.0%)	6 (42.9%)	6 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-eq5d-gba.sas V.03.05 Output file: t-subgrp-eq5d-det-gba-sex.pdf 24AUG2023:16:52

Table 2.8503: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 52)	BAT (N = 18)	MMB (N = 14)	BAT (N = 21)	p-value
EQ-5D-5L VAS Response Rate at Week 24					
Responder, n(%)	3 (5.8%)	2 (11.1%)	2 (14.3%)	0	
Unadjusted Relative Risk (95% CI)	0.52 (0.09, 2.86)		7.33 (0.38, 142.18)		
p-value [1]	0.45		0.19		
Unadjusted interaction test for Treatment*Gender [3]					NA
Unadjusted Odds Ratio (95% CI)	0.49 (0.08, 3.20)		8.60 (0.38, 193.87)		
p-value [1]	0.46		0.18		
Unadjusted Absolute Risk Difference (95% CI)	-0.05 (-0.21, 0.10)		0.14 (-0.05, 0.34)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Gender [3]					NA
Non-Responder, n(%)	49 (94.2%)	16 (88.9%)	12 (85.7%)	21 (100.0%)	
Non-missing	15 (28.8%)	6 (33.3%)	7 (50.0%)	15 (71.4%)	
Missing	34 (65.4%)	10 (55.6%)	5 (35.7%)	6 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8510: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N = 28)	BAT (N = 24)	MMB (N = 38)	BAT (N = 15)	p-value
EQ-5D-5L VAS Response Rate at Week 4					
Responder, n(%)	4 (14.3%)	2 (8.3%)	8 (21.1%)	2 (13.3%)	
Non-Responder, n(%)	24 (85.7%)	22 (91.7%)	30 (78.9%)	13 (86.7%)	
Non-missing	15 (53.6%)	14 (58.3%)	18 (47.4%)	8 (53.3%)	
Missing	9 (32.1%)	8 (33.3%)	12 (31.6%)	5 (33.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-eq5d-gba.sas V.03.05 Output file: t-subgrp-eq5d-det-gba-svb.pdf 24AUG2023:16:53

Table 2.8510: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N = 28)	BAT (N = 24)	MMB (N = 38)	BAT (N = 15)	p-value
EQ-5D-5L VAS Response Rate at Week 8					
Responder, n(%)	4 (14.3%)	4 (16.7%)	8 (21.1%)	1 (6.7%)	
Non-Responder, n(%)	24 (85.7%)	20 (83.3%)	30 (78.9%)	14 (93.3%)	
Non-missing	14 (50.0%)	13 (54.2%)	18 (47.4%)	6 (40.0%)	
Missing	10 (35.7%)	7 (29.2%)	12 (31.6%)	8 (53.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-eq5d-gba.sas V.03.05 Output file: t-subgrp-eq5d-det-gba-svb.pdf 24AUG2023:16:53

Table 2.8510: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N = 28)	BAT (N = 24)	MMB (N = 38)	BAT (N = 15)	p-value
EQ-5D-5L VAS Response Rate at Week 12					
Responder, n(%)	2 (7.1%)	4 (16.7%)	9 (23.7%)	1 (6.7%)	
Non-Responder, n(%)	26 (92.9%)	20 (83.3%)	29 (76.3%)	14 (93.3%)	
Non-missing	12 (42.9%)	13 (54.2%)	14 (36.8%)	8 (53.3%)	
Missing	14 (50.0%)	7 (29.2%)	15 (39.5%)	6 (40.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-eq5d-gba.sas V.03.05 Output file: t-subgrp-eq5d-det-gba-svb.pdf 24AUG2023:16:53

Table 2.8510: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N = 28)	BAT (N = 24)	MMB (N = 38)	BAT (N = 15)	p-value
EQ-5D-5L VAS Response Rate at Week 16					
Responder, n(%)	1 (3.6%)	3 (12.5%)	7 (18.4%)	1 (6.7%)	
Non-Responder, n(%)	27 (96.4%)	21 (87.5%)	31 (81.6%)	14 (93.3%)	
Non-missing	15 (53.6%)	14 (58.3%)	13 (34.2%)	8 (53.3%)	
Missing	12 (42.9%)	7 (29.2%)	18 (47.4%)	6 (40.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8510: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N = 28)	BAT (N = 24)	MMB (N = 38)	BAT (N = 15)	p-value
EQ-5D-5L VAS Response Rate at Week 20					
Responder, n(%)	2 (7.1%)	2 (8.3%)	5 (13.2%)	1 (6.7%)	
Non-Responder, n(%)	26 (92.9%)	22 (91.7%)	33 (86.8%)	14 (93.3%)	
Non-missing	13 (46.4%)	15 (62.5%)	12 (31.6%)	6 (40.0%)	
Missing	13 (46.4%)	7 (29.2%)	21 (55.3%)	8 (53.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-eq5d-gba.sas V.03.05 Output file: t-subgrp-eq5d-det-gba-svb.pdf 24AUG2023:16:53

Table 2.8510: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N = 28)	BAT (N = 24)	MMB (N = 38)	BAT (N = 15)	p-value
EQ-5D-5L VAS Response Rate at Week 24					
Responder, n(%)	0	1 (4.2%)	5 (13.2%)	1 (6.7%)	
Unadjusted Relative Risk (95% CI)	0.29 (0.01, 6.74)		1.97 (0.25, 15.52)		
p-value [1]	0.44		0.52		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Odds Ratio (95% CI)	0.27 (0.01, 7.07)		2.12 (0.23, 19.85)		
p-value [1]	0.44		0.51		
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.15, 0.06)		0.06 (-0.10, 0.23)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Non-Responder, n(%)	28 (100.0%)	23 (95.8%)	33 (86.8%)	14 (93.3%)	
Non-missing	12 (42.9%)	15 (62.5%)	10 (26.3%)	6 (40.0%)	
Missing	16 (57.1%)	8 (33.3%)	23 (60.5%)	8 (53.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8509: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 42)	BAT (N = 20)	MMB (N = 24)	BAT (N = 19)	p-value
EQ-5D-5L VAS Response Rate at Week 4					
Responder, n(%)	6 (14.3%)	2 (10.0%)	6 (25.0%)	2 (10.5%)	
Non-Responder, n(%)	36 (85.7%)	18 (90.0%)	18 (75.0%)	17 (89.5%)	
Non-missing	23 (54.8%)	11 (55.0%)	10 (41.7%)	11 (57.9%)	
Missing	13 (31.0%)	7 (35.0%)	8 (33.3%)	6 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-eq5d-gba.sas V.03.05 Output file: t-subgrp-eq5d-det-gba-tss.pdf 24AUG2023:16:53

Table 2.8509: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 42)	BAT (N = 20)	MMB (N = 24)	BAT (N = 19)	p-value
EQ-5D-5L VAS Response Rate at Week 8					
Responder, n(%)	9 (21.4%)	2 (10.0%)	3 (12.5%)	3 (15.8%)	
Non-Responder, n(%)	33 (78.6%)	18 (90.0%)	21 (87.5%)	16 (84.2%)	
Non-missing	19 (45.2%)	10 (50.0%)	13 (54.2%)	9 (47.4%)	
Missing	14 (33.3%)	8 (40.0%)	8 (33.3%)	7 (36.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8509: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 42)	BAT (N = 20)	MMB (N = 24)	BAT (N = 19)	p-value
EQ-5D-5L VAS Response Rate at Week 12					
Responder, n(%)	7 (16.7%)	3 (15.0%)	4 (16.7%)	2 (10.5%)	
Non-Responder, n(%)	35 (83.3%)	17 (85.0%)	20 (83.3%)	17 (89.5%)	
Non-missing	18 (42.9%)	10 (50.0%)	8 (33.3%)	11 (57.9%)	
Missing	17 (40.5%)	7 (35.0%)	12 (50.0%)	6 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8509: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 42)	BAT (N = 20)	MMB (N = 24)	BAT (N = 19)	p-value
EQ-5D-5L VAS Response Rate at Week 16					
Responder, n(%)	5 (11.9%)	2 (10.0%)	3 (12.5%)	2 (10.5%)	
Non-Responder, n(%)	37 (88.1%)	18 (90.0%)	21 (87.5%)	17 (89.5%)	
Non-missing	18 (42.9%)	11 (55.0%)	10 (41.7%)	11 (57.9%)	
Missing	19 (45.2%)	7 (35.0%)	11 (45.8%)	6 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8509: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 42)	BAT (N = 20)	MMB (N = 24)	BAT (N = 19)	p-value
EQ-5D-5L VAS Response Rate at Week 20					
Responder, n(%)	6 (14.3%)	1 (5.0%)	1 (4.2%)	2 (10.5%)	
Non-Responder, n(%)	36 (85.7%)	19 (95.0%)	23 (95.8%)	17 (89.5%)	
Non-missing	17 (40.5%)	10 (50.0%)	8 (33.3%)	11 (57.9%)	
Missing	19 (45.2%)	9 (45.0%)	15 (62.5%)	6 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8509: Analysis of Response Rate (deterioration) in EQ-5D-5L VAS by Visit and Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 42)	BAT (N = 20)	MMB (N = 24)	BAT (N = 19)	p-value
EQ-5D-5L VAS Response Rate at Week 24					
Responder, n(%)	3 (7.1%)	1 (5.0%)	2 (8.3%)	1 (5.3%)	
Unadjusted Relative Risk (95% CI)	1.43 (0.16, 12.89)		1.58 (0.16, 16.17)		
p-value [1]	0.75		0.70		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Unadjusted Odds Ratio (95% CI)	1.46 (0.14, 15.00)		1.64 (0.14, 19.54)		
p-value [1]	0.75		0.70		
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.10, 0.14)		0.03 (-0.12, 0.18)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Non-Responder, n(%)	39 (92.9%)	19 (95.0%)	22 (91.7%)	18 (94.7%)	
Non-missing	16 (38.1%)	10 (50.0%)	6 (25.0%)	11 (57.9%)	
Missing	23 (54.8%)	9 (45.0%)	16 (66.7%)	7 (36.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8402: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	BAT (N = 9)	MMB (N = 42)	BAT (N = 30)	p-value
EQ-5D-5L VAS Response Rate at Week 4					
Responder, n(%)	2 (8.3%)	3 (33.3%)	6 (14.3%)	4 (13.3%)	
Non-Responder, n(%)	22 (91.7%)	6 (66.7%)	36 (85.7%)	26 (86.7%)	
Non-missing	15 (62.5%)	2 (22.2%)	22 (52.4%)	17 (56.7%)	
Missing	7 (29.2%)	4 (44.4%)	14 (33.3%)	9 (30.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8402: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	BAT (N = 9)	MMB (N = 42)	BAT (N = 30)	p-value
EQ-5D-5L VAS Response Rate at Week 8					
Responder, n(%)	0	2 (22.2%)	5 (11.9%)	5 (16.7%)	
Non-Responder, n(%)	24 (100.0%)	7 (77.8%)	37 (88.1%)	25 (83.3%)	
Non-missing	17 (70.8%)	2 (22.2%)	22 (52.4%)	15 (50.0%)	
Missing	7 (29.2%)	5 (55.6%)	15 (35.7%)	10 (33.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8402: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	BAT (N = 9)	MMB (N = 42)	BAT (N = 30)	p-value
EQ-5D-5L VAS Response Rate at Week 12					
Responder, n(%)	2 (8.3%)	0	8 (19.0%)	6 (20.0%)	
Non-Responder, n(%)	22 (91.7%)	9 (100.0%)	34 (81.0%)	24 (80.0%)	
Non-missing	11 (45.8%)	4 (44.4%)	16 (38.1%)	16 (53.3%)	
Missing	11 (45.8%)	5 (55.6%)	18 (42.9%)	8 (26.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8402: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	BAT (N = 9)	MMB (N = 42)	BAT (N = 30)	p-value
EQ-5D-5L VAS Response Rate at Week 16					
Responder, n(%)	2 (8.3%)	2 (22.2%)	6 (14.3%)	2 (6.7%)	
Non-Responder, n(%)	22 (91.7%)	7 (77.8%)	36 (85.7%)	28 (93.3%)	
Non-missing	10 (41.7%)	2 (22.2%)	18 (42.9%)	20 (66.7%)	
Missing	12 (50.0%)	5 (55.6%)	18 (42.9%)	8 (26.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8402: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	BAT (N = 9)	MMB (N = 42)	BAT (N = 30)	p-value
EQ-5D-5L VAS Response Rate at Week 20					
Responder, n(%)	3 (12.5%)	1 (11.1%)	9 (21.4%)	2 (6.7%)	
Non-Responder, n(%)	21 (87.5%)	8 (88.9%)	33 (78.6%)	28 (93.3%)	
Non-missing	7 (29.2%)	3 (33.3%)	13 (31.0%)	18 (60.0%)	
Missing	14 (58.3%)	5 (55.6%)	20 (47.6%)	10 (33.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8402: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	BAT (N = 9)	MMB (N = 42)	BAT (N = 30)	p-value
EQ-5D-5L VAS Response Rate at Week 24					
Responder, n(%)	1 (4.2%)	2 (22.2%)	8 (19.0%)	4 (13.3%)	
Unadjusted Inverse Relative Risk (95% CI)	5.33 (0.55, 51.88)		0.70 (0.23, 2.11)		
p-value [1]	0.15		0.53		
Unadjusted interaction test for Treatment*Age Group [3]					0.18
Unadjusted Inverse Odds Ratio (95% CI)	6.57 (0.52, 83.76)		0.65 (0.18, 2.41)		
p-value [1]	0.15		0.52		
Unadjusted Absolute Risk Difference (95% CI)	-0.18 (-0.46, 0.10)		0.06 (-0.11, 0.23)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		0.62 (0.20, 1.90)		
p-value [2]	NE		0.40		
Adjusted interaction test for Treatment*Age Group [3]					0.17
Non-Responder, n(%)	23 (95.8%)	7 (77.8%)	34 (81.0%)	26 (86.7%)	
Non-missing	5 (20.8%)	2 (22.2%)	13 (31.0%)	15 (50.0%)	
Missing	18 (75.0%)	5 (55.6%)	21 (50.0%)	11 (36.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8406: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 49)	BAT (N = 31)	MMB (N = 17)	BAT (N = 8)	p-value
EQ-5D-5L VAS Response Rate at Week 4					
Responder, n(%)	7 (14.3%)	5 (16.1%)	1 (5.9%)	2 (25.0%)	
Non-Responder, n(%)	42 (85.7%)	26 (83.9%)	16 (94.1%)	6 (75.0%)	
Non-missing	27 (55.1%)	15 (48.4%)	10 (58.8%)	4 (50.0%)	
Missing	15 (30.6%)	11 (35.5%)	6 (35.3%)	2 (25.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-eq5d-gba.sas V.03.05 Output file: t-subgrp-eq5d-imp-gba-dip2.pdf 24AUG2023:16:52

Table 2.8406: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 49)	BAT (N = 31)	MMB (N = 17)	BAT (N = 8)	p-value
EQ-5D-5L VAS Response Rate at Week 8					
Responder, n(%)	4 (8.2%)	6 (19.4%)	1 (5.9%)	1 (12.5%)	
Non-Responder, n(%)	45 (91.8%)	25 (80.6%)	16 (94.1%)	7 (87.5%)	
Non-missing	29 (59.2%)	12 (38.7%)	10 (58.8%)	5 (62.5%)	
Missing	16 (32.7%)	13 (41.9%)	6 (35.3%)	2 (25.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8406: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 49)	BAT (N = 31)	MMB (N = 17)	BAT (N = 8)	p-value
EQ-5D-5L VAS Response Rate at Week 12					
Responder, n(%)	7 (14.3%)	4 (12.9%)	3 (17.6%)	2 (25.0%)	
Non-Responder, n(%)	42 (85.7%)	27 (87.1%)	14 (82.4%)	6 (75.0%)	
Non-missing	20 (40.8%)	16 (51.6%)	7 (41.2%)	4 (50.0%)	
Missing	22 (44.9%)	11 (35.5%)	7 (41.2%)	2 (25.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-eq5d-gba.sas V.03.05 Output file: t-subgrp-eq5d-imp-gba-dip2.pdf 24AUG2023:16:52

Table 2.8406: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 49)	BAT (N = 31)	MMB (N = 17)	BAT (N = 8)	p-value
EQ-5D-5L VAS Response Rate at Week 16					
Responder, n(%)	6 (12.2%)	4 (12.9%)	2 (11.8%)	0	
Non-Responder, n(%)	43 (87.8%)	27 (87.1%)	15 (88.2%)	8 (100.0%)	
Non-missing	21 (42.9%)	16 (51.6%)	7 (41.2%)	6 (75.0%)	
Missing	22 (44.9%)	11 (35.5%)	8 (47.1%)	2 (25.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8406: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 49)	BAT (N = 31)	MMB (N = 17)	BAT (N = 8)	p-value
EQ-5D-5L VAS Response Rate at Week 20					
Responder, n(%)	10 (20.4%)	3 (9.7%)	2 (11.8%)	0	
Non-Responder, n(%)	39 (79.6%)	28 (90.3%)	15 (88.2%)	8 (100.0%)	
Non-missing	15 (30.6%)	15 (48.4%)	5 (29.4%)	6 (75.0%)	
Missing	24 (49.0%)	13 (41.9%)	10 (58.8%)	2 (25.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8406: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 49)	BAT (N = 31)	MMB (N = 17)	BAT (N = 8)	p-value
EQ-5D-5L VAS Response Rate at Week 24					
Responder, n(%)	7 (14.3%)	5 (16.1%)	2 (11.8%)	1 (12.5%)	
Unadjusted Inverse Relative Risk (95% CI)	1.13 (0.39, 3.25)		1.06 (0.11, 10.07)		
p-value [1]	0.82		0.96		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					0.96
Unadjusted Inverse Odds Ratio (95% CI)	1.15 (0.33, 4.02)		1.07 (0.08, 13.90)		
p-value [1]	0.82		0.96		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.18, 0.14)		-0.01 (-0.28, 0.27)		
Adjusted Inverse Relative Risk (95% CI) [2]	1.17 (0.38, 3.55)		NE		
p-value [2]	0.79		NE		
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					0.99
Non-Responder, n(%)	42 (85.7%)	26 (83.9%)	15 (88.2%)	7 (87.5%)	
Non-missing	13 (26.5%)	13 (41.9%)	5 (29.4%)	4 (50.0%)	
Missing	29 (59.2%)	13 (41.9%)	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8405: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 5)	BAT (N = 7)	MMB (N = 44)	BAT (N = 24)
EQ-5D-5L VAS Response Rate at Week 4				
Responder, n(%)	0	2 (28.6%)	7 (15.9%)	3 (12.5%)
Non-Responder, n(%)	5 (100.0%)	5 (71.4%)	37 (84.1%)	21 (87.5%)
Non-missing	2 (40.0%)	1 (14.3%)	25 (56.8%)	14 (58.3%)
Missing	3 (60.0%)	4 (57.1%)	12 (27.3%)	7 (29.2%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8405: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 17)	BAT (N = 8)	p-value
EQ-5D-5L VAS Response Rate at Week 4			
Responder, n(%)	1 (5.9%)	2 (25.0%)	
Non-Responder, n(%)	16 (94.1%)	6 (75.0%)	
Non-missing	10 (58.8%)	4 (50.0%)	
Missing	6 (35.3%)	2 (25.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8405: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 5)	BAT (N = 7)	MMB (N = 44)	BAT (N = 24)
EQ-5D-5L VAS Response Rate at Week 8				
Responder, n(%)	0	2 (28.6%)	4 (9.1%)	4 (16.7%)
Non-Responder, n(%)	5 (100.0%)	5 (71.4%)	40 (90.9%)	20 (83.3%)
Non-missing	2 (40.0%)	2 (28.6%)	27 (61.4%)	10 (41.7%)
Missing	3 (60.0%)	3 (42.9%)	13 (29.5%)	10 (41.7%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8405: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 17)	BAT (N = 8)	p-value
EQ-5D-5L VAS Response Rate at Week 8			
Responder, n(%)	1 (5.9%)	1 (12.5%)	
Non-Responder, n(%)	16 (94.1%)	7 (87.5%)	
Non-missing	10 (58.8%)	5 (62.5%)	
Missing	6 (35.3%)	2 (25.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8405: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 5)	BAT (N = 7)	MMB (N = 44)	BAT (N = 24)
EQ-5D-5L VAS Response Rate at Week 12				
Responder, n(%)	0	0	7 (15.9%)	4 (16.7%)
Non-Responder, n(%)	5 (100.0%)	7 (100.0%)	37 (84.1%)	20 (83.3%)
Non-missing	1 (20.0%)	4 (57.1%)	19 (43.2%)	12 (50.0%)
Missing	4 (80.0%)	3 (42.9%)	18 (40.9%)	8 (33.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8405: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 17)	BAT (N = 8)	p-value
EQ-5D-5L VAS Response Rate at Week 12			
Responder, n(%)	3 (17.6%)	2 (25.0%)	
Non-Responder, n(%)	14 (82.4%)	6 (75.0%)	
Non-missing	7 (41.2%)	4 (50.0%)	
Missing	7 (41.2%)	2 (25.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8405: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 5)	BAT (N = 7)	MMB (N = 44)	BAT (N = 24)
EQ-5D-5L VAS Response Rate at Week 16				
Responder, n(%)	0	1 (14.3%)	6 (13.6%)	3 (12.5%)
Non-Responder, n(%)	5 (100.0%)	6 (85.7%)	38 (86.4%)	21 (87.5%)
Non-missing	1 (20.0%)	3 (42.9%)	20 (45.5%)	13 (54.2%)
Missing	4 (80.0%)	3 (42.9%)	18 (40.9%)	8 (33.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8405: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 17)	BAT (N = 8)	p-value
EQ-5D-5L VAS Response Rate at Week 16			
Responder, n(%)	2 (11.8%)	0	
Non-Responder, n(%)	15 (88.2%)	8 (100.0%)	
Non-missing	7 (41.2%)	6 (75.0%)	
Missing	8 (47.1%)	2 (25.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8405: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 5)	BAT (N = 7)	MMB (N = 44)	BAT (N = 24)
EQ-5D-5L VAS Response Rate at Week 20				
Responder, n(%)	0	1 (14.3%)	10 (22.7%)	2 (8.3%)
Non-Responder, n(%)	5 (100.0%)	6 (85.7%)	34 (77.3%)	22 (91.7%)
Non-missing	1 (20.0%)	2 (28.6%)	14 (31.8%)	13 (54.2%)
Missing	4 (80.0%)	4 (57.1%)	20 (45.5%)	9 (37.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8405: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 17)	BAT (N = 8)	p-value
EQ-5D-5L VAS Response Rate at Week 20			
Responder, n(%)	2 (11.8%)	0	
Non-Responder, n(%)	15 (88.2%)	8 (100.0%)	
Non-missing	5 (29.4%)	6 (75.0%)	
Missing	10 (58.8%)	2 (25.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8405: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 5)	BAT (N = 7)	MMB (N = 44)	BAT (N = 24)
EQ-5D-5L VAS Response Rate at Week 24				
Responder, n(%)	0	1 (14.3%)	7 (15.9%)	4 (16.7%)
Unadjusted Inverse Relative Risk (95% CI)	2.25 (0.11, 46.13)		1.05 (0.34, 3.22)	
p-value [1]	0.60		0.94	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	2.54 (0.09, 75.77)		1.06 (0.28, 4.05)	
p-value [1]	0.59		0.94	
Unadjusted Absolute Risk Difference (95% CI)	-0.10 (-0.45, 0.25)		-0.01 (-0.19, 0.18)	
Adjusted Inverse Relative Risk (95% CI) [2]	NE		1.10 (0.32, 3.84)	
p-value [2]	NE		0.88	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Non-Responder, n(%)	5 (100.0%)	6 (85.7%)	37 (84.1%)	20 (83.3%)
Non-missing	1 (20.0%)	2 (28.6%)	12 (27.3%)	11 (45.8%)
Missing	4 (80.0%)	4 (57.1%)	25 (56.8%)	9 (37.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8405: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 17)	BAT (N = 8)	p-value
EQ-5D-5L VAS Response Rate at Week 24			
Responder, n(%)	2 (11.8%)	1 (12.5%)	
Unadjusted Inverse Relative Risk (95% CI)	1.06 (0.11, 10.07)		
p-value [1]	0.96		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NE
Unadjusted Inverse Odds Ratio (95% CI)	1.07 (0.08, 13.90)		
p-value [1]	0.96		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.28, 0.27)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NE
Non-Responder, n(%)	15 (88.2%)	7 (87.5%)	
Non-missing	5 (29.4%)	4 (50.0%)	
Missing	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8404: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N = 29)	BAT (N = 7)	MMB (N = 37)	BAT (N = 32)	p-value
EQ-5D-5L VAS Response Rate at Week 4					
Responder, n(%)	3 (10.3%)	1 (14.3%)	5 (13.5%)	6 (18.8%)	
Non-Responder, n(%)	26 (89.7%)	6 (85.7%)	32 (86.5%)	26 (81.3%)	
Non-missing	13 (44.8%)	2 (28.6%)	24 (64.9%)	17 (53.1%)	
Missing	13 (44.8%)	4 (57.1%)	8 (21.6%)	9 (28.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-eq5d-gba.sas V.03.05 Output file: t-subgrp-eq5d-imp-gba-geo.pdf 24AUG2023:16:52

Table 2.8404: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N = 29)	BAT (N = 7)	MMB (N = 37)	BAT (N = 32)	p-value
EQ-5D-5L VAS Response Rate at Week 8					
Responder, n(%)	3 (10.3%)	2 (28.6%)	2 (5.4%)	5 (15.6%)	
Non-Responder, n(%)	26 (89.7%)	5 (71.4%)	35 (94.6%)	27 (84.4%)	
Non-missing	11 (37.9%)	0	28 (75.7%)	17 (53.1%)	
Missing	15 (51.7%)	5 (71.4%)	7 (18.9%)	10 (31.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-eq5d-gba.sas V.03.05 Output file: t-subgrp-eq5d-imp-gba-geo.pdf 24AUG2023:16:52

Table 2.8404: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N = 29)	BAT (N = 7)	MMB (N = 37)	BAT (N = 32)	p-value
EQ-5D-5L VAS Response Rate at Week 12					
Responder, n(%)	4 (13.8%)	2 (28.6%)	6 (16.2%)	4 (12.5%)	
Non-Responder, n(%)	25 (86.2%)	5 (71.4%)	31 (83.8%)	28 (87.5%)	
Non-missing	7 (24.1%)	1 (14.3%)	20 (54.1%)	19 (59.4%)	
Missing	18 (62.1%)	4 (57.1%)	11 (29.7%)	9 (28.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8404: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N = 29)	BAT (N = 7)	MMB (N = 37)	BAT (N = 32)	p-value
EQ-5D-5L VAS Response Rate at Week 16					
Responder, n(%)	5 (17.2%)	0	3 (8.1%)	4 (12.5%)	
Non-Responder, n(%)	24 (82.8%)	7 (100.0%)	34 (91.9%)	28 (87.5%)	
Non-missing	5 (17.2%)	3 (42.9%)	23 (62.2%)	19 (59.4%)	
Missing	19 (65.5%)	4 (57.1%)	11 (29.7%)	9 (28.1%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-eq5d-gba.sas V.03.05 Output file: t-subgrp-eq5d-imp-gba-geo.pdf 24AUG2023:16:52

Table 2.8404: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N = 29)	BAT (N = 7)	MMB (N = 37)	BAT (N = 32)	p-value
EQ-5D-5L VAS Response Rate at Week 20					
Responder, n(%)	4 (13.8%)	1 (14.3%)	8 (21.6%)	2 (6.3%)	
Non-Responder, n(%)	25 (86.2%)	6 (85.7%)	29 (78.4%)	30 (93.8%)	
Non-missing	7 (24.1%)	2 (28.6%)	13 (35.1%)	19 (59.4%)	
Missing	18 (62.1%)	4 (57.1%)	16 (43.2%)	11 (34.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-eq5d-gba.sas V.03.05 Output file: t-subgrp-eq5d-imp-gba-geo.pdf 24AUG2023:16:52

Table 2.8404: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N = 29)	BAT (N = 7)	MMB (N = 37)	BAT (N = 32)	p-value
EQ-5D-5L VAS Response Rate at Week 24					
Responder, n(%)	5 (17.2%)	2 (28.6%)	4 (10.8%)	4 (12.5%)	
Unadjusted Inverse Relative Risk (95% CI)	1.66 (0.40, 6.84)		1.16 (0.31, 4.25)		
p-value [1]	0.48		0.83		
Unadjusted interaction test for Treatment*Region [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	1.92 (0.29, 12.86)		1.18 (0.27, 5.15)		
p-value [1]	0.50		0.83		
Unadjusted Absolute Risk Difference (95% CI)	-0.11 (-0.48, 0.25)		-0.02 (-0.17, 0.14)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Region [3]					NA
Non-Responder, n(%)	24 (82.8%)	5 (71.4%)	33 (89.2%)	28 (87.5%)	
Non-missing	4 (13.8%)	1 (14.3%)	14 (37.8%)	16 (50.0%)	
Missing	20 (69.0%)	4 (57.1%)	19 (51.4%)	12 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-eq5d-gba.sas V.03.05 Output file: t-subgrp-eq5d-imp-gba-geo.pdf 24AUG2023:16:52

Table 2.8407: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 27)	BAT (N = 6)	MMB (N = 39)	BAT (N = 33)	p-value
EQ-5D-5L VAS Response Rate at Week 4					
Responder, n(%)	3 (11.1%)	0	5 (12.8%)	7 (21.2%)	
Non-Responder, n(%)	24 (88.9%)	6 (100.0%)	34 (87.2%)	26 (78.8%)	
Non-missing	15 (55.6%)	2 (33.3%)	22 (56.4%)	17 (51.5%)	
Missing	9 (33.3%)	4 (66.7%)	12 (30.8%)	9 (27.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8407: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 27)	BAT (N = 6)	MMB (N = 39)	BAT (N = 33)	p-value
EQ-5D-5L VAS Response Rate at Week 8					
Responder, n(%)	2 (7.4%)	0	3 (7.7%)	7 (21.2%)	
Non-Responder, n(%)	25 (92.6%)	6 (100.0%)	36 (92.3%)	26 (78.8%)	
Non-missing	14 (51.9%)	2 (33.3%)	25 (64.1%)	15 (45.5%)	
Missing	11 (40.7%)	4 (66.7%)	11 (28.2%)	11 (33.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8407: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 27)	BAT (N = 6)	MMB (N = 39)	BAT (N = 33)	p-value
EQ-5D-5L VAS Response Rate at Week 12					
Responder, n(%)	4 (14.8%)	0	6 (15.4%)	6 (18.2%)	
Non-Responder, n(%)	23 (85.2%)	6 (100.0%)	33 (84.6%)	27 (81.8%)	
Non-missing	10 (37.0%)	2 (33.3%)	17 (43.6%)	18 (54.5%)	
Missing	13 (48.1%)	4 (66.7%)	16 (41.0%)	9 (27.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-eq5d-gba.sas V.03.05 Output file: t-subgrp-eq5d-imp-gba-hgb.pdf 24AUG2023:16:52

Table 2.8407: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 27)	BAT (N = 6)	MMB (N = 39)	BAT (N = 33)	p-value
EQ-5D-5L VAS Response Rate at Week 16					
Responder, n(%)	4 (14.8%)	0	4 (10.3%)	4 (12.1%)	
Non-Responder, n(%)	23 (85.2%)	6 (100.0%)	35 (89.7%)	29 (87.9%)	
Non-missing	9 (33.3%)	2 (33.3%)	19 (48.7%)	20 (60.6%)	
Missing	14 (51.9%)	4 (66.7%)	16 (41.0%)	9 (27.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8407: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 27)	BAT (N = 6)	MMB (N = 39)	BAT (N = 33)	p-value
EQ-5D-5L VAS Response Rate at Week 20					
Responder, n(%)	5 (18.5%)	0	7 (17.9%)	3 (9.1%)	
Non-Responder, n(%)	22 (81.5%)	6 (100.0%)	32 (82.1%)	30 (90.9%)	
Non-missing	8 (29.6%)	2 (33.3%)	12 (30.8%)	19 (57.6%)	
Missing	14 (51.9%)	4 (66.7%)	20 (51.3%)	11 (33.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8407: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 27)	BAT (N = 6)	MMB (N = 39)	BAT (N = 33)	p-value
EQ-5D-5L VAS Response Rate at Week 24					
Responder, n(%)	4 (14.8%)	0	5 (12.8%)	6 (18.2%)	
Unadjusted Inverse Relative Risk (95% CI)	0.44 (0.03, 7.32)		1.42 (0.48, 4.23)		
p-value [1]	0.57		0.53		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE
Unadjusted Inverse Odds Ratio (95% CI)	0.40 (0.02, 8.47)		1.51 (0.42, 5.49)		
p-value [1]	0.56		0.53		
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.15, 0.32)		-0.05 (-0.22, 0.11)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		1.37 (0.45, 4.18)		
p-value [2]	NE		0.59		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE
Non-Responder, n(%)	23 (85.2%)	6 (100.0%)	34 (87.2%)	27 (81.8%)	
Non-missing	6 (22.2%)	2 (33.3%)	12 (30.8%)	15 (45.5%)	
Missing	17 (63.0%)	4 (66.7%)	22 (56.4%)	12 (36.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8408: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 45)	BAT (N = 23)	MMB (N = 13)	BAT (N = 8)
EQ-5D-5L VAS Response Rate at Week 4				
Responder, n(%)	6 (13.3%)	4 (17.4%)	2 (15.4%)	0
Non-Responder, n(%)	39 (86.7%)	19 (82.6%)	11 (84.6%)	8 (100.0%)
Non-missing	24 (53.3%)	11 (47.8%)	8 (61.5%)	4 (50.0%)
Missing	15 (33.3%)	8 (34.8%)	3 (23.1%)	4 (50.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-eq5d-gba.sas V.03.05 Output file: t-subgrp-eq5d-imp-gba-mf.pdf 24AUG2023:16:52

Table 2.8408: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 8)	BAT (N = 8)	p-value
EQ-5D-5L VAS Response Rate at Week 4			
Responder, n(%)	0	3 (37.5%)	
Non-Responder, n(%)	8 (100.0%)	5 (62.5%)	
Non-missing	5 (62.5%)	4 (50.0%)	
Missing	3 (37.5%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8408: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 45)	BAT (N = 23)	MMB (N = 13)	BAT (N = 8)
EQ-5D-5L VAS Response Rate at Week 8				
Responder, n(%)	3 (6.7%)	3 (13.0%)	2 (15.4%)	1 (12.5%)
Non-Responder, n(%)	42 (93.3%)	20 (87.0%)	11 (84.6%)	7 (87.5%)
Non-missing	27 (60.0%)	11 (47.8%)	7 (53.8%)	3 (37.5%)
Missing	15 (33.3%)	9 (39.1%)	4 (30.8%)	4 (50.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8408: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 8)	BAT (N = 8)	p-value
EQ-5D-5L VAS Response Rate at Week 8			
Responder, n(%)	0	3 (37.5%)	
Non-Responder, n(%)	8 (100.0%)	5 (62.5%)	
Non-missing	5 (62.5%)	3 (37.5%)	
Missing	3 (37.5%)	2 (25.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8408: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 45)	BAT (N = 23)	MMB (N = 13)	BAT (N = 8)
EQ-5D-5L VAS Response Rate at Week 12				
Responder, n(%)	7 (15.6%)	4 (17.4%)	3 (23.1%)	1 (12.5%)
Non-Responder, n(%)	38 (84.4%)	19 (82.6%)	10 (76.9%)	7 (87.5%)
Non-missing	19 (42.2%)	11 (47.8%)	3 (23.1%)	3 (37.5%)
Missing	19 (42.2%)	8 (34.8%)	7 (53.8%)	4 (50.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8408: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 8)	BAT (N = 8)	p-value
EQ-5D-5L VAS Response Rate at Week 12			
Responder, n(%)	0	1 (12.5%)	
Non-Responder, n(%)	8 (100.0%)	7 (87.5%)	
Non-missing	5 (62.5%)	6 (75.0%)	
Missing	3 (37.5%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8408: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 45)	BAT (N = 23)	MMB (N = 13)	BAT (N = 8)
EQ-5D-5L VAS Response Rate at Week 16				
Responder, n(%)	5 (11.1%)	1 (4.3%)	3 (23.1%)	0
Non-Responder, n(%)	40 (88.9%)	22 (95.7%)	10 (76.9%)	8 (100.0%)
Non-missing	20 (44.4%)	14 (60.9%)	3 (23.1%)	4 (50.0%)
Missing	20 (44.4%)	8 (34.8%)	7 (53.8%)	4 (50.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8408: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 8)	BAT (N = 8)	p-value
EQ-5D-5L VAS Response Rate at Week 16			
Responder, n(%)	0	3 (37.5%)	
Non-Responder, n(%)	8 (100.0%)	5 (62.5%)	
Non-missing	5 (62.5%)	4 (50.0%)	
Missing	3 (37.5%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8408: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 45)	BAT (N = 23)	MMB (N = 13)	BAT (N = 8)
EQ-5D-5L VAS Response Rate at Week 20				
Responder, n(%)	8 (17.8%)	1 (4.3%)	3 (23.1%)	1 (12.5%)
Non-Responder, n(%)	37 (82.2%)	22 (95.7%)	10 (76.9%)	7 (87.5%)
Non-missing	13 (28.9%)	12 (52.2%)	4 (30.8%)	3 (37.5%)
Missing	24 (53.3%)	10 (43.5%)	6 (46.2%)	4 (50.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8408: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 8)	BAT (N = 8)	p-value
EQ-5D-5L VAS Response Rate at Week 20			
Responder, n(%)	1 (12.5%)	1 (12.5%)	
Non-Responder, n(%)	7 (87.5%)	7 (87.5%)	
Non-missing	3 (37.5%)	6 (75.0%)	
Missing	4 (50.0%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8408: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 45)	BAT (N = 23)	MMB (N = 13)	BAT (N = 8)
EQ-5D-5L VAS Response Rate at Week 24				
Responder, n(%)	5 (11.1%)	3 (13.0%)	4 (30.8%)	0
Unadjusted Inverse Relative Risk (95% CI)	1.17 (0.31, 4.48)		0.17 (0.01, 2.84)	
p-value [1]	0.81		0.22	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	1.20 (0.26, 5.53)		0.12 (0.01, 2.66)	
p-value [1]	0.82		0.18	
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.18, 0.15)		0.27 (-0.02, 0.55)	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	40 (88.9%)	20 (87.0%)	9 (69.2%)	8 (100.0%)
Non-missing	14 (31.1%)	10 (43.5%)	1 (7.7%)	3 (37.5%)
Missing	26 (57.8%)	10 (43.5%)	8 (61.5%)	5 (62.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8408: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 8)	BAT (N = 8)	p-value
EQ-5D-5L VAS Response Rate at Week 24			
Responder, n(%)	0	3 (37.5%)	
Unadjusted Inverse Relative Risk (95% CI)	7.00 (0.42, 116.91)		
p-value [1]	0.18		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	10.82 (0.46, 252.80		
p-value [1]	0.14		
Unadjusted Absolute Risk Difference (95% CI)	-0.33 (-0.69, 0.02)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Non-Responder, n(%)	8 (100.0%)	5 (62.5%)	
Non-missing	3 (37.5%)	4 (50.0%)	
Missing	5 (62.5%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8403: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 52)	BAT (N = 18)	MMB (N = 14)	BAT (N = 21)	p-value
EQ-5D-5L VAS Response Rate at Week 4					
Responder, n(%)	5 (9.6%)	1 (5.6%)	3 (21.4%)	6 (28.6%)	
Non-Responder, n(%)	47 (90.4%)	17 (94.4%)	11 (78.6%)	15 (71.4%)	
Non-missing	29 (55.8%)	10 (55.6%)	8 (57.1%)	9 (42.9%)	
Missing	18 (34.6%)	7 (38.9%)	3 (21.4%)	6 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8403: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 52)	BAT (N = 18)	MMB (N = 14)	BAT (N = 21)	p-value
EQ-5D-5L VAS Response Rate at Week 8					
Responder, n(%)	1 (1.9%)	2 (11.1%)	4 (28.6%)	5 (23.8%)	
Non-Responder, n(%)	51 (98.1%)	16 (88.9%)	10 (71.4%)	16 (76.2%)	
Non-missing	32 (61.5%)	8 (44.4%)	7 (50.0%)	9 (42.9%)	
Missing	19 (36.5%)	8 (44.4%)	3 (21.4%)	7 (33.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-eq5d-gba.sas V.03.05 Output file: t-subgrp-eq5d-imp-gba-sex.pdf 24AUG2023:16:52

Table 2.8403: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 52)	BAT (N = 18)	MMB (N = 14)	BAT (N = 21)	p-value
EQ-5D-5L VAS Response Rate at Week 12					
Responder, n(%)	7 (13.5%)	2 (11.1%)	3 (21.4%)	4 (19.0%)	
Non-Responder, n(%)	45 (86.5%)	16 (88.9%)	11 (78.6%)	17 (81.0%)	
Non-missing	22 (42.3%)	8 (44.4%)	5 (35.7%)	12 (57.1%)	
Missing	23 (44.2%)	8 (44.4%)	6 (42.9%)	5 (23.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-eq5d-gba.sas V.03.05 Output file: t-subgrp-eq5d-imp-gba-sex.pdf 24AUG2023:16:52

Table 2.8403: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 52)	BAT (N = 18)	MMB (N = 14)	BAT (N = 21)	p-value
EQ-5D-5L VAS Response Rate at Week 16					
Responder, n(%)	5 (9.6%)	0	3 (21.4%)	4 (19.0%)	
Non-Responder, n(%)	47 (90.4%)	18 (100.0%)	11 (78.6%)	17 (81.0%)	
Non-missing	22 (42.3%)	10 (55.6%)	6 (42.9%)	12 (57.1%)	
Missing	25 (48.1%)	8 (44.4%)	5 (35.7%)	5 (23.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-eq5d-gba.sas V.03.05 Output file: t-subgrp-eq5d-imp-gba-sex.pdf 24AUG2023:16:52

Table 2.8403: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 52)	BAT (N = 18)	MMB (N = 14)	BAT (N = 21)	p-value
EQ-5D-5L VAS Response Rate at Week 20					
Responder, n(%)	9 (17.3%)	1 (5.6%)	3 (21.4%)	2 (9.5%)	
Non-Responder, n(%)	43 (82.7%)	17 (94.4%)	11 (78.6%)	19 (90.5%)	
Non-missing	15 (28.8%)	8 (44.4%)	5 (35.7%)	13 (61.9%)	
Missing	28 (53.8%)	9 (50.0%)	6 (42.9%)	6 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-eq5d-gba.sas V.03.05 Output file: t-subgrp-eq5d-imp-gba-sex.pdf 24AUG2023:16:52

Table 2.8403: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 52)	BAT (N = 18)	MMB (N = 14)	BAT (N = 21)	p-value
EQ-5D-5L VAS Response Rate at Week 24					
Responder, n(%)	5 (9.6%)	1 (5.6%)	4 (28.6%)	5 (23.8%)	
Unadjusted Inverse Relative Risk (95% CI)	0.58 (0.07, 4.62)		0.83 (0.27, 2.57)		
p-value [1]	0.61		0.75		
Unadjusted interaction test for Treatment*Gender [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.55 (0.06, 5.08)		0.78 (0.17, 3.62)		
p-value [1]	0.60		0.75		
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.09, 0.17)		0.05 (-0.25, 0.35)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Gender [3]					NA
Non-Responder, n(%)	47 (90.4%)	17 (94.4%)	10 (71.4%)	16 (76.2%)	
Non-missing	13 (25.0%)	7 (38.9%)	5 (35.7%)	10 (47.6%)	
Missing	34 (65.4%)	10 (55.6%)	5 (35.7%)	6 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8410: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N = 28)	BAT (N = 24)	MMB (N = 38)	BAT (N = 15)	p-value
EQ-5D-5L VAS Response Rate at Week 4					
Responder, n(%)	4 (14.3%)	6 (25.0%)	4 (10.5%)	1 (6.7%)	
Non-Responder, n(%)	24 (85.7%)	18 (75.0%)	34 (89.5%)	14 (93.3%)	
Non-missing	15 (53.6%)	10 (41.7%)	22 (57.9%)	9 (60.0%)	
Missing	9 (32.1%)	8 (33.3%)	12 (31.6%)	5 (33.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-eq5d-gba.sas V.03.05 Output file: t-subgrp-eq5d-imp-gba-svb.pdf 24AUG2023:16:52

Table 2.8410: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N = 28)	BAT (N = 24)	MMB (N = 38)	BAT (N = 15)	p-value
EQ-5D-5L VAS Response Rate at Week 8					
Responder, n(%)	3 (10.7%)	5 (20.8%)	2 (5.3%)	2 (13.3%)	
Non-Responder, n(%)	25 (89.3%)	19 (79.2%)	36 (94.7%)	13 (86.7%)	
Non-missing	15 (53.6%)	12 (50.0%)	24 (63.2%)	5 (33.3%)	
Missing	10 (35.7%)	7 (29.2%)	12 (31.6%)	8 (53.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-eq5d-gba.sas V.03.05 Output file: t-subgrp-eq5d-imp-gba-svb.pdf 24AUG2023:16:52

Table 2.8410: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N = 28)	BAT (N = 24)	MMB (N = 38)	BAT (N = 15)	p-value
EQ-5D-5L VAS Response Rate at Week 12					
Responder, n(%)	4 (14.3%)	6 (25.0%)	6 (15.8%)	0	
Non-Responder, n(%)	24 (85.7%)	18 (75.0%)	32 (84.2%)	15 (100.0%)	
Non-missing	10 (35.7%)	11 (45.8%)	17 (44.7%)	9 (60.0%)	
Missing	14 (50.0%)	7 (29.2%)	15 (39.5%)	6 (40.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-eq5d-gba.sas V.03.05 Output file: t-subgrp-eq5d-imp-gba-svb.pdf 24AUG2023:16:52

Table 2.8410: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N = 28)	BAT (N = 24)	MMB (N = 38)	BAT (N = 15)	p-value
EQ-5D-5L VAS Response Rate at Week 16					
Responder, n(%)	4 (14.3%)	2 (8.3%)	4 (10.5%)	2 (13.3%)	
Non-Responder, n(%)	24 (85.7%)	22 (91.7%)	34 (89.5%)	13 (86.7%)	
Non-missing	12 (42.9%)	15 (62.5%)	16 (42.1%)	7 (46.7%)	
Missing	12 (42.9%)	7 (29.2%)	18 (47.4%)	6 (40.0%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-eq5d-gba.sas V.03.05 Output file: t-subgrp-eq5d-imp-gba-svb.pdf 24AUG2023:16:52

Table 2.8410: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N = 28)	BAT (N = 24)	MMB (N = 38)	BAT (N = 15)	p-value
EQ-5D-5L VAS Response Rate at Week 20					
Responder, n(%)	5 (17.9%)	2 (8.3%)	7 (18.4%)	1 (6.7%)	
Non-Responder, n(%)	23 (82.1%)	22 (91.7%)	31 (81.6%)	14 (93.3%)	
Non-missing	10 (35.7%)	15 (62.5%)	10 (26.3%)	6 (40.0%)	
Missing	13 (46.4%)	7 (29.2%)	21 (55.3%)	8 (53.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8410: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N = 28)	BAT (N = 24)	MMB (N = 38)	BAT (N = 15)	p-value
EQ-5D-5L VAS Response Rate at Week 24					
Responder, n(%)	5 (17.9%)	4 (16.7%)	4 (10.5%)	2 (13.3%)	
Unadjusted Inverse Relative Risk (95% CI)	0.93 (0.28, 3.09)		1.27 (0.26, 6.20)		
p-value [1]	0.91		0.77		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.92 (0.22, 3.90)		1.31 (0.21, 8.02)		
p-value [1]	0.91		0.77		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.19, 0.22)		-0.03 (-0.23, 0.17)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Non-Responder, n(%)	23 (82.1%)	20 (83.3%)	34 (89.5%)	13 (86.7%)	
Non-missing	7 (25.0%)	12 (50.0%)	11 (28.9%)	5 (33.3%)	
Missing	16 (57.1%)	8 (33.3%)	23 (60.5%)	8 (53.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8409: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 42)	BAT (N = 20)	MMB (N = 24)	BAT (N = 19)	p-value
EQ-5D-5L VAS Response Rate at Week 4					
Responder, n(%)	5 (11.9%)	5 (25.0%)	3 (12.5%)	2 (10.5%)	
Non-Responder, n(%)	37 (88.1%)	15 (75.0%)	21 (87.5%)	17 (89.5%)	
Non-missing	24 (57.1%)	8 (40.0%)	13 (54.2%)	11 (57.9%)	
Missing	13 (31.0%)	7 (35.0%)	8 (33.3%)	6 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-eq5d-gba.sas V.03.05 Output file: t-subgrp-eq5d-imp-gba-tss.pdf 24AUG2023:16:52

Table 2.8409: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 42)	BAT (N = 20)	MMB (N = 24)	BAT (N = 19)	p-value
EQ-5D-5L VAS Response Rate at Week 8					
Responder, n(%)	3 (7.1%)	4 (20.0%)	2 (8.3%)	3 (15.8%)	
Non-Responder, n(%)	39 (92.9%)	16 (80.0%)	22 (91.7%)	16 (84.2%)	
Non-missing	25 (59.5%)	8 (40.0%)	14 (58.3%)	9 (47.4%)	
Missing	14 (33.3%)	8 (40.0%)	8 (33.3%)	7 (36.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-eq5d-gba.sas V.03.05 Output file: t-subgrp-eq5d-imp-gba-tss.pdf 24AUG2023:16:52

Table 2.8409: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 42)	BAT (N = 20)	MMB (N = 24)	BAT (N = 19)	p-value
EQ-5D-5L VAS Response Rate at Week 12					
Responder, n(%)	7 (16.7%)	3 (15.0%)	3 (12.5%)	3 (15.8%)	
Non-Responder, n(%)	35 (83.3%)	17 (85.0%)	21 (87.5%)	16 (84.2%)	
Non-missing	18 (42.9%)	10 (50.0%)	9 (37.5%)	10 (52.6%)	
Missing	17 (40.5%)	7 (35.0%)	12 (50.0%)	6 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8409: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 42)	BAT (N = 20)	MMB (N = 24)	BAT (N = 19)	p-value
EQ-5D-5L VAS Response Rate at Week 16					
Responder, n(%)	4 (9.5%)	3 (15.0%)	4 (16.7%)	1 (5.3%)	
Non-Responder, n(%)	38 (90.5%)	17 (85.0%)	20 (83.3%)	18 (94.7%)	
Non-missing	19 (45.2%)	10 (50.0%)	9 (37.5%)	12 (63.2%)	
Missing	19 (45.2%)	7 (35.0%)	11 (45.8%)	6 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8409: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 42)	BAT (N = 20)	MMB (N = 24)	BAT (N = 19)	p-value
EQ-5D-5L VAS Response Rate at Week 20					
Responder, n(%)	8 (19.0%)	1 (5.0%)	4 (16.7%)	2 (10.5%)	
Non-Responder, n(%)	34 (81.0%)	19 (95.0%)	20 (83.3%)	17 (89.5%)	
Non-missing	15 (35.7%)	10 (50.0%)	5 (20.8%)	11 (57.9%)	
Missing	19 (45.2%)	9 (45.0%)	15 (62.5%)	6 (31.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8409: Analysis of Response Rate (improvement) in EQ-5D-5L VAS by Visit and Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 42)	BAT (N = 20)	MMB (N = 24)	BAT (N = 19)	p-value
EQ-5D-5L VAS Response Rate at Week 24					
Responder, n(%)	5 (11.9%)	3 (15.0%)	4 (16.7%)	3 (15.8%)	
Unadjusted Inverse Relative Risk (95% CI)	1.26 (0.33, 4.76)		0.95 (0.24, 3.73)		
p-value [1]	0.73		0.94		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	1.31 (0.28, 6.11)		0.94 (0.18, 4.81)		
p-value [1]	0.73		0.94		
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.22, 0.15)		0.01 (-0.21, 0.23)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Non-Responder, n(%)	37 (88.1%)	17 (85.0%)	20 (83.3%)	16 (84.2%)	
Non-missing	14 (33.3%)	8 (40.0%)	4 (16.7%)	9 (47.4%)	
Missing	23 (54.8%)	9 (45.0%)	16 (66.7%)	7 (36.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8202: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	BAT (N = 9)	MMB (N = 42)	BAT (N = 30)	p-value
SF3602-Physical Functioning: NBS at Week 24					
Responder, n(%)	0	0	4 (9.5%)	4 (13.3%)	
Unadjusted Relative Risk (95% CI)	NA		0.71 (0.19, 2.63)		
p-value [1]	NA		0.61		
Unadjusted interaction test for Treatment*Age Group [3]					NA
Unadjusted Odds Ratio (95% CI)	NA		0.68 (0.16, 2.98)		
p-value [1]	NA		0.61		
Unadjusted Absolute Risk Difference (95% CI)	NA		-0.04 (-0.19, 0.11)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Age Group [3]					NA
Non-Responder, n(%)	24 (100.0%)	9 (100.0%)	38 (90.5%)	26 (86.7%)	
Non-missing	6 (25.0%)	4 (44.4%)	16 (38.1%)	15 (50.0%)	
Missing	18 (75.0%)	5 (55.6%)	22 (52.4%)	11 (36.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8202: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	BAT (N = 9)	MMB (N = 42)	BAT (N = 30)	p-value
SF3602-Role Physical: NBS at Week 24					
Responder, n(%)	2 (8.3%)	0	5 (11.9%)	1 (3.3%)	
Unadjusted Relative Risk (95% CI)	2.00 (0.11, 38.08)		3.57 (0.44, 29.03)		
p-value [1]	0.64		0.23		
Unadjusted interaction test for Treatment*Age Group [3]					NA
Unadjusted Odds Ratio (95% CI)	2.11 (0.09, 48.27)		3.92 (0.43, 35.42)		
p-value [1]	0.64		0.22		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.13, 0.23)		0.09 (-0.03, 0.20)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Age Group [3]					NA
Non-Responder, n(%)	22 (91.7%)	9 (100.0%)	37 (88.1%)	29 (96.7%)	
Non-missing	4 (16.7%)	4 (44.4%)	15 (35.7%)	18 (60.0%)	
Missing	18 (75.0%)	5 (55.6%)	22 (52.4%)	11 (36.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8202: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	BAT (N = 9)	MMB (N = 42)	BAT (N = 30)	p-value
SF3602-Bodily Pain: NBS at Week 24					
Responder, n(%)	1 (4.2%)	0	5 (11.9%)	5 (16.7%)	
Unadjusted Relative Risk (95% CI)	1.20 (0.05, 27.05)		0.71 (0.23, 2.25)		
p-value [1]	0.91		0.57		
Unadjusted interaction test for Treatment*Age Group [3]					NE
Unadjusted Odds Ratio (95% CI)	1.21 (0.05, 32.49)		0.68 (0.18, 2.58)		
p-value [1]	0.91		0.57		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.15, 0.17)		-0.05 (-0.21, 0.12)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Age Group [3]					NE
Non-Responder, n(%)	23 (95.8%)	9 (100.0%)	37 (88.1%)	25 (83.3%)	
Non-missing	5 (20.8%)	4 (44.4%)	15 (35.7%)	14 (46.7%)	
Missing	18 (75.0%)	5 (55.6%)	22 (52.4%)	11 (36.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8202: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	BAT (N = 9)	MMB (N = 42)	BAT (N = 30)	p-value
SF3602-General Health: NBS at Week 24					
Responder, n(%)	0	0	2 (4.8%)	7 (23.3%)	
Unadjusted Relative Risk (95% CI)	NA		0.20 (0.05, 0.91)		
p-value [1]	NA		0.038		
Unadjusted interaction test for Treatment*Age Group [3]					NA
Unadjusted Odds Ratio (95% CI)	NA		0.16 (0.03, 0.86)		
p-value [1]	NA		0.032		
Unadjusted Absolute Risk Difference (95% CI)	NA		-0.19 (-0.35, -0.02)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Age Group [3]					NA
Non-Responder, n(%)	24 (100.0%)	9 (100.0%)	40 (95.2%)	23 (76.7%)	
Non-missing	6 (25.0%)	4 (44.4%)	18 (42.9%)	12 (40.0%)	
Missing	18 (75.0%)	5 (55.6%)	22 (52.4%)	11 (36.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8202: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	BAT (N = 9)	MMB (N = 42)	BAT (N = 30)	p-value
SF3602-Vitality: NBS at Week 24					
Responder, n(%)	2 (8.3%)	0	2 (4.8%)	2 (6.7%)	
Unadjusted Relative Risk (95% CI)	2.00 (0.11, 38.08)		0.71 (0.11, 4.79)		
p-value [1]	0.64		0.73		
Unadjusted interaction test for Treatment*Age Group [3]					NA
Unadjusted Odds Ratio (95% CI)	2.11 (0.09, 48.27)		0.70 (0.09, 5.27)		
p-value [1]	0.64		0.73		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.13, 0.23)		-0.02 (-0.13, 0.09)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Age Group [3]					NA
Non-Responder, n(%)	22 (91.7%)	9 (100.0%)	40 (95.2%)	28 (93.3%)	
Non-missing	4 (16.7%)	4 (44.4%)	18 (42.9%)	17 (56.7%)	
Missing	18 (75.0%)	5 (55.6%)	22 (52.4%)	11 (36.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8202: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	BAT (N = 9)	MMB (N = 42)	BAT (N = 30)	p-value
SF3602-Social Functioning: NBS at Week 24					
Responder, n(%)	0	0	2 (4.8%)	5 (16.7%)	
Unadjusted Relative Risk (95% CI)	NA		0.29 (0.06, 1.38)		
p-value [1]	NA		0.12		
Unadjusted interaction test for Treatment*Age Group [3]					NA
Unadjusted Odds Ratio (95% CI)	NA		0.25 (0.05, 1.39)		
p-value [1]	NA		0.11		
Unadjusted Absolute Risk Difference (95% CI)	NA		-0.12 (-0.27, 0.03)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Age Group [3]					NA
Non-Responder, n(%)	24 (100.0%)	9 (100.0%)	40 (95.2%)	25 (83.3%)	
Non-missing	6 (25.0%)	4 (44.4%)	18 (42.9%)	14 (46.7%)	
Missing	18 (75.0%)	5 (55.6%)	22 (52.4%)	11 (36.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8202: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	BAT (N = 9)	MMB (N = 42)	BAT (N = 30)	p-value
SF3602-Role Emotional: NBS at Week 24					
Responder, n(%)	1 (4.2%)	0	7 (16.7%)	3 (10.0%)	
Unadjusted Relative Risk (95% CI)	1.20 (0.05, 27.05)		1.67 (0.47, 5.93)		
p-value [1]	0.91		0.43		
Unadjusted interaction test for Treatment*Age Group [3]					NE
Unadjusted Odds Ratio (95% CI)	1.21 (0.05, 32.49)		1.80 (0.43, 7.62)		
p-value [1]	0.91		0.42		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.15, 0.17)		0.07 (-0.09, 0.22)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Age Group [3]					NE
Non-Responder, n(%)	23 (95.8%)	9 (100.0%)	35 (83.3%)	27 (90.0%)	
Non-missing	5 (20.8%)	4 (44.4%)	13 (31.0%)	16 (53.3%)	
Missing	18 (75.0%)	5 (55.6%)	22 (52.4%)	11 (36.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8202: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	BAT (N = 9)	MMB (N = 42)	BAT (N = 30)	p-value
SF3602-Mental Health: NBS at Week 24					
Responder, n(%)	0	0	4 (9.5%)	5 (16.7%)	
Unadjusted Relative Risk (95% CI)	NA		0.57 (0.17, 1.95)		
p-value [1]	NA		0.37		
Unadjusted interaction test for Treatment*Age Group [3]					NA
Unadjusted Odds Ratio (95% CI)	NA		0.53 (0.13, 2.15)		
p-value [1]	NA		0.37		
Unadjusted Absolute Risk Difference (95% CI)	NA		-0.07 (-0.23, 0.09)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Age Group [3]					NA
Non-Responder, n(%)	24 (100.0%)	9 (100.0%)	38 (90.5%)	25 (83.3%)	
Non-missing	6 (25.0%)	4 (44.4%)	16 (38.1%)	14 (46.7%)	
Missing	18 (75.0%)	5 (55.6%)	22 (52.4%)	11 (36.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8202: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	BAT (N = 9)	MMB (N = 42)	BAT (N = 30)	p-value
SF3602-Physical Component Summary at Week 24					
Responder, n(%)	0	0	2 (4.8%)	1 (3.3%)	
Unadjusted Relative Risk (95% CI)	NA		1.43 (0.14, 15.04)		
p-value [1]	NA		0.77		
Unadjusted interaction test for Treatment*Age Group [3]					NA
Unadjusted Odds Ratio (95% CI)	NA		1.45 (0.13, 16.76)		
p-value [1]	NA		0.77		
Unadjusted Absolute Risk Difference (95% CI)	NA		0.01 (-0.08, 0.11)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Age Group [3]					NA
Non-Responder, n(%)	24 (100.0%)	9 (100.0%)	40 (95.2%)	29 (96.7%)	
Non-missing	6 (25.0%)	4 (44.4%)	18 (42.9%)	18 (60.0%)	
Missing	18 (75.0%)	5 (55.6%)	22 (52.4%)	11 (36.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8202: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	BAT (N = 9)	MMB (N = 42)	BAT (N = 30)	p-value
SF3602-Mental Component Summary at Week 24					
Responder, n(%)	1 (4.2%)	0	2 (4.8%)	3 (10.0%)	
Unadjusted Relative Risk (95% CI)	1.20 (0.05, 27.05)		0.48 (0.08, 2.68)		
p-value [1]	0.91		0.40		
Unadjusted interaction test for Treatment*Age Group [3]					NA
Unadjusted Odds Ratio (95% CI)	1.21 (0.05, 32.49)		0.45 (0.07, 2.88)		
p-value [1]	0.91		0.40		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.15, 0.17)		-0.05 (-0.18, 0.07)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Age Group [3]					NA
Non-Responder, n(%)	23 (95.8%)	9 (100.0%)	40 (95.2%)	27 (90.0%)	
Non-missing	5 (20.8%)	4 (44.4%)	18 (42.9%)	16 (53.3%)	
Missing	18 (75.0%)	5 (55.6%)	22 (52.4%)	11 (36.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8204: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N = 29)	BAT (N = 7)	MMB (N = 37)	BAT (N = 32)	p-value
SF3602-Physical Functioning: NBS at Week 24					
Responder, n(%)	2 (6.9%)	1 (14.3%)	2 (5.4%)	3 (9.4%)	
Unadjusted Relative Risk (95% CI)	0.48 (0.05, 4.60)		0.58 (0.10, 3.24)		
p-value [1]	0.53		0.53		
Unadjusted interaction test for Treatment*Region [3]					NA
Unadjusted Odds Ratio (95% CI)	0.44 (0.03, 5.74)		0.55 (0.09, 3.53)		
p-value [1]	0.53		0.53		
Unadjusted Absolute Risk Difference (95% CI)	-0.07 (-0.35, 0.20)		-0.04 (-0.16, 0.08)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Region [3]					NA
Non-Responder, n(%)	27 (93.1%)	6 (85.7%)	35 (94.6%)	29 (90.6%)	
Non-missing	6 (20.7%)	2 (28.6%)	16 (43.2%)	17 (53.1%)	
Missing	21 (72.4%)	4 (57.1%)	19 (51.4%)	12 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8204: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N = 29)	BAT (N = 7)	MMB (N = 37)	BAT (N = 32)	p-value
SF3602-Role Physical: NBS at Week 24					
Responder, n(%)	1 (3.4%)	0	6 (16.2%)	1 (3.1%)	
Unadjusted Relative Risk (95% CI)	0.80 (0.04, 17.83)		5.19 (0.66, 40.86)		
p-value [1]	0.89		0.12		
Unadjusted interaction test for Treatment*Region [3]					NA
Unadjusted Odds Ratio (95% CI)	0.79 (0.03, 21.41)		6.00 (0.68, 52.80)		
p-value [1]	0.89		0.11		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.20, 0.17)		0.13 (0.00, 0.26)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Region [3]					NA
Non-Responder, n(%)	28 (96.6%)	7 (100.0%)	31 (83.8%)	31 (96.9%)	
Non-missing	7 (24.1%)	3 (42.9%)	12 (32.4%)	19 (59.4%)	
Missing	21 (72.4%)	4 (57.1%)	19 (51.4%)	12 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8204: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N = 29)	BAT (N = 7)	MMB (N = 37)	BAT (N = 32)	p-value
SF3602-Bodily Pain: NBS at Week 24					
Responder, n(%)	1 (3.4%)	0	5 (13.5%)	5 (15.6%)	
Unadjusted Relative Risk (95% CI)	0.80 (0.04, 17.83)		0.86 (0.28, 2.72)		
p-value [1]	0.89		0.80		
Unadjusted interaction test for Treatment*Region [3]					NE
Unadjusted Odds Ratio (95% CI)	0.79 (0.03, 21.41)		0.84 (0.22, 3.23)		
p-value [1]	0.89		0.80		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.20, 0.17)		-0.02 (-0.19, 0.15)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Region [3]					NE
Non-Responder, n(%)	28 (96.6%)	7 (100.0%)	32 (86.5%)	27 (84.4%)	
Non-missing	7 (24.1%)	3 (42.9%)	13 (35.1%)	15 (46.9%)	
Missing	21 (72.4%)	4 (57.1%)	19 (51.4%)	12 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8204: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N = 29)	BAT (N = 7)	MMB (N = 37)	BAT (N = 32)	p-value
SF3602-General Health: NBS at Week 24					
Responder, n(%)	0	2 (28.6%)	2 (5.4%)	5 (15.6%)	
Unadjusted Relative Risk (95% CI)	0.05 (0.00, 1.00)		0.35 (0.07, 1.66)		
p-value [1]	0.050		0.19		
Unadjusted interaction test for Treatment*Region [3]					NA
Unadjusted Odds Ratio (95% CI)	0.04 (0.00, 0.89)		0.31 (0.06, 1.71)		
p-value [1]	0.042		0.18		
Unadjusted Absolute Risk Difference (95% CI)	-0.30 (-0.62, 0.03)		-0.10 (-0.25, 0.04)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Region [3]					NA
Non-Responder, n(%)	29 (100.0%)	5 (71.4%)	35 (94.6%)	27 (84.4%)	
Non-missing	8 (27.6%)	1 (14.3%)	16 (43.2%)	15 (46.9%)	
Missing	21 (72.4%)	4 (57.1%)	19 (51.4%)	12 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8204: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N = 29)	BAT (N = 7)	MMB (N = 37)	BAT (N = 32)	p-value
SF3602-Vitality: NBS at Week 24					
Responder, n(%)	1 (3.4%)	1 (14.3%)	3 (8.1%)	1 (3.1%)	
Unadjusted Relative Risk (95% CI)	0.24 (0.02, 3.40)		2.59 (0.28, 23.73)		
p-value [1]	0.29		0.40		
Unadjusted interaction test for Treatment*Region [3]					NA
Unadjusted Odds Ratio (95% CI)	0.21 (0.01, 3.93)		2.74 (0.27, 27.69)		
p-value [1]	0.30		0.39		
Unadjusted Absolute Risk Difference (95% CI)	-0.11 (-0.38, 0.16)		0.05 (-0.06, 0.16)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Region [3]					NA
Non-Responder, n(%)	28 (96.6%)	6 (85.7%)	34 (91.9%)	31 (96.9%)	
Non-missing	7 (24.1%)	2 (28.6%)	15 (40.5%)	19 (59.4%)	
Missing	21 (72.4%)	4 (57.1%)	19 (51.4%)	12 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8204: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N = 29)	BAT (N = 7)	MMB (N = 37)	BAT (N = 32)	p-value
SF3602-Social Functioning: NBS at Week 24					
Responder, n(%)	0	1 (14.3%)	2 (5.4%)	4 (12.5%)	
Unadjusted Relative Risk (95% CI)	0.09 (0.00, 1.98)		0.43 (0.08, 2.21)		
p-value [1]	0.13		0.31		
Unadjusted interaction test for Treatment*Region [3]					NA
Unadjusted Odds Ratio (95% CI)	0.07 (0.00, 2.01)		0.40 (0.07, 2.35)		
p-value [1]	0.12		0.31		
Unadjusted Absolute Risk Difference (95% CI)	-0.17 (-0.45, 0.10)		-0.07 (-0.21, 0.06)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Region [3]					NA
Non-Responder, n(%)	29 (100.0%)	6 (85.7%)	35 (94.6%)	28 (87.5%)	
Non-missing	8 (27.6%)	2 (28.6%)	16 (43.2%)	16 (50.0%)	
Missing	21 (72.4%)	4 (57.1%)	19 (51.4%)	12 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8204: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N = 29)	BAT (N = 7)	MMB (N = 37)	BAT (N = 32)	p-value
SF3602-Role Emotional: NBS at Week 24					
Responder, n(%)	3 (10.3%)	1 (14.3%)	5 (13.5%)	2 (6.3%)	
Unadjusted Relative Risk (95% CI)	0.72 (0.09, 5.96)		2.16 (0.45, 10.39)		
p-value [1]	0.76		0.34		
Unadjusted interaction test for Treatment*Region [3]					NA
Unadjusted Odds Ratio (95% CI)	0.69 (0.06, 7.87)		2.34 (0.42, 13.01)		
p-value [1]	0.77		0.33		
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.32, 0.24)		0.07 (-0.07, 0.21)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Region [3]					NA
Non-Responder, n(%)	26 (89.7%)	6 (85.7%)	32 (86.5%)	30 (93.8%)	
Non-missing	5 (17.2%)	2 (28.6%)	13 (35.1%)	18 (56.3%)	
Missing	21 (72.4%)	4 (57.1%)	19 (51.4%)	12 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8204: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N = 29)	BAT (N = 7)	MMB (N = 37)	BAT (N = 32)	p-value
SF3602-Mental Health: NBS at Week 24					
Responder, n(%)	2 (6.9%)	1 (14.3%)	2 (5.4%)	4 (12.5%)	
Unadjusted Relative Risk (95% CI)	0.48 (0.05, 4.60)		0.43 (0.08, 2.21)		
p-value [1]	0.53		0.31		
Unadjusted interaction test for Treatment*Region [3]					NA
Unadjusted Odds Ratio (95% CI)	0.44 (0.03, 5.74)		0.40 (0.07, 2.35)		
p-value [1]	0.53		0.31		
Unadjusted Absolute Risk Difference (95% CI)	-0.07 (-0.35, 0.20)		-0.07 (-0.21, 0.06)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Region [3]					NA
Non-Responder, n(%)	27 (93.1%)	6 (85.7%)	35 (94.6%)	28 (87.5%)	
Non-missing	6 (20.7%)	2 (28.6%)	16 (43.2%)	16 (50.0%)	
Missing	21 (72.4%)	4 (57.1%)	19 (51.4%)	12 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8204: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N = 29)	BAT (N = 7)	MMB (N = 37)	BAT (N = 32)	p-value
SF3602-Physical Component Summary at Week 24					
Responder, n(%)	1 (3.4%)	0	1 (2.7%)	1 (3.1%)	
Unadjusted Relative Risk (95% CI)	0.80 (0.04, 17.83)		0.86 (0.06, 13.28)		
p-value [1]	0.89		0.92		
Unadjusted interaction test for Treatment*Region [3]					NA
Unadjusted Odds Ratio (95% CI)	0.79 (0.03, 21.41)		0.86 (0.05, 14.35)		
p-value [1]	0.89		0.92		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.20, 0.17)		0.00 (-0.08, 0.08)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Region [3]					NA
Non-Responder, n(%)	28 (96.6%)	7 (100.0%)	36 (97.3%)	31 (96.9%)	
Non-missing	7 (24.1%)	3 (42.9%)	17 (45.9%)	19 (59.4%)	
Missing	21 (72.4%)	4 (57.1%)	19 (51.4%)	12 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8204: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N = 29)	BAT (N = 7)	MMB (N = 37)	BAT (N = 32)	p-value
SF3602-Mental Component Summary at Week 24					
Responder, n(%)	1 (3.4%)	1 (14.3%)	2 (5.4%)	2 (6.3%)	
Unadjusted Relative Risk (95% CI)	0.24 (0.02, 3.40)		0.86 (0.13, 5.79)		
p-value [1]	0.29		0.88		
Unadjusted interaction test for Treatment*Region [3]					NA
Unadjusted Odds Ratio (95% CI)	0.21 (0.01, 3.93)		0.86 (0.11, 6.46)		
p-value [1]	0.30		0.88		
Unadjusted Absolute Risk Difference (95% CI)	-0.11 (-0.38, 0.16)		-0.01 (-0.12, 0.10)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Region [3]					NA
Non-Responder, n(%)	28 (96.6%)	6 (85.7%)	35 (94.6%)	30 (93.8%)	
Non-missing	7 (24.1%)	2 (28.6%)	16 (43.2%)	18 (56.3%)	
Missing	21 (72.4%)	4 (57.1%)	19 (51.4%)	12 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8207: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 27)	BAT (N = 6)	MMB (N = 39)	BAT (N = 33)	p-value
SF3602-Physical Functioning: NBS at Week 24					
Responder, n(%)	3 (11.1%)	0	1 (2.6%)	4 (12.1%)	
Unadjusted Relative Risk (95% CI)	1.75 (0.10, 30.11)		0.21 (0.02, 1.80)		
p-value [1]	0.70		0.16		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Unadjusted Odds Ratio (95% CI)	1.86 (0.08, 40.69)		0.19 (0.02, 1.80)		
p-value [1]	0.69		0.15		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.17, 0.28)		-0.10 (-0.22, 0.03)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Non-Responder, n(%)	24 (88.9%)	6 (100.0%)	38 (97.4%)	29 (87.9%)	
Non-missing	7 (25.9%)	2 (33.3%)	15 (38.5%)	17 (51.5%)	
Missing	17 (63.0%)	4 (66.7%)	23 (59.0%)	12 (36.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8207: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 27)	BAT (N = 6)	MMB (N = 39)	BAT (N = 33)	p-value
SF3602-Role Physical: NBS at Week 24					
Responder, n(%)	2 (7.4%)	0	5 (12.8%)	1 (3.0%)	
Unadjusted Relative Risk (95% CI)	1.25 (0.07, 23.21)		4.23 (0.52, 34.43)		
p-value [1]	0.88		0.18		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Unadjusted Odds Ratio (95% CI)	1.27 (0.05, 29.93)		4.71 (0.52, 42.50)		
p-value [1]	0.88		0.17		
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.20, 0.24)		0.10 (-0.02, 0.22)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Non-Responder, n(%)	25 (92.6%)	6 (100.0%)	34 (87.2%)	32 (97.0%)	
Non-missing	8 (29.6%)	2 (33.3%)	11 (28.2%)	20 (60.6%)	
Missing	17 (63.0%)	4 (66.7%)	23 (59.0%)	12 (36.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8207: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 27)	BAT (N = 6)	MMB (N = 39)	BAT (N = 33)	p-value
SF3602-Bodily Pain: NBS at Week 24					
Responder, n(%)	2 (7.4%)	1 (16.7%)	4 (10.3%)	4 (12.1%)	
Unadjusted Relative Risk (95% CI)	0.44 (0.05, 4.14)		0.85 (0.23, 3.12)		
p-value [1]	0.48		0.80		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Unadjusted Odds Ratio (95% CI)	0.40 (0.03, 5.31)		0.83 (0.19, 3.61)		
p-value [1]	0.49		0.80		
Unadjusted Absolute Risk Difference (95% CI)	-0.09 (-0.41, 0.22)		-0.02 (-0.17, 0.13)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Non-Responder, n(%)	25 (92.6%)	5 (83.3%)	35 (89.7%)	29 (87.9%)	
Non-missing	8 (29.6%)	1 (16.7%)	12 (30.8%)	17 (51.5%)	
Missing	17 (63.0%)	4 (66.7%)	23 (59.0%)	12 (36.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8207: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 27)	BAT (N = 6)	MMB (N = 39)	BAT (N = 33)	p-value
SF3602-General Health: NBS at Week 24					
Responder, n(%)	1 (3.7%)	1 (16.7%)	1 (2.6%)	6 (18.2%)	
Unadjusted Relative Risk (95% CI)	0.22 (0.02, 3.07)		0.14 (0.02, 1.11)		
p-value [1]	0.26		0.063		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Unadjusted Odds Ratio (95% CI)	0.19 (0.01, 3.61)		0.12 (0.01, 1.04)		
p-value [1]	0.27		0.054		
Unadjusted Absolute Risk Difference (95% CI)	-0.13 (-0.44, 0.18)		-0.16 (-0.30, -0.02)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Non-Responder, n(%)	26 (96.3%)	5 (83.3%)	38 (97.4%)	27 (81.8%)	
Non-missing	9 (33.3%)	1 (16.7%)	15 (38.5%)	15 (45.5%)	
Missing	17 (63.0%)	4 (66.7%)	23 (59.0%)	12 (36.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8207: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 27)	BAT (N = 6)	MMB (N = 39)	BAT (N = 33)	p-value
SF3602-Vitality: NBS at Week 24					
Responder, n(%)	1 (3.7%)	0	3 (7.7%)	2 (6.1%)	
Unadjusted Relative Risk (95% CI)	0.75 (0.03, 16.51)		1.27 (0.23, 7.15)		
p-value [1]	0.86		0.79		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Unadjusted Odds Ratio (95% CI)	0.74 (0.03, 20.22)		1.29 (0.20, 8.24)		
p-value [1]	0.86		0.79		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.23, 0.19)		0.02 (-0.10, 0.13)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Non-Responder, n(%)	26 (96.3%)	6 (100.0%)	36 (92.3%)	31 (93.9%)	
Non-missing	9 (33.3%)	2 (33.3%)	13 (33.3%)	19 (57.6%)	
Missing	17 (63.0%)	4 (66.7%)	23 (59.0%)	12 (36.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8207: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 27)	BAT (N = 6)	MMB (N = 39)	BAT (N = 33)	p-value
SF3602-Social Functioning: NBS at Week 24					
Responder, n(%)	1 (3.7%)	0	1 (2.6%)	5 (15.2%)	
Unadjusted Relative Risk (95% CI)	0.75 (0.03, 16.51)		0.17 (0.02, 1.38)		
p-value [1]	0.86		0.097		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Unadjusted Odds Ratio (95% CI)	0.74 (0.03, 20.22)		0.15 (0.02, 1.33)		
p-value [1]	0.86		0.088		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.23, 0.19)		-0.13 (-0.26, 0.01)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Non-Responder, n(%)	26 (96.3%)	6 (100.0%)	38 (97.4%)	28 (84.8%)	
Non-missing	9 (33.3%)	2 (33.3%)	15 (38.5%)	16 (48.5%)	
Missing	17 (63.0%)	4 (66.7%)	23 (59.0%)	12 (36.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8207: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 27)	BAT (N = 6)	MMB (N = 39)	BAT (N = 33)	p-value
SF3602-Role Emotional: NBS at Week 24					
Responder, n(%)	3 (11.1%)	0	5 (12.8%)	3 (9.1%)	
Unadjusted Relative Risk (95% CI)	1.75 (0.10, 30.11)		1.41 (0.36, 5.46)		
p-value [1]	0.70		0.62		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Unadjusted Odds Ratio (95% CI)	1.86 (0.08, 40.69)		1.47 (0.32, 6.68)		
p-value [1]	0.69		0.62		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.17, 0.28)		0.04 (-0.11, 0.18)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Non-Responder, n(%)	24 (88.9%)	6 (100.0%)	34 (87.2%)	30 (90.9%)	
Non-missing	7 (25.9%)	2 (33.3%)	11 (28.2%)	18 (54.5%)	
Missing	17 (63.0%)	4 (66.7%)	23 (59.0%)	12 (36.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8207: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 27)	BAT (N = 6)	MMB (N = 39)	BAT (N = 33)	p-value
SF3602-Mental Health: NBS at Week 24					
Responder, n(%)	2 (7.4%)	0	2 (5.1%)	5 (15.2%)	
Unadjusted Relative Risk (95% CI)	1.25 (0.07, 23.21)		0.34 (0.07, 1.63)		
p-value [1]	0.88		0.18		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Unadjusted Odds Ratio (95% CI)	1.27 (0.05, 29.93)		0.30 (0.05, 1.68)		
p-value [1]	0.88		0.17		
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.20, 0.24)		-0.10 (-0.24, 0.04)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Non-Responder, n(%)	25 (92.6%)	6 (100.0%)	37 (94.9%)	28 (84.8%)	
Non-missing	8 (29.6%)	2 (33.3%)	14 (35.9%)	16 (48.5%)	
Missing	17 (63.0%)	4 (66.7%)	23 (59.0%)	12 (36.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8207: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 27)	BAT (N = 6)	MMB (N = 39)	BAT (N = 33)	p-value
SF3602-Physical Component Summary at Week 24					
Responder, n(%)	1 (3.7%)	0	1 (2.6%)	1 (3.0%)	
Unadjusted Relative Risk (95% CI)	0.75 (0.03, 16.51)		0.85 (0.06, 13.01)		
p-value [1]	0.86		0.90		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Unadjusted Odds Ratio (95% CI)	0.74 (0.03, 20.22)		0.84 (0.05, 14.01)		
p-value [1]	0.86		0.90		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.23, 0.19)		0.00 (-0.08, 0.07)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Non-Responder, n(%)	26 (96.3%)	6 (100.0%)	38 (97.4%)	32 (97.0%)	
Non-missing	9 (33.3%)	2 (33.3%)	15 (38.5%)	20 (60.6%)	
Missing	17 (63.0%)	4 (66.7%)	23 (59.0%)	12 (36.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8207: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 27)	BAT (N = 6)	MMB (N = 39)	BAT (N = 33)	p-value
SF3602-Mental Component Summary at Week 24					
Responder, n(%)	1 (3.7%)	0	2 (5.1%)	3 (9.1%)	
Unadjusted Relative Risk (95% CI)	0.75 (0.03, 16.51)		0.56 (0.10, 3.18)		
p-value [1]	0.86		0.52		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Unadjusted Odds Ratio (95% CI)	0.74 (0.03, 20.22)		0.54 (0.08, 3.45)		
p-value [1]	0.86		0.52		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.23, 0.19)		-0.04 (-0.16, 0.08)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Non-Responder, n(%)	26 (96.3%)	6 (100.0%)	37 (94.9%)	30 (90.9%)	
Non-missing	9 (33.3%)	2 (33.3%)	14 (35.9%)	18 (54.5%)	
Missing	17 (63.0%)	4 (66.7%)	23 (59.0%)	12 (36.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8206: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 49)	BAT (N = 31)	MMB (N = 17)	BAT (N = 8)	p-value
SF3602-Physical Functioning: NBS at Week 24					
Responder, n(%)	3 (6.1%)	2 (6.5%)	1 (5.9%)	2 (25.0%)	
Unadjusted Relative Risk (95% CI)	0.95 (0.17, 5.36)		0.24 (0.02, 2.23)		
p-value [1]	0.95		0.21		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Unadjusted Odds Ratio (95% CI)	0.95 (0.15, 6.01)		0.19 (0.01, 2.47)		
p-value [1]	0.95		0.20		
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.11, 0.11)		-0.19 (-0.51, 0.13)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Non-Responder, n(%)	46 (93.9%)	29 (93.5%)	16 (94.1%)	6 (75.0%)	
Non-missing	16 (32.7%)	16 (51.6%)	6 (35.3%)	3 (37.5%)	
Missing	30 (61.2%)	13 (41.9%)	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8206: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 49)	BAT (N = 31)	MMB (N = 17)	BAT (N = 8)	p-value
SF3602-Role Physical: NBS at Week 24					
Responder, n(%)	6 (12.2%)	1 (3.2%)	1 (5.9%)	0	
Unadjusted Relative Risk (95% CI)	3.80 (0.48, 30.04)		1.50 (0.07, 33.26)		
p-value [1]	0.21		0.80		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Unadjusted Odds Ratio (95% CI)	4.19 (0.48, 36.58)		1.55 (0.06, 42.15)		
p-value [1]	0.20		0.80		
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.02, 0.20)		0.03 (-0.17, 0.22)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Non-Responder, n(%)	43 (87.8%)	30 (96.8%)	16 (94.1%)	8 (100.0%)	
Non-missing	13 (26.5%)	17 (54.8%)	6 (35.3%)	5 (62.5%)	
Missing	30 (61.2%)	13 (41.9%)	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8206: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 49)	BAT (N = 31)	MMB (N = 17)	BAT (N = 8)	p-value
SF3602-Bodily Pain: NBS at Week 24					
Responder, n(%)	3 (6.1%)	5 (16.1%)	3 (17.6%)	0	
Unadjusted Relative Risk (95% CI)	0.38 (0.10, 1.48)		3.50 (0.20, 60.70)		
p-value [1]	0.16		0.39		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Unadjusted Odds Ratio (95% CI)	0.34 (0.07, 1.54)		4.10 (0.19, 89.45)		
p-value [1]	0.16		0.37		
Unadjusted Absolute Risk Difference (95% CI)	-0.10 (-0.25, 0.05)		0.14 (-0.10, 0.38)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Non-Responder, n(%)	46 (93.9%)	26 (83.9%)	14 (82.4%)	8 (100.0%)	
Non-missing	16 (32.7%)	13 (41.9%)	4 (23.5%)	5 (62.5%)	
Missing	30 (61.2%)	13 (41.9%)	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8206: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 49)	BAT (N = 31)	MMB (N = 17)	BAT (N = 8)	p-value
SF3602-General Health: NBS at Week 24					
Responder, n(%)	2 (4.1%)	4 (12.9%)	0	3 (37.5%)	
Unadjusted Relative Risk (95% CI)	0.32 (0.06, 1.63)		0.07 (0.00, 1.24)		
p-value [1]	0.17		0.070		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Unadjusted Odds Ratio (95% CI)	0.29 (0.05, 1.67)		0.04 (0.00, 1.01)		
p-value [1]	0.17		0.051		
Unadjusted Absolute Risk Difference (95% CI)	-0.09 (-0.22, 0.04)		-0.36 (-0.69, -0.03)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Non-Responder, n(%)	47 (95.9%)	27 (87.1%)	17 (100.0%)	5 (62.5%)	
Non-missing	17 (34.7%)	14 (45.2%)	7 (41.2%)	2 (25.0%)	
Missing	30 (61.2%)	13 (41.9%)	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8206: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 49)	BAT (N = 31)	MMB (N = 17)	BAT (N = 8)	p-value
SF3602-Vitality: NBS at Week 24					
Responder, n(%)	3 (6.1%)	0	1 (5.9%)	2 (25.0%)	
Unadjusted Relative Risk (95% CI)	4.48 (0.24, 83.89)		0.24 (0.02, 2.23)		
p-value [1]	0.32		0.21		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Unadjusted Odds Ratio (95% CI)	4.74 (0.24, 95.01)		0.19 (0.01, 2.47)		
p-value [1]	0.31		0.20		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.03, 0.14)		-0.19 (-0.51, 0.13)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Non-Responder, n(%)	46 (93.9%)	31 (100.0%)	16 (94.1%)	6 (75.0%)	
Non-missing	16 (32.7%)	18 (58.1%)	6 (35.3%)	3 (37.5%)	
Missing	30 (61.2%)	13 (41.9%)	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8206: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 49)	BAT (N = 31)	MMB (N = 17)	BAT (N = 8)	p-value
SF3602-Social Functioning: NBS at Week 24					
Responder, n(%)	2 (4.1%)	3 (9.7%)	0	2 (25.0%)	
Unadjusted Relative Risk (95% CI)	0.42 (0.07, 2.38)		0.10 (0.01, 1.87)		
p-value [1]	0.33		0.12		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Unadjusted Odds Ratio (95% CI)	0.40 (0.06, 2.52)		0.07 (0.00, 1.76)		
p-value [1]	0.33		0.11		
Unadjusted Absolute Risk Difference (95% CI)	-0.06 (-0.17, 0.06)		-0.25 (-0.55, 0.05)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Non-Responder, n(%)	47 (95.9%)	28 (90.3%)	17 (100.0%)	6 (75.0%)	
Non-missing	17 (34.7%)	15 (48.4%)	7 (41.2%)	3 (37.5%)	
Missing	30 (61.2%)	13 (41.9%)	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8206: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 49)	BAT (N = 31)	MMB (N = 17)	BAT (N = 8)	p-value
SF3602-Role Emotional: NBS at Week 24					
Responder, n(%)	7 (14.3%)	1 (3.2%)	1 (5.9%)	2 (25.0%)	
Unadjusted Relative Risk (95% CI)	4.43 (0.57, 34.28)		0.24 (0.02, 2.23)		
p-value [1]	0.15		0.21		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Unadjusted Odds Ratio (95% CI)	5.00 (0.58, 42.80)		0.19 (0.01, 2.47)		
p-value [1]	0.14		0.20		
Unadjusted Absolute Risk Difference (95% CI)	0.11 (-0.01, 0.23)		-0.19 (-0.51, 0.13)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Non-Responder, n(%)	42 (85.7%)	30 (96.8%)	16 (94.1%)	6 (75.0%)	
Non-missing	12 (24.5%)	17 (54.8%)	6 (35.3%)	3 (37.5%)	
Missing	30 (61.2%)	13 (41.9%)	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8206: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 49)	BAT (N = 31)	MMB (N = 17)	BAT (N = 8)	p-value
SF3602-Mental Health: NBS at Week 24					
Responder, n(%)	3 (6.1%)	3 (9.7%)	1 (5.9%)	2 (25.0%)	
Unadjusted Relative Risk (95% CI)	0.63 (0.14, 2.94)		0.24 (0.02, 2.23)		
p-value [1]	0.56		0.21		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Unadjusted Odds Ratio (95% CI)	0.61 (0.11, 3.23)		0.19 (0.01, 2.47)		
p-value [1]	0.56		0.20		
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.16, 0.09)		-0.19 (-0.51, 0.13)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Non-Responder, n(%)	46 (93.9%)	28 (90.3%)	16 (94.1%)	6 (75.0%)	
Non-missing	16 (32.7%)	15 (48.4%)	6 (35.3%)	3 (37.5%)	
Missing	30 (61.2%)	13 (41.9%)	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8206: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 49)	BAT (N = 31)	MMB (N = 17)	BAT (N = 8)	p-value
SF3602-Physical Component Summary at Week 24					
Responder, n(%)	1 (2.0%)	1 (3.2%)	1 (5.9%)	0	
Unadjusted Relative Risk (95% CI)	0.63 (0.04, 9.75)		1.50 (0.07, 33.26)		
p-value [1]	0.74		0.80		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Unadjusted Odds Ratio (95% CI)	0.63 (0.04, 10.37)		1.55 (0.06, 42.15)		
p-value [1]	0.74		0.80		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.09, 0.06)		0.03 (-0.17, 0.22)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Non-Responder, n(%)	48 (98.0%)	30 (96.8%)	16 (94.1%)	8 (100.0%)	
Non-missing	18 (36.7%)	17 (54.8%)	6 (35.3%)	5 (62.5%)	
Missing	30 (61.2%)	13 (41.9%)	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8206: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 49)	BAT (N = 31)	MMB (N = 17)	BAT (N = 8)	p-value
SF3602-Mental Component Summary at Week 24					
Responder, n(%)	3 (6.1%)	1 (3.2%)	0	2 (25.0%)	
Unadjusted Relative Risk (95% CI)	1.90 (0.21, 17.44)		0.10 (0.01, 1.87)		
p-value [1]	0.57		0.12		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Unadjusted Odds Ratio (95% CI)	1.96 (0.19, 19.70)		0.07 (0.00, 1.76)		
p-value [1]	0.57		0.11		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.06, 0.12)		-0.25 (-0.55, 0.05)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Non-Responder, n(%)	46 (93.9%)	30 (96.8%)	17 (100.0%)	6 (75.0%)	
Non-missing	16 (32.7%)	17 (54.8%)	7 (41.2%)	3 (37.5%)	
Missing	30 (61.2%)	13 (41.9%)	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8205: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 5)	BAT (N = 7)	MMB (N = 44)	BAT (N = 24)
SF3602-Physical Functioning: NBS at Week 24				
Responder, n(%)	0	0	3 (6.8%)	2 (8.3%)
Unadjusted Relative Risk (95% CI)	NA		0.82 (0.15, 4.56)	
p-value [1]	NA		0.82	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Unadjusted Odds Ratio (95% CI)	NA		0.80 (0.12, 5.18)	
p-value [1]	NA		0.82	
Unadjusted Absolute Risk Difference (95% CI)	NA		-0.02 (-0.15, 0.12)	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Non-Responder, n(%)	5 (100.0%)	7 (100.0%)	41 (93.2%)	22 (91.7%)
Non-missing	1 (20.0%)	3 (42.9%)	15 (34.1%)	13 (54.2%)
Missing	4 (80.0%)	4 (57.1%)	26 (59.1%)	9 (37.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8205: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 17)	BAT (N = 8)	p-value
SF3602-Physical Functioning: NBS at Week 24			
Responder, n(%)	1 (5.9%)	2 (25.0%)	
Unadjusted Relative Risk (95% CI)	0.24 (0.02, 2.23)		
p-value [1]	0.21		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Unadjusted Odds Ratio (95% CI)	0.19 (0.01, 2.47)		
p-value [1]	0.20		
Unadjusted Absolute Risk Difference (95% CI)	-0.19 (-0.51, 0.13)		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	16 (94.1%)	6 (75.0%)	
Non-missing	6 (35.3%)	3 (37.5%)	
Missing	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8205: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 5)	BAT (N = 7)	MMB (N = 44)	BAT (N = 24)
SF3602-Role Physical: NBS at Week 24				
Responder, n(%)	1 (20.0%)	0	5 (11.4%)	1 (4.2%)
Unadjusted Relative Risk (95% CI)	4.00 (0.20, 82.01)		2.73 (0.34, 22.02)	
p-value [1]	0.37		0.35	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Unadjusted Odds Ratio (95% CI)	5.00 (0.17, 150.93)		2.95 (0.32, 26.83)	
p-value [1]	0.35		0.34	
Unadjusted Absolute Risk Difference (95% CI)	0.19 (-0.20, 0.57)		0.07 (-0.05, 0.20)	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Non-Responder, n(%)	4 (80.0%)	7 (100.0%)	39 (88.6%)	23 (95.8%)
Non-missing	0	3 (42.9%)	13 (29.5%)	14 (58.3%)
Missing	4 (80.0%)	4 (57.1%)	26 (59.1%)	9 (37.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8205: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 17)	BAT (N = 8)	p-value
SF3602-Role Physical: NBS at Week 24			
Responder, n(%)	1 (5.9%)	0	
Unadjusted Relative Risk (95% CI)	1.50 (0.07, 33.26)		
p-value [1]	0.80		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Unadjusted Odds Ratio (95% CI)	1.55 (0.06, 42.15)		
p-value [1]	0.80		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.17, 0.22)		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	16 (94.1%)	8 (100.0%)	
Non-missing	6 (35.3%)	5 (62.5%)	
Missing	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8205: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 5)	BAT (N = 7)	MMB (N = 44)	BAT (N = 24)
SF3602-Bodily Pain: NBS at Week 24				
Responder, n(%)	1 (20.0%)	2 (28.6%)	2 (4.5%)	3 (12.5%)
Unadjusted Relative Risk (95% CI)	0.70 (0.09, 5.76)		0.36 (0.07, 2.03)	
p-value [1]	0.74		0.25	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Unadjusted Odds Ratio (95% CI)	0.63 (0.04, 9.65)		0.33 (0.05, 2.15)	
p-value [1]	0.74		0.25	
Unadjusted Absolute Risk Difference (95% CI)	-0.09 (-0.57, 0.40)		-0.08 (-0.23, 0.07)	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Non-Responder, n(%)	4 (80.0%)	5 (71.4%)	42 (95.5%)	21 (87.5%)
Non-missing	0	1 (14.3%)	16 (36.4%)	12 (50.0%)
Missing	4 (80.0%)	4 (57.1%)	26 (59.1%)	9 (37.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8205: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 17)	BAT (N = 8)	p-value
SF3602-Bodily Pain: NBS at Week 24			
Responder, n(%)	3 (17.6%)	0	
Unadjusted Relative Risk (95% CI)	3.50 (0.20, 60.70)		
p-value [1]	0.39		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Unadjusted Odds Ratio (95% CI)	4.10 (0.19, 89.45)		
p-value [1]	0.37		
Unadjusted Absolute Risk Difference (95% CI)	0.14 (-0.10, 0.38)		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	14 (82.4%)	8 (100.0%)	
Non-missing	4 (23.5%)	5 (62.5%)	
Missing	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8205: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 5)	BAT (N = 7)	MMB (N = 44)	BAT (N = 24)
SF3602-General Health: NBS at Week 24				
Responder, n(%)	1 (20.0%)	1 (14.3%)	1 (2.3%)	3 (12.5%)
Unadjusted Relative Risk (95% CI)	1.40 (0.11, 17.45)		0.18 (0.02, 1.65)	
p-value [1]	0.79		0.13	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Unadjusted Odds Ratio (95% CI)	1.50 (0.07, 31.58)		0.16 (0.02, 1.66)	
p-value [1]	0.79		0.13	
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.38, 0.49)		-0.10 (-0.24, 0.04)	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Non-Responder, n(%)	4 (80.0%)	6 (85.7%)	43 (97.7%)	21 (87.5%)
Non-missing	0	2 (28.6%)	17 (38.6%)	12 (50.0%)
Missing	4 (80.0%)	4 (57.1%)	26 (59.1%)	9 (37.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8205: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 17)	BAT (N = 8)	p-value
SF3602-General Health: NBS at Week 24			
Responder, n(%)	0	3 (37.5%)	
Unadjusted Relative Risk (95% CI)	0.07 (0.00, 1.24)		
p-value [1]	0.070		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Unadjusted Odds Ratio (95% CI)	0.04 (0.00, 1.01)		
p-value [1]	0.051		
Unadjusted Absolute Risk Difference (95% CI)	-0.36 (-0.69, -0.03		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	17 (100.0%)	5 (62.5%)	
Non-missing	7 (41.2%)	2 (25.0%)	
Missing	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8205: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 5)	BAT (N = 7)	MMB (N = 44)	BAT (N = 24)
SF3602-Vitality: NBS at Week 24				
Responder, n(%)	0	0	3 (6.8%)	0
Unadjusted Relative Risk (95% CI)	NA		3.89 (0.21, 72.29)	
p-value [1]	NA		0.36	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Unadjusted Odds Ratio (95% CI)	NA		4.13 (0.20, 83.42)	
p-value [1]	NA		0.35	
Unadjusted Absolute Risk Difference (95% CI)	NA		0.06 (-0.04, 0.15)	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Non-Responder, n(%)	5 (100.0%)	7 (100.0%)	41 (93.2%)	24 (100.0%)
Non-missing	1 (20.0%)	3 (42.9%)	15 (34.1%)	15 (62.5%)
Missing	4 (80.0%)	4 (57.1%)	26 (59.1%)	9 (37.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8205: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 17)	BAT (N = 8)	p-value
SF3602-Vitality: NBS at Week 24			
Responder, n(%)	1 (5.9%)	2 (25.0%)	
Unadjusted Relative Risk (95% CI)	0.24 (0.02, 2.23)		
p-value [1]	0.21		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Unadjusted Odds Ratio (95% CI)	0.19 (0.01, 2.47)		
p-value [1]	0.20		
Unadjusted Absolute Risk Difference (95% CI)	-0.19 (-0.51, 0.13)		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	16 (94.1%)	6 (75.0%)	
Non-missing	6 (35.3%)	3 (37.5%)	
Missing	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8205: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 5)	BAT (N = 7)	MMB (N = 44)	BAT (N = 24)
SF3602-Social Functioning: NBS at Week 24				
Responder, n(%)	0	0	2 (4.5%)	3 (12.5%)
Unadjusted Relative Risk (95% CI)	NA		0.36 (0.07, 2.03)	
p-value [1]	NA		0.25	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Unadjusted Odds Ratio (95% CI)	NA		0.33 (0.05, 2.15)	
p-value [1]	NA		0.25	
Unadjusted Absolute Risk Difference (95% CI)	NA		-0.08 (-0.23, 0.07)	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Non-Responder, n(%)	5 (100.0%)	7 (100.0%)	42 (95.5%)	21 (87.5%)
Non-missing	1 (20.0%)	3 (42.9%)	16 (36.4%)	12 (50.0%)
Missing	4 (80.0%)	4 (57.1%)	26 (59.1%)	9 (37.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8205: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 17)	BAT (N = 8)	p-value
SF3602-Social Functioning: NBS at Week 24			
Responder, n(%)	0	2 (25.0%)	
Unadjusted Relative Risk (95% CI)	0.10 (0.01, 1.87)		
p-value [1]	0.12		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Unadjusted Odds Ratio (95% CI)	0.07 (0.00, 1.76)		
p-value [1]	0.11		
Unadjusted Absolute Risk Difference (95% CI)	-0.25 (-0.55, 0.05)		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	17 (100.0%)	6 (75.0%)	
Non-missing	7 (41.2%)	3 (37.5%)	
Missing	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8205: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 5)	BAT (N = 7)	MMB (N = 44)	BAT (N = 24)
SF3602-Role Emotional: NBS at Week 24				
Responder, n(%)	1 (20.0%)	0	6 (13.6%)	1 (4.2%)
Unadjusted Relative Risk (95% CI)	4.00 (0.20, 82.01)		3.27 (0.42, 25.62)	
p-value [1]	0.37		0.26	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Unadjusted Odds Ratio (95% CI)	5.00 (0.17, 150.93)		3.63 (0.41, 32.11)	
p-value [1]	0.35		0.25	
Unadjusted Absolute Risk Difference (95% CI)	0.19 (-0.20, 0.57)		0.09 (-0.03, 0.22)	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Non-Responder, n(%)	4 (80.0%)	7 (100.0%)	38 (86.4%)	23 (95.8%)
Non-missing	0	3 (42.9%)	12 (27.3%)	14 (58.3%)
Missing	4 (80.0%)	4 (57.1%)	26 (59.1%)	9 (37.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8205: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 17)	BAT (N = 8)	p-value
SF3602-Role Emotional: NBS at Week 24			
Responder, n(%)	1 (5.9%)	2 (25.0%)	
Unadjusted Relative Risk (95% CI)	0.24 (0.02, 2.23)		
p-value [1]	0.21		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Unadjusted Odds Ratio (95% CI)	0.19 (0.01, 2.47)		
p-value [1]	0.20		
Unadjusted Absolute Risk Difference (95% CI)	-0.19 (-0.51, 0.13)		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	16 (94.1%)	6 (75.0%)	
Non-missing	6 (35.3%)	3 (37.5%)	
Missing	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8205: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 5)	BAT (N = 7)	MMB (N = 44)	BAT (N = 24)
SF3602-Mental Health: NBS at Week 24				
Responder, n(%)	0	2 (28.6%)	3 (6.8%)	1 (4.2%)
Unadjusted Relative Risk (95% CI)	0.27 (0.02, 4.59)		1.64 (0.18, 14.89)	
p-value [1]	0.36		0.66	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Unadjusted Odds Ratio (95% CI)	0.20 (0.01, 5.20)		1.68 (0.17, 17.13)	
p-value [1]	0.33		0.66	
Unadjusted Absolute Risk Difference (95% CI)	-0.23 (-0.62, 0.16)		0.03 (-0.08, 0.14)	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Non-Responder, n(%)	5 (100.0%)	5 (71.4%)	41 (93.2%)	23 (95.8%)
Non-missing	1 (20.0%)	1 (14.3%)	15 (34.1%)	14 (58.3%)
Missing	4 (80.0%)	4 (57.1%)	26 (59.1%)	9 (37.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8205: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 17)	BAT (N = 8)	p-value
SF3602-Mental Health: NBS at Week 24			
Responder, n(%)	1 (5.9%)	2 (25.0%)	
Unadjusted Relative Risk (95% CI)	0.24 (0.02, 2.23)		
p-value [1]	0.21		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Unadjusted Odds Ratio (95% CI)	0.19 (0.01, 2.47)		
p-value [1]	0.20		
Unadjusted Absolute Risk Difference (95% CI)	-0.19 (-0.51, 0.13)		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	16 (94.1%)	6 (75.0%)	
Non-missing	6 (35.3%)	3 (37.5%)	
Missing	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8205: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 5)	BAT (N = 7)	MMB (N = 44)	BAT (N = 24)
SF3602-Physical Component Summary at Week 24				
Responder, n(%)	0	0	1 (2.3%)	1 (4.2%)
Unadjusted Relative Risk (95% CI)	NA		0.55 (0.04, 8.34)	
p-value [1]	NA		0.66	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Unadjusted Odds Ratio (95% CI)	NA		0.53 (0.03, 8.95)	
p-value [1]	NA		0.66	
Unadjusted Absolute Risk Difference (95% CI)	NA		-0.02 (-0.11, 0.07)	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Non-Responder, n(%)	5 (100.0%)	7 (100.0%)	43 (97.7%)	23 (95.8%)
Non-missing	1 (20.0%)	3 (42.9%)	17 (38.6%)	14 (58.3%)
Missing	4 (80.0%)	4 (57.1%)	26 (59.1%)	9 (37.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8205: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 17)	BAT (N = 8)	p-value
SF3602-Physical Component Summary at Week 24			
Responder, n(%)	1 (5.9%)	0	
Unadjusted Relative Risk (95% CI)	1.50 (0.07, 33.26)		
p-value [1]	0.80		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Unadjusted Odds Ratio (95% CI)	1.55 (0.06, 42.15)		
p-value [1]	0.80		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.17, 0.22)		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	16 (94.1%)	8 (100.0%)	
Non-missing	6 (35.3%)	5 (62.5%)	
Missing	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8205: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 5)	BAT (N = 7)	MMB (N = 44)	BAT (N = 24)
SF3602-Mental Component Summary at Week 24				
Responder, n(%)	0	0	3 (6.8%)	1 (4.2%)
Unadjusted Relative Risk (95% CI)	NA		1.64 (0.18, 14.89)	
p-value [1]	NA		0.66	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Unadjusted Odds Ratio (95% CI)	NA		1.68 (0.17, 17.13)	
p-value [1]	NA		0.66	
Unadjusted Absolute Risk Difference (95% CI)	NA		0.03 (-0.08, 0.14)	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Non-Responder, n(%)	5 (100.0%)	7 (100.0%)	41 (93.2%)	23 (95.8%)
Non-missing	1 (20.0%)	3 (42.9%)	15 (34.1%)	14 (58.3%)
Missing	4 (80.0%)	4 (57.1%)	26 (59.1%)	9 (37.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8205: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 17)	BAT (N = 8)	p-value
SF3602-Mental Component Summary at Week 24			
Responder, n(%)	0	2 (25.0%)	
Unadjusted Relative Risk (95% CI)	0.10 (0.01, 1.87)		
p-value [1]	0.12		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Unadjusted Odds Ratio (95% CI)	0.07 (0.00, 1.76)		
p-value [1]	0.11		
Unadjusted Absolute Risk Difference (95% CI)	-0.25 (-0.55, 0.05)		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	17 (100.0%)	6 (75.0%)	
Non-missing	7 (41.2%)	3 (37.5%)	
Missing	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8208: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 45)	BAT (N = 23)	MMB (N = 13)	BAT (N = 8)
SF3602-Physical Functioning: NBS at Week 24				
Responder, n(%)	3 (6.7%)	3 (13.0%)	1 (7.7%)	1 (12.5%)
Unadjusted Relative Risk (95% CI)	0.51 (0.11, 2.34)		0.62 (0.04, 8.52)	
p-value [1]	0.39		0.72	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Odds Ratio (95% CI)	0.48 (0.09, 2.57)		0.58 (0.03, 10.86)	
p-value [1]	0.39		0.72	
Unadjusted Absolute Risk Difference (95% CI)	-0.06 (-0.22, 0.09)		-0.05 (-0.32, 0.22)	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	42 (93.3%)	20 (87.0%)	12 (92.3%)	7 (87.5%)
Non-missing	15 (33.3%)	10 (43.5%)	4 (30.8%)	2 (25.0%)
Missing	27 (60.0%)	10 (43.5%)	8 (61.5%)	5 (62.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8208: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 8)	BAT (N = 8)	p-value
SF3602-Physical Functioning: NBS at Week 24			
Responder, n(%)	0	0	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Non-Responder, n(%)	8 (100.0%)	8 (100.0%)	
Non-missing	3 (37.5%)	7 (87.5%)	
Missing	5 (62.5%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8208: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 45)	BAT (N = 23)	MMB (N = 13)	BAT (N = 8)
SF3602-Role Physical: NBS at Week 24				
Responder, n(%)	5 (11.1%)	0	1 (7.7%)	0
Unadjusted Relative Risk (95% CI)	5.74 (0.33, 99.49)		1.93 (0.09, 42.35)	
p-value [1]	0.23		0.68	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Odds Ratio (95% CI)	6.38 (0.34, 120.66)		2.04 (0.07, 56.27)	
p-value [1]	0.22		0.67	
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.01, 0.21)		0.05 (-0.17, 0.27)	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	40 (88.9%)	23 (100.0%)	12 (92.3%)	8 (100.0%)
Non-missing	13 (28.9%)	13 (56.5%)	4 (30.8%)	3 (37.5%)
Missing	27 (60.0%)	10 (43.5%)	8 (61.5%)	5 (62.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8208: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 8)	BAT (N = 8)	p-value
SF3602-Role Physical: NBS at Week 24			
Responder, n(%)	1 (12.5%)	1 (12.5%)	
Unadjusted Relative Risk (95% CI)	1.00 (0.07, 13.37)		
p-value [1]	1.00		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Unadjusted Odds Ratio (95% CI)	1.00 (0.05, 19.36)		
p-value [1]	1.00		
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.32, 0.32)		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Non-Responder, n(%)	7 (87.5%)	7 (87.5%)	
Non-missing	2 (25.0%)	6 (75.0%)	
Missing	5 (62.5%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8208: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 45)	BAT (N = 23)	MMB (N = 13)	BAT (N = 8)
SF3602-Bodily Pain: NBS at Week 24				
Responder, n(%)	6 (13.3%)	4 (17.4%)	0	0
Unadjusted Relative Risk (95% CI)	0.77 (0.24, 2.45)		NA	
p-value [1]	0.65		NA	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Odds Ratio (95% CI)	0.73 (0.18, 2.90)		NA	
p-value [1]	0.66		NA	
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.22, 0.14)		NA	
Adjusted Relative Risk (95% CI) [2]	NE		NA	
p-value [2]	NE		NA	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	39 (86.7%)	19 (82.6%)	13 (100.0%)	8 (100.0%)
Non-missing	12 (26.7%)	9 (39.1%)	5 (38.5%)	3 (37.5%)
Missing	27 (60.0%)	10 (43.5%)	8 (61.5%)	5 (62.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8208: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 8)	BAT (N = 8)	p-value
SF3602-Bodily Pain: NBS at Week 24			
Responder, n(%)	0	1 (12.5%)	
Unadjusted Relative Risk (95% CI)	0.33 (0.02, 7.14)		
p-value [1]	0.48		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NE
Unadjusted Odds Ratio (95% CI)	0.29 (0.01, 8.37)		
p-value [1]	0.47		
Unadjusted Absolute Risk Difference (95% CI)	-0.11 (-0.40, 0.17)		
Adjusted Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NE
Non-Responder, n(%)	8 (100.0%)	7 (87.5%)	
Non-missing	3 (37.5%)	6 (75.0%)	
Missing	5 (62.5%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8208: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 45)	BAT (N = 23)	MMB (N = 13)	BAT (N = 8)
SF3602-General Health: NBS at Week 24				
Responder, n(%)	2 (4.4%)	7 (30.4%)	0	0
Unadjusted Relative Risk (95% CI)	0.15 (0.03, 0.65)		NA	
p-value [1]	0.011		NA	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Odds Ratio (95% CI)	0.11 (0.02, 0.57)		NA	
p-value [1]	0.009		NA	
Unadjusted Absolute Risk Difference (95% CI)	-0.26 (-0.46, -0.06		NA	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	43 (95.6%)	16 (69.6%)	13 (100.0%)	8 (100.0%)
Non-missing	16 (35.6%)	6 (26.1%)	5 (38.5%)	3 (37.5%)
Missing	27 (60.0%)	10 (43.5%)	8 (61.5%)	5 (62.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8208: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 8)	BAT (N = 8)	p-value
SF3602-General Health: NBS at Week 24			
Responder, n(%)	0	0	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Non-Responder, n(%)	8 (100.0%)	8 (100.0%)	
Non-missing	3 (37.5%)	7 (87.5%)	
Missing	5 (62.5%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8208: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 45)	BAT (N = 23)	MMB (N = 13)	BAT (N = 8)
SF3602-Vitality: NBS at Week 24				
Responder, n(%)	3 (6.7%)	2 (8.7%)	1 (7.7%)	0
Unadjusted Relative Risk (95% CI)	0.77 (0.14, 4.27)		1.93 (0.09, 42.35)	
p-value [1]	0.76		0.68	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Odds Ratio (95% CI)	0.75 (0.12, 4.84)		2.04 (0.07, 56.27)	
p-value [1]	0.76		0.67	
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.16, 0.12)		0.05 (-0.17, 0.27)	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	42 (93.3%)	21 (91.3%)	12 (92.3%)	8 (100.0%)
Non-missing	15 (33.3%)	11 (47.8%)	4 (30.8%)	3 (37.5%)
Missing	27 (60.0%)	10 (43.5%)	8 (61.5%)	5 (62.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8208: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 8)	BAT (N = 8)	p-value
SF3602-Vitality: NBS at Week 24			
Responder, n(%)	0	0	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Non-Responder, n(%)	8 (100.0%)	8 (100.0%)	
Non-missing	3 (37.5%)	7 (87.5%)	
Missing	5 (62.5%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8208: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 45)	BAT (N = 23)	MMB (N = 13)	BAT (N = 8)
SF3602-Social Functioning: NBS at Week 24				
Responder, n(%)	1 (2.2%)	2 (8.7%)	0	1 (12.5%)
Unadjusted Relative Risk (95% CI)	0.26 (0.02, 2.67)		0.21 (0.01, 4.71)	
p-value [1]	0.25		0.33	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Odds Ratio (95% CI)	0.24 (0.02, 2.78)		0.19 (0.01, 5.14)	
p-value [1]	0.25		0.32	
Unadjusted Absolute Risk Difference (95% CI)	-0.06 (-0.19, 0.06)		-0.13 (-0.39, 0.13)	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	44 (97.8%)	21 (91.3%)	13 (100.0%)	7 (87.5%)
Non-missing	17 (37.8%)	11 (47.8%)	5 (38.5%)	2 (25.0%)
Missing	27 (60.0%)	10 (43.5%)	8 (61.5%)	5 (62.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8208: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 8)	BAT (N = 8)	p-value
SF3602-Social Functioning: NBS at Week 24			
Responder, n(%)	1 (12.5%)	2 (25.0%)	
Unadjusted Relative Risk (95% CI)	0.50 (0.06, 4.47)		
p-value [1]	0.54		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Unadjusted Odds Ratio (95% CI)	0.43 (0.03, 5.99)		
p-value [1]	0.53		
Unadjusted Absolute Risk Difference (95% CI)	-0.13 (-0.50, 0.25)		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Non-Responder, n(%)	7 (87.5%)	6 (75.0%)	
Non-missing	2 (25.0%)	5 (62.5%)	
Missing	5 (62.5%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8208: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 45)	BAT (N = 23)	MMB (N = 13)	BAT (N = 8)
SF3602-Role Emotional: NBS at Week 24				
Responder, n(%)	4 (8.9%)	2 (8.7%)	2 (15.4%)	0
Unadjusted Relative Risk (95% CI)	1.02 (0.20, 5.17)		3.21 (0.17, 59.52)	
p-value [1]	0.98		0.43	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Odds Ratio (95% CI)	1.02 (0.17, 6.06)		3.70 (0.16, 87.39)	
p-value [1]	0.98		0.42	
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.14, 0.14)		0.12 (-0.13, 0.37)	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	41 (91.1%)	21 (91.3%)	11 (84.6%)	8 (100.0%)
Non-missing	14 (31.1%)	11 (47.8%)	3 (23.1%)	3 (37.5%)
Missing	27 (60.0%)	10 (43.5%)	8 (61.5%)	5 (62.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8208: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 8)	BAT (N = 8)	p-value
SF3602-Role Emotional: NBS at Week 24			
Responder, n(%)	2 (25.0%)	1 (12.5%)	
Unadjusted Relative Risk (95% CI)	2.00 (0.22, 17.89)		
p-value [1]	0.54		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Unadjusted Odds Ratio (95% CI)	2.33 (0.17, 32.59)		
p-value [1]	0.53		
Unadjusted Absolute Risk Difference (95% CI)	0.13 (-0.25, 0.50)		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Non-Responder, n(%)	6 (75.0%)	7 (87.5%)	
Non-missing	1 (12.5%)	6 (75.0%)	
Missing	5 (62.5%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8208: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 45)	BAT (N = 23)	MMB (N = 13)	BAT (N = 8)
SF3602-Mental Health: NBS at Week 24				
Responder, n(%)	3 (6.7%)	4 (17.4%)	0	1 (12.5%)
Unadjusted Relative Risk (95% CI)	0.38 (0.09, 1.57)		0.21 (0.01, 4.71)	
p-value [1]	0.18		0.33	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Odds Ratio (95% CI)	0.34 (0.07, 1.67)		0.19 (0.01, 5.14)	
p-value [1]	0.18		0.32	
Unadjusted Absolute Risk Difference (95% CI)	-0.11 (-0.28, 0.06)		-0.13 (-0.39, 0.13)	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	42 (93.3%)	19 (82.6%)	13 (100.0%)	7 (87.5%)
Non-missing	15 (33.3%)	9 (39.1%)	5 (38.5%)	2 (25.0%)
Missing	27 (60.0%)	10 (43.5%)	8 (61.5%)	5 (62.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8208: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 8)	BAT (N = 8)	p-value
SF3602-Mental Health: NBS at Week 24			
Responder, n(%)	1 (12.5%)	0	
Unadjusted Relative Risk (95% CI)	3.00 (0.14, 64.27)		
p-value [1]	0.48		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Unadjusted Odds Ratio (95% CI)	3.40 (0.12, 96.71)		
p-value [1]	0.47		
Unadjusted Absolute Risk Difference (95% CI)	0.11 (-0.17, 0.40)		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Non-Responder, n(%)	7 (87.5%)	8 (100.0%)	
Non-missing	2 (25.0%)	7 (87.5%)	
Missing	5 (62.5%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8208: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 45)	BAT (N = 23)	MMB (N = 13)	BAT (N = 8)
SF3602-Physical Component Summary at Week 24				
Responder, n(%)	2 (4.4%)	1 (4.3%)	0	0
Unadjusted Relative Risk (95% CI)	1.02 (0.10, 10.69)		NA	
p-value [1]	0.99		NA	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Odds Ratio (95% CI)	1.02 (0.09, 11.92)		NA	
p-value [1]	0.99		NA	
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.10, 0.10)		NA	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	43 (95.6%)	22 (95.7%)	13 (100.0%)	8 (100.0%)
Non-missing	16 (35.6%)	12 (52.2%)	5 (38.5%)	3 (37.5%)
Missing	27 (60.0%)	10 (43.5%)	8 (61.5%)	5 (62.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8208: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 8)	BAT (N = 8)	p-value
SF3602-Physical Component Summary at Week 24			
Responder, n(%)	0	0	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Non-Responder, n(%)	8 (100.0%)	8 (100.0%)	
Non-missing	3 (37.5%)	7 (87.5%)	
Missing	5 (62.5%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8208: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 45)	BAT (N = 23)	MMB (N = 13)	BAT (N = 8)
SF3602-Mental Component Summary at Week 24				
Responder, n(%)	2 (4.4%)	2 (8.7%)	0	0
Unadjusted Relative Risk (95% CI)	0.51 (0.08, 3.40)		NA	
p-value [1]	0.49		NA	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Odds Ratio (95% CI)	0.49 (0.06, 3.71)		NA	
p-value [1]	0.49		NA	
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.17, 0.09)		NA	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	43 (95.6%)	21 (91.3%)	13 (100.0%)	8 (100.0%)
Non-missing	16 (35.6%)	11 (47.8%)	5 (38.5%)	3 (37.5%)
Missing	27 (60.0%)	10 (43.5%)	8 (61.5%)	5 (62.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8208: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 8)	BAT (N = 8)	p-value
SF3602-Mental Component Summary at Week 24			
Responder, n(%)	1 (12.5%)	1 (12.5%)	
Unadjusted Relative Risk (95% CI)	1.00 (0.07, 13.37)		
p-value [1]	1.00		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Unadjusted Odds Ratio (95% CI)	1.00 (0.05, 19.36)		
p-value [1]	1.00		
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.32, 0.32)		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Non-Responder, n(%)	7 (87.5%)	7 (87.5%)	
Non-missing	2 (25.0%)	6 (75.0%)	
Missing	5 (62.5%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8203: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 52)	BAT (N = 18)	MMB (N = 14)	BAT (N = 21)	p-value
SF3602-Physical Functioning: NBS at Week 24					
Responder, n(%)	1 (1.9%)	2 (11.1%)	3 (21.4%)	2 (9.5%)	
Unadjusted Relative Risk (95% CI)	0.17 (0.02, 1.80)		2.25 (0.43, 11.79)		
p-value [1]	0.14		0.34		
Unadjusted interaction test for Treatment*Gender [3]					NA
Unadjusted Odds Ratio (95% CI)	0.16 (0.01, 1.85)		2.59 (0.37, 17.98)		
p-value [1]	0.14		0.34		
Unadjusted Absolute Risk Difference (95% CI)	-0.09 (-0.24, 0.06)		0.12 (-0.13, 0.37)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Gender [3]					NA
Non-Responder, n(%)	51 (98.1%)	16 (88.9%)	11 (78.6%)	19 (90.5%)	
Non-missing	17 (32.7%)	6 (33.3%)	5 (35.7%)	13 (61.9%)	
Missing	34 (65.4%)	10 (55.6%)	6 (42.9%)	6 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8203: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 52)	BAT (N = 18)	MMB (N = 14)	BAT (N = 21)	p-value
SF3602-Role Physical: NBS at Week 24					
Responder, n(%)	6 (11.5%)	0	1 (7.1%)	1 (4.8%)	
Unadjusted Relative Risk (95% CI)	4.66 (0.28, 78.84)		1.50 (0.10, 22.06)		
p-value [1]	0.29		0.77		
Unadjusted interaction test for Treatment*Gender [3]					NA
Unadjusted Odds Ratio (95% CI)	5.17 (0.28, 96.52)		1.54 (0.09, 26.82)		
p-value [1]	0.27		0.77		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.02, 0.21)		0.02 (-0.14, 0.19)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Gender [3]					NA
Non-Responder, n(%)	46 (88.5%)	18 (100.0%)	13 (92.9%)	20 (95.2%)	
Non-missing	12 (23.1%)	8 (44.4%)	7 (50.0%)	14 (66.7%)	
Missing	34 (65.4%)	10 (55.6%)	6 (42.9%)	6 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8203: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 52)	BAT (N = 18)	MMB (N = 14)	BAT (N = 21)	p-value
SF3602-Bodily Pain: NBS at Week 24					
Responder, n(%)	3 (5.8%)	2 (11.1%)	3 (21.4%)	3 (14.3%)	
Unadjusted Relative Risk (95% CI)	0.52 (0.09, 2.86)		1.50 (0.35, 6.40)		
p-value [1]	0.45		0.58		
Unadjusted interaction test for Treatment*Gender [3]					NA
Unadjusted Odds Ratio (95% CI)	0.49 (0.08, 3.20)		1.64 (0.28, 9.58)		
p-value [1]	0.46		0.58		
Unadjusted Absolute Risk Difference (95% CI)	-0.05 (-0.21, 0.10)		0.07 (-0.19, 0.33)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Gender [3]					NA
Non-Responder, n(%)	49 (94.2%)	16 (88.9%)	11 (78.6%)	18 (85.7%)	
Non-missing	15 (28.8%)	6 (33.3%)	5 (35.7%)	12 (57.1%)	
Missing	34 (65.4%)	10 (55.6%)	6 (42.9%)	6 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8203: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 52)	BAT (N = 18)	MMB (N = 14)	BAT (N = 21)	p-value
SF3602-General Health: NBS at Week 24					
Responder, n(%)	2 (3.8%)	4 (22.2%)	0	3 (14.3%)	
Unadjusted Relative Risk (95% CI)	0.17 (0.03, 0.87)		0.21 (0.01, 3.77)		
p-value [1]	0.033		0.29		
Unadjusted interaction test for Treatment*Gender [3]					NA
Unadjusted Odds Ratio (95% CI)	0.14 (0.02, 0.85)		0.18 (0.01, 3.82)		
p-value [1]	0.032		0.27		
Unadjusted Absolute Risk Difference (95% CI)	-0.18 (-0.38, 0.02)		-0.13 (-0.30, 0.05)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Gender [3]					NA
Non-Responder, n(%)	50 (96.2%)	14 (77.8%)	14 (100.0%)	18 (85.7%)	
Non-missing	16 (30.8%)	4 (22.2%)	8 (57.1%)	12 (57.1%)	
Missing	34 (65.4%)	10 (55.6%)	6 (42.9%)	6 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8203: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 52)	BAT (N = 18)	MMB (N = 14)	BAT (N = 21)	p-value
SF3602-Vitality: NBS at Week 24					
Responder, n(%)	3 (5.8%)	1 (5.6%)	1 (7.1%)	1 (4.8%)	
Unadjusted Relative Risk (95% CI)	1.04 (0.12, 9.36)		1.50 (0.10, 22.06)		
p-value [1]	0.97		0.77		
Unadjusted interaction test for Treatment*Gender [3]					NA
Unadjusted Odds Ratio (95% CI)	1.04 (0.10, 10.69)		1.54 (0.09, 26.82)		
p-value [1]	0.97		0.77		
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.12, 0.13)		0.02 (-0.14, 0.19)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Gender [3]					NA
Non-Responder, n(%)	49 (94.2%)	17 (94.4%)	13 (92.9%)	20 (95.2%)	
Non-missing	15 (28.8%)	7 (38.9%)	7 (50.0%)	14 (66.7%)	
Missing	34 (65.4%)	10 (55.6%)	6 (42.9%)	6 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8203: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 52)	BAT (N = 18)	MMB (N = 14)	BAT (N = 21)	p-value
SF3602-Social Functioning: NBS at Week 24					
Responder, n(%)	2 (3.8%)	1 (5.6%)	0	4 (19.0%)	
Unadjusted Relative Risk (95% CI)	0.69 (0.07, 7.19)		0.16 (0.01, 2.81)		
p-value [1]	0.76		0.21		
Unadjusted interaction test for Treatment*Gender [3]					NA
Unadjusted Odds Ratio (95% CI)	0.68 (0.06, 7.98)		0.13 (0.01, 2.70)		
p-value [1]	0.76		0.19		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.14, 0.10)		-0.17 (-0.36, 0.02)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Gender [3]					NA
Non-Responder, n(%)	50 (96.2%)	17 (94.4%)	14 (100.0%)	17 (81.0%)	
Non-missing	16 (30.8%)	7 (38.9%)	8 (57.1%)	11 (52.4%)	
Missing	34 (65.4%)	10 (55.6%)	6 (42.9%)	6 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8203: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 52)	BAT (N = 18)	MMB (N = 14)	BAT (N = 21)	p-value
SF3602-Role Emotional: NBS at Week 24					
Responder, n(%)	6 (11.5%)	1 (5.6%)	2 (14.3%)	2 (9.5%)	
Unadjusted Relative Risk (95% CI)	2.08 (0.27, 16.10)		1.50 (0.24, 9.44)		
p-value [1]	0.48		0.67		
Unadjusted interaction test for Treatment*Gender [3]					NA
Unadjusted Odds Ratio (95% CI)	2.22 (0.25, 19.79)		1.58 (0.20, 12.79)		
p-value [1]	0.48		0.67		
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.08, 0.20)		0.05 (-0.17, 0.27)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Gender [3]					NA
Non-Responder, n(%)	46 (88.5%)	17 (94.4%)	12 (85.7%)	19 (90.5%)	
Non-missing	12 (23.1%)	7 (38.9%)	6 (42.9%)	13 (61.9%)	
Missing	34 (65.4%)	10 (55.6%)	6 (42.9%)	6 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8203: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 52)	BAT (N = 18)	MMB (N = 14)	BAT (N = 21)	p-value
SF3602-Mental Health: NBS at Week 24					
Responder, n(%)	3 (5.8%)	1 (5.6%)	1 (7.1%)	4 (19.0%)	
Unadjusted Relative Risk (95% CI)	1.04 (0.12, 9.36)		0.38 (0.05, 3.01)		
p-value [1]	0.97		0.36		
Unadjusted interaction test for Treatment*Gender [3]					NA
Unadjusted Odds Ratio (95% CI)	1.04 (0.10, 10.69)		0.33 (0.03, 3.28)		
p-value [1]	0.97		0.34		
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.12, 0.13)		-0.12 (-0.33, 0.10)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Gender [3]					NA
Non-Responder, n(%)	49 (94.2%)	17 (94.4%)	13 (92.9%)	17 (81.0%)	
Non-missing	15 (28.8%)	7 (38.9%)	7 (50.0%)	11 (52.4%)	
Missing	34 (65.4%)	10 (55.6%)	6 (42.9%)	6 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8203: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 52)	BAT (N = 18)	MMB (N = 14)	BAT (N = 21)	p-value
SF3602-Physical Component Summary at Week 24					
Responder, n(%)	1 (1.9%)	1 (5.6%)	1 (7.1%)	0	
Unadjusted Relative Risk (95% CI)	0.35 (0.02, 5.25)		4.40 (0.19, 100.91)		
p-value [1]	0.44		0.35		
Unadjusted interaction test for Treatment*Gender [3]					NA
Unadjusted Odds Ratio (95% CI)	0.33 (0.02, 5.62)		4.78 (0.18, 125.99)		
p-value [1]	0.45		0.35		
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.15, 0.08)		0.08 (-0.09, 0.24)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Gender [3]					NA
Non-Responder, n(%)	51 (98.1%)	17 (94.4%)	13 (92.9%)	21 (100.0%)	
Non-missing	17 (32.7%)	7 (38.9%)	7 (50.0%)	15 (71.4%)	
Missing	34 (65.4%)	10 (55.6%)	6 (42.9%)	6 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8203: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 52)	BAT (N = 18)	MMB (N = 14)	BAT (N = 21)	p-value
SF3602-Mental Component Summary at Week 24					
Responder, n(%)	3 (5.8%)	1 (5.6%)	0	2 (9.5%)	
Unadjusted Relative Risk (95% CI)	1.04 (0.12, 9.36)		0.29 (0.02, 5.69)		
p-value [1]	0.97		0.42		
Unadjusted interaction test for Treatment*Gender [3]					NA
Unadjusted Odds Ratio (95% CI)	1.04 (0.10, 10.69)		0.27 (0.01, 6.04)		
p-value [1]	0.97		0.41		
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.12, 0.13)		-0.08 (-0.24, 0.08)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Gender [3]					NA
Non-Responder, n(%)	49 (94.2%)	17 (94.4%)	14 (100.0%)	19 (90.5%)	
Non-missing	15 (28.8%)	7 (38.9%)	8 (57.1%)	13 (61.9%)	
Missing	34 (65.4%)	10 (55.6%)	6 (42.9%)	6 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8210: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N = 28)	BAT (N = 24)	MMB (N = 38)	BAT (N = 15)	p-value
SF3602-Physical Functioning: NBS at Week 24					
Responder, n(%)	3 (10.7%)	2 (8.3%)	1 (2.6%)	2 (13.3%)	
Unadjusted Relative Risk (95% CI)	1.29 (0.23, 7.07)		0.20 (0.02, 2.02)		
p-value [1]	0.77		0.17		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Odds Ratio (95% CI)	1.32 (0.20, 8.64)		0.18 (0.01, 2.10)		
p-value [1]	0.77		0.17		
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.14, 0.18)		-0.11 (-0.29, 0.07)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Non-Responder, n(%)	25 (89.3%)	22 (91.7%)	37 (97.4%)	13 (86.7%)	
Non-missing	9 (32.1%)	14 (58.3%)	13 (34.2%)	5 (33.3%)	
Missing	16 (57.1%)	8 (33.3%)	24 (63.2%)	8 (53.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8210: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N = 28)	BAT (N = 24)	MMB (N = 38)	BAT (N = 15)	p-value
SF3602-Role Physical: NBS at Week 24					
Responder, n(%)	3 (10.7%)	1 (4.2%)	4 (10.5%)	0	
Unadjusted Relative Risk (95% CI)	2.57 (0.29, 23.13)		3.69 (0.21, 64.68)		
p-value [1]	0.40		0.37		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Odds Ratio (95% CI)	2.76 (0.27, 28.45)		4.04 (0.20, 79.82)		
p-value [1]	0.39		0.36		
Unadjusted Absolute Risk Difference (95% CI)	0.07 (-0.07, 0.21)		0.08 (-0.05, 0.22)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Non-Responder, n(%)	25 (89.3%)	23 (95.8%)	34 (89.5%)	15 (100.0%)	
Non-missing	9 (32.1%)	15 (62.5%)	10 (26.3%)	7 (46.7%)	
Missing	16 (57.1%)	8 (33.3%)	24 (63.2%)	8 (53.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8210: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N = 28)	BAT (N = 24)	MMB (N = 38)	BAT (N = 15)	p-value
SF3602-Bodily Pain: NBS at Week 24					
Responder, n(%)	1 (3.6%)	5 (20.8%)	5 (13.2%)	0	
Unadjusted Relative Risk (95% CI)	0.17 (0.02, 1.37)		4.51 (0.26, 76.93)		
p-value [1]	0.096		0.30		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Odds Ratio (95% CI)	0.14 (0.02, 1.30)		5.09 (0.26, 97.93)		
p-value [1]	0.084		0.28		
Unadjusted Absolute Risk Difference (95% CI)	-0.17 (-0.35, 0.00)		0.11 (-0.03, 0.25)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Non-Responder, n(%)	27 (96.4%)	19 (79.2%)	33 (86.8%)	15 (100.0%)	
Non-missing	11 (39.3%)	11 (45.8%)	9 (23.7%)	7 (46.7%)	
Missing	16 (57.1%)	8 (33.3%)	24 (63.2%)	8 (53.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8210: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N = 28)	BAT (N = 24)	MMB (N = 38)	BAT (N = 15)	p-value
SF3602-General Health: NBS at Week 24					
Responder, n(%)	0	5 (20.8%)	2 (5.3%)	2 (13.3%)	
Unadjusted Relative Risk (95% CI)	0.08 (0.00, 1.35)		0.39 (0.06, 2.55)		
p-value [1]	0.079		0.33		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Odds Ratio (95% CI)	0.06 (0.00, 1.19)		0.36 (0.05, 2.83)		
p-value [1]	0.065		0.33		
Unadjusted Absolute Risk Difference (95% CI)	-0.20 (-0.37, -0.03)		-0.08 (-0.27, 0.11)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Non-Responder, n(%)	28 (100.0%)	19 (79.2%)	36 (94.7%)	13 (86.7%)	
Non-missing	12 (42.9%)	11 (45.8%)	12 (31.6%)	5 (33.3%)	
Missing	16 (57.1%)	8 (33.3%)	24 (63.2%)	8 (53.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8210: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N = 28)	BAT (N = 24)	MMB (N = 38)	BAT (N = 15)	p-value
SF3602-Vitality: NBS at Week 24					
Responder, n(%)	2 (7.1%)	1 (4.2%)	2 (5.3%)	1 (6.7%)	
Unadjusted Relative Risk (95% CI)	1.71 (0.17, 17.76)		0.79 (0.08, 8.07)		
p-value [1]	0.65		0.84		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Odds Ratio (95% CI)	1.77 (0.15, 20.82)		0.78 (0.07, 9.27)		
p-value [1]	0.65		0.84		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.09, 0.15)		-0.01 (-0.16, 0.13)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Non-Responder, n(%)	26 (92.9%)	23 (95.8%)	36 (94.7%)	14 (93.3%)	
Non-missing	10 (35.7%)	15 (62.5%)	12 (31.6%)	6 (40.0%)	
Missing	16 (57.1%)	8 (33.3%)	24 (63.2%)	8 (53.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8210: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N = 28)	BAT (N = 24)	MMB (N = 38)	BAT (N = 15)	p-value
SF3602-Social Functioning: NBS at Week 24					
Responder, n(%)	0	3 (12.5%)	2 (5.3%)	2 (13.3%)	
Unadjusted Relative Risk (95% CI)	0.12 (0.01, 2.27)		0.39 (0.06, 2.55)		
p-value [1]	0.16		0.33		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Odds Ratio (95% CI)	0.11 (0.01, 2.20)		0.36 (0.05, 2.83)		
p-value [1]	0.15		0.33		
Unadjusted Absolute Risk Difference (95% CI)	-0.12 (-0.27, 0.02)		-0.08 (-0.27, 0.11)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Non-Responder, n(%)	28 (100.0%)	21 (87.5%)	36 (94.7%)	13 (86.7%)	
Non-missing	12 (42.9%)	13 (54.2%)	12 (31.6%)	5 (33.3%)	
Missing	16 (57.1%)	8 (33.3%)	24 (63.2%)	8 (53.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8210: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N = 28)	BAT (N = 24)	MMB (N = 38)	BAT (N = 15)	p-value
SF3602-Role Emotional: NBS at Week 24					
Responder, n(%)	1 (3.6%)	2 (8.3%)	7 (18.4%)	1 (6.7%)	
Unadjusted Relative Risk (95% CI)	0.43 (0.04, 4.44)		2.76 (0.37, 20.59)		
p-value [1]	0.48		0.32		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Odds Ratio (95% CI)	0.41 (0.03, 4.80)		3.16 (0.35, 28.20)		
p-value [1]	0.48		0.30		
Unadjusted Absolute Risk Difference (95% CI)	-0.05 (-0.18, 0.08)		0.12 (-0.06, 0.29)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Non-Responder, n(%)	27 (96.4%)	22 (91.7%)	31 (81.6%)	14 (93.3%)	
Non-missing	11 (39.3%)	14 (58.3%)	7 (18.4%)	6 (40.0%)	
Missing	16 (57.1%)	8 (33.3%)	24 (63.2%)	8 (53.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8210: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N = 28)	BAT (N = 24)	MMB (N = 38)	BAT (N = 15)	p-value
SF3602-Mental Health: NBS at Week 24					
Responder, n(%)	1 (3.6%)	3 (12.5%)	3 (7.9%)	2 (13.3%)	
Unadjusted Relative Risk (95% CI)	0.29 (0.03, 2.57)		0.59 (0.11, 3.20)		
p-value [1]	0.26		0.54		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Odds Ratio (95% CI)	0.26 (0.03, 2.68)		0.56 (0.08, 3.72)		
p-value [1]	0.26		0.55		
Unadjusted Absolute Risk Difference (95% CI)	-0.09 (-0.24, 0.06)		-0.05 (-0.25, 0.14)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Non-Responder, n(%)	27 (96.4%)	21 (87.5%)	35 (92.1%)	13 (86.7%)	
Non-missing	11 (39.3%)	13 (54.2%)	11 (28.9%)	5 (33.3%)	
Missing	16 (57.1%)	8 (33.3%)	24 (63.2%)	8 (53.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8210: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N = 28)	BAT (N = 24)	MMB (N = 38)	BAT (N = 15)	p-value
SF3602-Physical Component Summary at Week 24					
Responder, n(%)	1 (3.6%)	1 (4.2%)	1 (2.6%)	0	
Unadjusted Relative Risk (95% CI)	0.86 (0.06, 12.98)		1.23 (0.05, 28.64)		
p-value [1]	0.91		0.90		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Odds Ratio (95% CI)	0.85 (0.05, 14.39)		1.24 (0.05, 32.14)		
p-value [1]	0.91		0.90		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.11, 0.10)		0.01 (-0.10, 0.11)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Non-Responder, n(%)	27 (96.4%)	23 (95.8%)	37 (97.4%)	15 (100.0%)	
Non-missing	11 (39.3%)	15 (62.5%)	13 (34.2%)	7 (46.7%)	
Missing	16 (57.1%)	8 (33.3%)	24 (63.2%)	8 (53.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8210: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N = 28)	BAT (N = 24)	MMB (N = 38)	BAT (N = 15)	p-value
SF3602-Mental Component Summary at Week 24					
Responder, n(%)	0	2 (8.3%)	3 (7.9%)	1 (6.7%)	
Unadjusted Relative Risk (95% CI)	0.17 (0.01, 3.42)		1.18 (0.13, 10.51)		
p-value [1]	0.25		0.88		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Odds Ratio (95% CI)	0.16 (0.01, 3.46)		1.20 (0.11, 12.54)		
p-value [1]	0.24		0.88		
Unadjusted Absolute Risk Difference (95% CI)	-0.08 (-0.21, 0.04)		0.01 (-0.14, 0.16)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Non-Responder, n(%)	28 (100.0%)	22 (91.7%)	35 (92.1%)	14 (93.3%)	
Non-missing	12 (42.9%)	14 (58.3%)	11 (28.9%)	6 (40.0%)	
Missing	16 (57.1%)	8 (33.3%)	24 (63.2%)	8 (53.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8209: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 42)	BAT (N = 20)	MMB (N = 24)	BAT (N = 19)	p-value
SF3602-Physical Functioning: NBS at Week 24					
Responder, n(%)	4 (9.5%)	1 (5.0%)	0	3 (15.8%)	
Unadjusted Relative Risk (95% CI)	1.90 (0.23, 15.96)		0.11 (0.01, 2.09)		
p-value [1]	0.55		0.14		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Unadjusted Odds Ratio (95% CI)	2.00 (0.21, 19.16)		0.10 (0.00, 1.99)		
p-value [1]	0.55		0.13		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.09, 0.18)		-0.16 (-0.33, 0.02)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Non-Responder, n(%)	38 (90.5%)	19 (95.0%)	24 (100.0%)	16 (84.2%)	
Non-missing	14 (33.3%)	10 (50.0%)	8 (33.3%)	9 (47.4%)	
Missing	24 (57.1%)	9 (45.0%)	16 (66.7%)	7 (36.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8209: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 42)	BAT (N = 20)	MMB (N = 24)	BAT (N = 19)	p-value
SF3602-Role Physical: NBS at Week 24					
Responder, n(%)	7 (16.7%)	1 (5.0%)	0	0	
Unadjusted Relative Risk (95% CI)	3.33 (0.44, 25.29)		NA		
p-value [1]	0.24		NA		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Unadjusted Odds Ratio (95% CI)	3.80 (0.43, 33.23)		NA		
p-value [1]	0.23		NA		
Unadjusted Absolute Risk Difference (95% CI)	0.12 (-0.03, 0.26)		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Non-Responder, n(%)	35 (83.3%)	19 (95.0%)	24 (100.0%)	19 (100.0%)	
Non-missing	11 (26.2%)	10 (50.0%)	8 (33.3%)	12 (63.2%)	
Missing	24 (57.1%)	9 (45.0%)	16 (66.7%)	7 (36.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8209: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 42)	BAT (N = 20)	MMB (N = 24)	BAT (N = 19)	p-value
SF3602-Bodily Pain: NBS at Week 24					
Responder, n(%)	4 (9.5%)	3 (15.0%)	2 (8.3%)	2 (10.5%)	
Unadjusted Relative Risk (95% CI)	0.63 (0.16, 2.57)		0.79 (0.12, 5.11)		
p-value [1]	0.52		0.81		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Unadjusted Odds Ratio (95% CI)	0.60 (0.12, 2.96)		0.77 (0.10, 6.06)		
p-value [1]	0.53		0.81		
Unadjusted Absolute Risk Difference (95% CI)	-0.05 (-0.23, 0.13)		-0.02 (-0.20, 0.15)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Non-Responder, n(%)	38 (90.5%)	17 (85.0%)	22 (91.7%)	17 (89.5%)	
Non-missing	14 (33.3%)	8 (40.0%)	6 (25.0%)	10 (52.6%)	
Missing	24 (57.1%)	9 (45.0%)	16 (66.7%)	7 (36.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8209: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 42)	BAT (N = 20)	MMB (N = 24)	BAT (N = 19)	p-value
SF3602-General Health: NBS at Week 24					
Responder, n(%)	1 (2.4%)	2 (10.0%)	1 (4.2%)	5 (26.3%)	
Unadjusted Relative Risk (95% CI)	0.24 (0.02, 2.47)		0.16 (0.02, 1.24)		
p-value [1]	0.23		0.080		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Unadjusted Odds Ratio (95% CI)	0.22 (0.02, 2.58)		0.12 (0.01, 1.15)		
p-value [1]	0.23		0.066		
Unadjusted Absolute Risk Difference (95% CI)	-0.08 (-0.22, 0.06)		-0.22 (-0.44, -0.01)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Non-Responder, n(%)	41 (97.6%)	18 (90.0%)	23 (95.8%)	14 (73.7%)	
Non-missing	17 (40.5%)	9 (45.0%)	7 (29.2%)	7 (36.8%)	
Missing	24 (57.1%)	9 (45.0%)	16 (66.7%)	7 (36.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8209: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 42)	BAT (N = 20)	MMB (N = 24)	BAT (N = 19)	p-value
SF3602-Vitality: NBS at Week 24					
Responder, n(%)	4 (9.5%)	1 (5.0%)	0	1 (5.3%)	
Unadjusted Relative Risk (95% CI)	1.90 (0.23, 15.96)		0.27 (0.01, 6.20)		
p-value [1]	0.55		0.41		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Unadjusted Odds Ratio (95% CI)	2.00 (0.21, 19.16)		0.25 (0.01, 6.54)		
p-value [1]	0.55		0.41		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.09, 0.18)		-0.06 (-0.18, 0.07)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Non-Responder, n(%)	38 (90.5%)	19 (95.0%)	24 (100.0%)	18 (94.7%)	
Non-missing	14 (33.3%)	10 (50.0%)	8 (33.3%)	11 (57.9%)	
Missing	24 (57.1%)	9 (45.0%)	16 (66.7%)	7 (36.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8209: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 42)	BAT (N = 20)	MMB (N = 24)	BAT (N = 19)	p-value
SF3602-Social Functioning: NBS at Week 24					
Responder, n(%)	1 (2.4%)	1 (5.0%)	1 (4.2%)	4 (21.1%)	
Unadjusted Relative Risk (95% CI)	0.48 (0.03, 7.23)		0.20 (0.02, 1.63)		
p-value [1]	0.59		0.13		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Unadjusted Odds Ratio (95% CI)	0.46 (0.03, 7.81)		0.16 (0.02, 1.60)		
p-value [1]	0.59		0.12		
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.13, 0.08)		-0.17 (-0.37, 0.03)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Non-Responder, n(%)	41 (97.6%)	19 (95.0%)	23 (95.8%)	15 (78.9%)	
Non-missing	17 (40.5%)	10 (50.0%)	7 (29.2%)	8 (42.1%)	
Missing	24 (57.1%)	9 (45.0%)	16 (66.7%)	7 (36.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8209: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 42)	BAT (N = 20)	MMB (N = 24)	BAT (N = 19)	p-value
SF3602-Role Emotional: NBS at Week 24					
Responder, n(%)	6 (14.3%)	2 (10.0%)	2 (8.3%)	1 (5.3%)	
Unadjusted Relative Risk (95% CI)	1.43 (0.32, 6.46)		1.58 (0.16, 16.17)		
p-value [1]	0.64		0.70		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Unadjusted Odds Ratio (95% CI)	1.50 (0.27, 8.19)		1.64 (0.14, 19.54)		
p-value [1]	0.64		0.70		
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.13, 0.21)		0.03 (-0.12, 0.18)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Non-Responder, n(%)	36 (85.7%)	18 (90.0%)	22 (91.7%)	18 (94.7%)	
Non-missing	12 (28.6%)	9 (45.0%)	6 (25.0%)	11 (57.9%)	
Missing	24 (57.1%)	9 (45.0%)	16 (66.7%)	7 (36.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8209: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 42)	BAT (N = 20)	MMB (N = 24)	BAT (N = 19)	p-value
SF3602-Mental Health: NBS at Week 24					
Responder, n(%)	3 (7.1%)	2 (10.0%)	1 (4.2%)	3 (15.8%)	
Unadjusted Relative Risk (95% CI)	0.71 (0.13, 3.94)		0.26 (0.03, 2.34)		
p-value [1]	0.70		0.23		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Unadjusted Odds Ratio (95% CI)	0.69 (0.11, 4.51)		0.23 (0.02, 2.43)		
p-value [1]	0.70		0.22		
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.18, 0.12)		-0.12 (-0.30, 0.07)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Non-Responder, n(%)	39 (92.9%)	18 (90.0%)	23 (95.8%)	16 (84.2%)	
Non-missing	15 (35.7%)	9 (45.0%)	7 (29.2%)	9 (47.4%)	
Missing	24 (57.1%)	9 (45.0%)	16 (66.7%)	7 (36.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8209: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 42)	BAT (N = 20)	MMB (N = 24)	BAT (N = 19)	p-value
SF3602-Physical Component Summary at Week 24					
Responder, n(%)	2 (4.8%)	0	0	1 (5.3%)	
Unadjusted Relative Risk (95% CI)	2.44 (0.12, 48.62)		0.27 (0.01, 6.20)		
p-value [1]	0.56		0.41		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Unadjusted Odds Ratio (95% CI)	2.53 (0.12, 55.21)		0.25 (0.01, 6.54)		
p-value [1]	0.55		0.41		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.06, 0.13)		-0.06 (-0.18, 0.07)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Non-Responder, n(%)	40 (95.2%)	20 (100.0%)	24 (100.0%)	18 (94.7%)	
Non-missing	16 (38.1%)	11 (55.0%)	8 (33.3%)	11 (57.9%)	
Missing	24 (57.1%)	9 (45.0%)	16 (66.7%)	7 (36.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8209: Analysis of Response Rate (deterioration) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 42)	BAT (N = 20)	MMB (N = 24)	BAT (N = 19)	p-value
SF3602-Mental Component Summary at Week 24					
Responder, n(%)	2 (4.8%)	2 (10.0%)	1 (4.2%)	1 (5.3%)	
Unadjusted Relative Risk (95% CI)	0.48 (0.07, 3.14)		0.79 (0.05, 11.85)		
p-value [1]	0.44		0.87		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Unadjusted Odds Ratio (95% CI)	0.45 (0.06, 3.45)		0.78 (0.05, 13.39)		
p-value [1]	0.44		0.87		
Unadjusted Absolute Risk Difference (95% CI)	-0.05 (-0.20, 0.09)		-0.01 (-0.14, 0.12)		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Non-Responder, n(%)	40 (95.2%)	18 (90.0%)	23 (95.8%)	18 (94.7%)	
Non-missing	16 (38.1%)	9 (45.0%)	7 (29.2%)	11 (57.9%)	
Missing	24 (57.1%)	9 (45.0%)	16 (66.7%)	7 (36.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8102: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	BAT (N = 9)	MMB (N = 42)	BAT (N = 30)	p-value
SF3602-Physical Functioning: NBS at Week 24					
Responder, n(%)	3 (12.5%)	1 (11.1%)	9 (21.4%)	0	
Unadjusted Inverse Relative Risk (95% CI)	0.89 (0.11, 7.48)		0.07 (0.00, 1.21)		
p-value [1]	0.91		0.068		
Unadjusted interaction test for Treatment*Age Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.88 (0.08, 9.70)		0.06 (0.00, 1.04)		
p-value [1]	0.91		0.053		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.23, 0.26)		0.20 (0.07, 0.34)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Age Group [3]					NA
Non-Responder, n(%)	21 (87.5%)	8 (88.9%)	33 (78.6%)	30 (100.0%)	
Non-missing	3 (12.5%)	3 (33.3%)	11 (26.2%)	19 (63.3%)	
Missing	18 (75.0%)	5 (55.6%)	22 (52.4%)	11 (36.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8102: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	BAT (N = 9)	MMB (N = 42)	BAT (N = 30)	p-value
SF3602-Role Physical: NBS at Week 24					
Responder, n(%)	2 (8.3%)	0	4 (9.5%)	2 (6.7%)	
Unadjusted Inverse Relative Risk (95% CI)	0.50 (0.03, 9.52)		0.70 (0.14, 3.58)		
p-value [1]	0.64		0.67		
Unadjusted interaction test for Treatment*Age Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.47 (0.02, 10.83)		0.68 (0.12, 3.97)		
p-value [1]	0.64		0.67		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.13, 0.23)		0.03 (-0.10, 0.15)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Age Group [3]					NA
Non-Responder, n(%)	22 (91.7%)	9 (100.0%)	38 (90.5%)	28 (93.3%)	
Non-missing	4 (16.7%)	4 (44.4%)	16 (38.1%)	17 (56.7%)	
Missing	18 (75.0%)	5 (55.6%)	22 (52.4%)	11 (36.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8102: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	BAT (N = 9)	MMB (N = 42)	BAT (N = 30)	p-value
SF3602-Bodily Pain: NBS at Week 24					
Responder, n(%)	2 (8.3%)	1 (11.1%)	4 (9.5%)	1 (3.3%)	
Unadjusted Inverse Relative Risk (95% CI)	1.33 (0.14, 12.97)		0.35 (0.04, 2.98)		
p-value [1]	0.80		0.34		
Unadjusted interaction test for Treatment*Age Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	1.38 (0.11, 17.32)		0.33 (0.03, 3.09)		
p-value [1]	0.81		0.33		
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.26, 0.21)		0.06 (-0.05, 0.17)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Age Group [3]					NA
Non-Responder, n(%)	22 (91.7%)	8 (88.9%)	38 (90.5%)	29 (96.7%)	
Non-missing	4 (16.7%)	3 (33.3%)	16 (38.1%)	18 (60.0%)	
Missing	18 (75.0%)	5 (55.6%)	22 (52.4%)	11 (36.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8102: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	BAT (N = 9)	MMB (N = 42)	BAT (N = 30)	p-value
SF3602-General Health: NBS at Week 24					
Responder, n(%)	0	1 (11.1%)	5 (11.9%)	2 (6.7%)	
Unadjusted Inverse Relative Risk (95% CI)	7.50 (0.33, 169.09)		0.56 (0.12, 2.70)		
p-value [1]	0.20		0.47		
Unadjusted interaction test for Treatment*Age Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	8.65 (0.32, 233.13)		0.53 (0.10, 2.93)		
p-value [1]	0.20		0.47		
Unadjusted Absolute Risk Difference (95% CI)	-0.13 (-0.36, 0.10)		0.05 (-0.08, 0.18)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Age Group [3]					NA
Non-Responder, n(%)	24 (100.0%)	8 (88.9%)	37 (88.1%)	28 (93.3%)	
Non-missing	6 (25.0%)	3 (33.3%)	15 (35.7%)	17 (56.7%)	
Missing	18 (75.0%)	5 (55.6%)	22 (52.4%)	11 (36.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8102: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	BAT (N = 9)	MMB (N = 42)	BAT (N = 30)	p-value
SF3602-Vitality: NBS at Week 24					
Responder, n(%)	2 (8.3%)	1 (11.1%)	2 (4.8%)	0	
Unadjusted Inverse Relative Risk (95% CI)	1.33 (0.14, 12.97)		0.28 (0.01, 5.58)		
p-value [1]	0.80		0.40		
Unadjusted interaction test for Treatment*Age Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	1.38 (0.11, 17.32)		0.27 (0.01, 5.74)		
p-value [1]	0.81		0.40		
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.26, 0.21)		0.04 (-0.04, 0.12)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Age Group [3]					NA
Non-Responder, n(%)	22 (91.7%)	8 (88.9%)	40 (95.2%)	30 (100.0%)	
Non-missing	4 (16.7%)	3 (33.3%)	18 (42.9%)	19 (63.3%)	
Missing	18 (75.0%)	5 (55.6%)	22 (52.4%)	11 (36.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8102: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	BAT (N = 9)	MMB (N = 42)	BAT (N = 30)	p-value
SF3602-Social Functioning: NBS at Week 24					
Responder, n(%)	2 (8.3%)	1 (11.1%)	4 (9.5%)	4 (13.3%)	
Unadjusted Inverse Relative Risk (95% CI)	1.33 (0.14, 12.97)		1.40 (0.38, 5.16)		
p-value [1]	0.80		0.61		
Unadjusted interaction test for Treatment*Age Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	1.38 (0.11, 17.32)		1.46 (0.34, 6.38)		
p-value [1]	0.81		0.61		
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.26, 0.21)		-0.04 (-0.19, 0.11)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Age Group [3]					NA
Non-Responder, n(%)	22 (91.7%)	8 (88.9%)	38 (90.5%)	26 (86.7%)	
Non-missing	4 (16.7%)	3 (33.3%)	16 (38.1%)	15 (50.0%)	
Missing	18 (75.0%)	5 (55.6%)	22 (52.4%)	11 (36.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8102: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	BAT (N = 9)	MMB (N = 42)	BAT (N = 30)	p-value
SF3602-Role Emotional: NBS at Week 24					
Responder, n(%)	1 (4.2%)	2 (22.2%)	4 (9.5%)	5 (16.7%)	
Unadjusted Inverse Relative Risk (95% CI)	5.33 (0.55, 51.88)		1.75 (0.51, 5.98)		
p-value [1]	0.15		0.37		
Unadjusted interaction test for Treatment*Age Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	6.57 (0.52, 83.76)		1.90 (0.46, 7.77)		
p-value [1]	0.15		0.37		
Unadjusted Absolute Risk Difference (95% CI)	-0.18 (-0.46, 0.10)		-0.07 (-0.23, 0.09)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Age Group [3]					NA
Non-Responder, n(%)	23 (95.8%)	7 (77.8%)	38 (90.5%)	25 (83.3%)	
Non-missing	5 (20.8%)	2 (22.2%)	16 (38.1%)	14 (46.7%)	
Missing	18 (75.0%)	5 (55.6%)	22 (52.4%)	11 (36.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8102: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	BAT (N = 9)	MMB (N = 42)	BAT (N = 30)	p-value
SF3602-Mental Health: NBS at Week 24					
Responder, n(%)	0	1 (11.1%)	4 (9.5%)	3 (10.0%)	
Unadjusted Inverse Relative Risk (95% CI)	7.50 (0.33, 169.09)		1.05 (0.25, 4.35)		
p-value [1]	0.20		0.95		
Unadjusted interaction test for Treatment*Age Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	8.65 (0.32, 233.13)		1.06 (0.22, 5.11)		
p-value [1]	0.20		0.95		
Unadjusted Absolute Risk Difference (95% CI)	-0.13 (-0.36, 0.10)		0.00 (-0.14, 0.13)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Age Group [3]					NA
Non-Responder, n(%)	24 (100.0%)	8 (88.9%)	38 (90.5%)	27 (90.0%)	
Non-missing	6 (25.0%)	3 (33.3%)	16 (38.1%)	16 (53.3%)	
Missing	18 (75.0%)	5 (55.6%)	22 (52.4%)	11 (36.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8102: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	BAT (N = 9)	MMB (N = 42)	BAT (N = 30)	p-value
SF3602-Physical Component Summary at Week 24					
Responder, n(%)	1 (4.2%)	0	3 (7.1%)	0	
Unadjusted Inverse Relative Risk (95% CI)	0.83 (0.04, 18.79)		0.20 (0.01, 3.70)		
p-value [1]	0.91		0.28		
Unadjusted interaction test for Treatment*Age Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.82 (0.03, 22.09)		0.19 (0.01, 3.72)		
p-value [1]	0.91		0.27		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.15, 0.17)		0.07 (-0.03, 0.16)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Age Group [3]					NA
Non-Responder, n(%)	23 (95.8%)	9 (100.0%)	39 (92.9%)	30 (100.0%)	
Non-missing	5 (20.8%)	4 (44.4%)	17 (40.5%)	19 (63.3%)	
Missing	18 (75.0%)	5 (55.6%)	22 (52.4%)	11 (36.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8102: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N = 24)	BAT (N = 9)	MMB (N = 42)	BAT (N = 30)	p-value
SF3602-Mental Component Summary at Week 24					
Responder, n(%)	1 (4.2%)	1 (11.1%)	2 (4.8%)	3 (10.0%)	
Unadjusted Inverse Relative Risk (95% CI)	2.67 (0.19, 38.27)		2.10 (0.37, 11.81)		
p-value [1]	0.47		0.40		
Unadjusted interaction test for Treatment*Age Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	2.88 (0.16, 51.54)		2.22 (0.35, 14.20)		
p-value [1]	0.47		0.40		
Unadjusted Absolute Risk Difference (95% CI)	-0.07 (-0.29, 0.15)		-0.05 (-0.18, 0.07)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Age Group [3]					NA
Non-Responder, n(%)	23 (95.8%)	8 (88.9%)	40 (95.2%)	27 (90.0%)	
Non-missing	5 (20.8%)	3 (33.3%)	18 (42.9%)	16 (53.3%)	
Missing	18 (75.0%)	5 (55.6%)	22 (52.4%)	11 (36.7%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8104: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N = 29)	BAT (N = 7)	MMB (N = 37)	BAT (N = 32)	p-value
SF3602-Physical Functioning: NBS at Week 24					
Responder, n(%)	5 (17.2%)	0	7 (18.9%)	1 (3.1%)	
Unadjusted Inverse Relative Risk (95% CI)	0.34 (0.02, 5.54)		0.17 (0.02, 1.27)		
p-value [1]	0.45		0.084		
Unadjusted interaction test for Treatment*Region [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.30 (0.01, 6.02)		0.14 (0.02, 1.19)		
p-value [1]	0.43		0.072		
Unadjusted Absolute Risk Difference (95% CI)	0.12 (-0.10, 0.34)		0.16 (0.02, 0.30)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Region [3]					NA
Non-Responder, n(%)	24 (82.8%)	7 (100.0%)	30 (81.1%)	31 (96.9%)	
Non-missing	3 (10.3%)	3 (42.9%)	11 (29.7%)	19 (59.4%)	
Missing	21 (72.4%)	4 (57.1%)	19 (51.4%)	12 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8104: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N = 29)	BAT (N = 7)	MMB (N = 37)	BAT (N = 32)	p-value
SF3602-Role Physical: NBS at Week 24					
Responder, n(%)	3 (10.3%)	0	3 (8.1%)	2 (6.3%)	
Unadjusted Inverse Relative Risk (95% CI)	0.54 (0.03, 9.34)		0.77 (0.14, 4.33)		
p-value [1]	0.67		0.77		
Unadjusted interaction test for Treatment*Region [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.50 (0.02, 10.90)		0.76 (0.12, 4.83)		
p-value [1]	0.66		0.77		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.15, 0.26)		0.02 (-0.10, 0.14)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Region [3]					NA
Non-Responder, n(%)	26 (89.7%)	7 (100.0%)	34 (91.9%)	30 (93.8%)	
Non-missing	5 (17.2%)	3 (42.9%)	15 (40.5%)	18 (56.3%)	
Missing	21 (72.4%)	4 (57.1%)	19 (51.4%)	12 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8104: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N = 29)	BAT (N = 7)	MMB (N = 37)	BAT (N = 32)	p-value
SF3602-Bodily Pain: NBS at Week 24					
Responder, n(%)	4 (13.8%)	0	2 (5.4%)	2 (6.3%)	
Unadjusted Inverse Relative Risk (95% CI)	0.42 (0.02, 6.96)		1.16 (0.17, 7.75)		
p-value [1]	0.54		0.88		
Unadjusted interaction test for Treatment*Region [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.38 (0.02, 7.84)		1.17 (0.15, 8.79)		
p-value [1]	0.53		0.88		
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.12, 0.30)		-0.01 (-0.12, 0.10)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Region [3]					NA
Non-Responder, n(%)	25 (86.2%)	7 (100.0%)	35 (94.6%)	30 (93.8%)	
Non-missing	4 (13.8%)	3 (42.9%)	16 (43.2%)	18 (56.3%)	
Missing	21 (72.4%)	4 (57.1%)	19 (51.4%)	12 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8104: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N = 29)	BAT (N = 7)	MMB (N = 37)	BAT (N = 32)	p-value
SF3602-General Health: NBS at Week 24					
Responder, n(%)	2 (6.9%)	1 (14.3%)	3 (8.1%)	2 (6.3%)	
Unadjusted Inverse Relative Risk (95% CI)	2.07 (0.22, 19.73)		0.77 (0.14, 4.33)		
p-value [1]	0.53		0.77		
Unadjusted interaction test for Treatment*Region [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	2.25 (0.17, 29.06)		0.76 (0.12, 4.83)		
p-value [1]	0.53		0.77		
Unadjusted Absolute Risk Difference (95% CI)	-0.07 (-0.35, 0.20)		0.02 (-0.10, 0.14)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Region [3]					NA
Non-Responder, n(%)	27 (93.1%)	6 (85.7%)	34 (91.9%)	30 (93.8%)	
Non-missing	6 (20.7%)	2 (28.6%)	15 (40.5%)	18 (56.3%)	
Missing	21 (72.4%)	4 (57.1%)	19 (51.4%)	12 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8104: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N = 29)	BAT (N = 7)	MMB (N = 37)	BAT (N = 32)	p-value
SF3602-Vitality: NBS at Week 24					
Responder, n(%)	1 (3.4%)	0	3 (8.1%)	1 (3.1%)	
Unadjusted Inverse Relative Risk (95% CI)	1.25 (0.06, 27.86)		0.39 (0.04, 3.52)		
p-value [1]	0.89		0.40		
Unadjusted interaction test for Treatment*Region [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	1.27 (0.05, 34.35)		0.37 (0.04, 3.70)		
p-value [1]	0.89		0.39		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.20, 0.17)		0.05 (-0.06, 0.16)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Region [3]					NA
Non-Responder, n(%)	28 (96.6%)	7 (100.0%)	34 (91.9%)	31 (96.9%)	
Non-missing	7 (24.1%)	3 (42.9%)	15 (40.5%)	19 (59.4%)	
Missing	21 (72.4%)	4 (57.1%)	19 (51.4%)	12 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8104: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N = 29)	BAT (N = 7)	MMB (N = 37)	BAT (N = 32)	p-value
SF3602-Social Functioning: NBS at Week 24					
Responder, n(%)	4 (13.8%)	0	2 (5.4%)	5 (15.6%)	
Unadjusted Inverse Relative Risk (95% CI)	0.42 (0.02, 6.96)		2.89 (0.60, 13.90)		
p-value [1]	0.54		0.19		
Unadjusted interaction test for Treatment*Region [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.38 (0.02, 7.84)		3.24 (0.58, 18.01)		
p-value [1]	0.53		0.18		
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.12, 0.30)		-0.10 (-0.25, 0.04)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Region [3]					NA
Non-Responder, n(%)	25 (86.2%)	7 (100.0%)	35 (94.6%)	27 (84.4%)	
Non-missing	4 (13.8%)	3 (42.9%)	16 (43.2%)	15 (46.9%)	
Missing	21 (72.4%)	4 (57.1%)	19 (51.4%)	12 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8104: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N = 29)	BAT (N = 7)	MMB (N = 37)	BAT (N = 32)	p-value
SF3602-Role Emotional: NBS at Week 24					
Responder, n(%)	1 (3.4%)	0	4 (10.8%)	7 (21.9%)	
Unadjusted Inverse Relative Risk (95% CI)	1.25 (0.06, 27.86)		2.02 (0.65, 6.29)		
p-value [1]	0.89		0.22		
Unadjusted interaction test for Treatment*Region [3]					NE
Unadjusted Inverse Odds Ratio (95% CI)	1.27 (0.05, 34.35)		2.31 (0.61, 8.77)		
p-value [1]	0.89		0.22		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.20, 0.17)		-0.11 (-0.29, 0.06)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		1.76 (0.63, 4.92)		
p-value [2]	NE		0.28		
Adjusted interaction test for Treatment*Region [3]					NE
Non-Responder, n(%)	28 (96.6%)	7 (100.0%)	33 (89.2%)	25 (78.1%)	
Non-missing	7 (24.1%)	3 (42.9%)	14 (37.8%)	13 (40.6%)	
Missing	21 (72.4%)	4 (57.1%)	19 (51.4%)	12 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8104: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N = 29)	BAT (N = 7)	MMB (N = 37)	BAT (N = 32)	p-value
SF3602-Mental Health: NBS at Week 24					
Responder, n(%)	1 (3.4%)	0	3 (8.1%)	4 (12.5%)	
Unadjusted Inverse Relative Risk (95% CI)	1.25 (0.06, 27.86)		1.54 (0.37, 6.38)		
p-value [1]	0.89		0.55		
Unadjusted interaction test for Treatment*Region [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	1.27 (0.05, 34.35)		1.62 (0.33, 7.85)		
p-value [1]	0.89		0.55		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.20, 0.17)		-0.04 (-0.19, 0.10)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Region [3]					NA
Non-Responder, n(%)	28 (96.6%)	7 (100.0%)	34 (91.9%)	28 (87.5%)	
Non-missing	7 (24.1%)	3 (42.9%)	15 (40.5%)	16 (50.0%)	
Missing	21 (72.4%)	4 (57.1%)	19 (51.4%)	12 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8104: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N = 29)	BAT (N = 7)	MMB (N = 37)	BAT (N = 32)	p-value
SF3602-Physical Component Summary at Week 24					
Responder, n(%)	3 (10.3%)	0	1 (2.7%)	0	
Unadjusted Inverse Relative Risk (95% CI)	0.54 (0.03, 9.34)		0.38 (0.02, 9.11)		
p-value [1]	0.67		0.55		
Unadjusted interaction test for Treatment*Region [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.50 (0.02, 10.90)		0.37 (0.01, 9.51)		
p-value [1]	0.66		0.55		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.15, 0.26)		0.02 (-0.05, 0.10)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Region [3]					NA
Non-Responder, n(%)	26 (89.7%)	7 (100.0%)	36 (97.3%)	32 (100.0%)	
Non-missing	5 (17.2%)	3 (42.9%)	17 (45.9%)	20 (62.5%)	
Missing	21 (72.4%)	4 (57.1%)	19 (51.4%)	12 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8104: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Region
Randomized Treatment Phase
ITT-Anemic Analysis Set

	North America		Europe		
	MMB (N = 29)	BAT (N = 7)	MMB (N = 37)	BAT (N = 32)	p-value
SF3602-Mental Component Summary at Week 24					
Responder, n(%)	1 (3.4%)	0	2 (5.4%)	4 (12.5%)	
Unadjusted Inverse Relative Risk (95% CI)	1.25 (0.06, 27.86)		2.31 (0.45, 11.80)		
p-value [1]	0.89		0.31		
Unadjusted interaction test for Treatment*Region [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	1.27 (0.05, 34.35)		2.50 (0.43, 14.66)		
p-value [1]	0.89		0.31		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.20, 0.17)		-0.07 (-0.21, 0.06)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Region [3]					NA
Non-Responder, n(%)	28 (96.6%)	7 (100.0%)	35 (94.6%)	28 (87.5%)	
Non-missing	7 (24.1%)	3 (42.9%)	16 (43.2%)	16 (50.0%)	
Missing	21 (72.4%)	4 (57.1%)	19 (51.4%)	12 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8107: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 27)	BAT (N = 6)	MMB (N = 39)	BAT (N = 33)	p-value
SF3602-Physical Functioning: NBS at Week 24					
Responder, n(%)	5 (18.5%)	0	7 (17.9%)	1 (3.0%)	
Unadjusted Inverse Relative Risk (95% CI)	0.36 (0.02, 5.83)		0.17 (0.02, 1.30)		
p-value [1]	0.47		0.088		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.31 (0.02, 6.47)		0.14 (0.02, 1.23)		
p-value [1]	0.45		0.076		
Unadjusted Absolute Risk Difference (95% CI)	0.13 (-0.12, 0.37)		0.15 (0.02, 0.28)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Non-Responder, n(%)	22 (81.5%)	6 (100.0%)	32 (82.1%)	32 (97.0%)	
Non-missing	5 (18.5%)	2 (33.3%)	9 (23.1%)	20 (60.6%)	
Missing	17 (63.0%)	4 (66.7%)	23 (59.0%)	12 (36.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8107: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 27)	BAT (N = 6)	MMB (N = 39)	BAT (N = 33)	p-value
SF3602-Role Physical: NBS at Week 24					
Responder, n(%)	1 (3.7%)	1 (16.7%)	5 (12.8%)	1 (3.0%)	
Unadjusted Inverse Relative Risk (95% CI)	4.50 (0.33, 62.24)		0.24 (0.03, 1.92)		
p-value [1]	0.26		0.18		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	5.20 (0.28, 97.62)		0.21 (0.02, 1.92)		
p-value [1]	0.27		0.17		
Unadjusted Absolute Risk Difference (95% CI)	-0.13 (-0.44, 0.18)		0.10 (-0.02, 0.22)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Non-Responder, n(%)	26 (96.3%)	5 (83.3%)	34 (87.2%)	32 (97.0%)	
Non-missing	9 (33.3%)	1 (16.7%)	11 (28.2%)	20 (60.6%)	
Missing	17 (63.0%)	4 (66.7%)	23 (59.0%)	12 (36.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8107: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 27)	BAT (N = 6)	MMB (N = 39)	BAT (N = 33)	p-value
SF3602-Bodily Pain: NBS at Week 24					
Responder, n(%)	2 (7.4%)	0	4 (10.3%)	2 (6.1%)	
Unadjusted Inverse Relative Risk (95% CI)	0.80 (0.04, 14.85)		0.59 (0.12, 3.02)		
p-value [1]	0.88		0.53		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.78 (0.03, 18.42)		0.56 (0.10, 3.30)		
p-value [1]	0.88		0.53		
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.20, 0.24)		0.04 (-0.08, 0.17)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Non-Responder, n(%)	25 (92.6%)	6 (100.0%)	35 (89.7%)	31 (93.9%)	
Non-missing	8 (29.6%)	2 (33.3%)	12 (30.8%)	19 (57.6%)	
Missing	17 (63.0%)	4 (66.7%)	23 (59.0%)	12 (36.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8107: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 27)	BAT (N = 6)	MMB (N = 39)	BAT (N = 33)	p-value
SF3602-General Health: NBS at Week 24					
Responder, n(%)	2 (7.4%)	0	3 (7.7%)	3 (9.1%)	
Unadjusted Inverse Relative Risk (95% CI)	0.80 (0.04, 14.85)		1.18 (0.26, 5.47)		
p-value [1]	0.88		0.83		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.78 (0.03, 18.42)		1.20 (0.23, 6.39)		
p-value [1]	0.88		0.83		
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.20, 0.24)		-0.01 (-0.14, 0.11)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Non-Responder, n(%)	25 (92.6%)	6 (100.0%)	36 (92.3%)	30 (90.9%)	
Non-missing	8 (29.6%)	2 (33.3%)	13 (33.3%)	18 (54.5%)	
Missing	17 (63.0%)	4 (66.7%)	23 (59.0%)	12 (36.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8107: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 27)	BAT (N = 6)	MMB (N = 39)	BAT (N = 33)	p-value
SF3602-Vitality: NBS at Week 24					
Responder, n(%)	1 (3.7%)	0	3 (7.7%)	1 (3.0%)	
Unadjusted Inverse Relative Risk (95% CI)	1.33 (0.06, 29.35)		0.39 (0.04, 3.61)		
p-value [1]	0.86		0.41		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	1.36 (0.05, 37.35)		0.38 (0.04, 3.79)		
p-value [1]	0.86		0.41		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.23, 0.19)		0.05 (-0.06, 0.15)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Non-Responder, n(%)	26 (96.3%)	6 (100.0%)	36 (92.3%)	32 (97.0%)	
Non-missing	9 (33.3%)	2 (33.3%)	13 (33.3%)	20 (60.6%)	
Missing	17 (63.0%)	4 (66.7%)	23 (59.0%)	12 (36.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8107: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 27)	BAT (N = 6)	MMB (N = 39)	BAT (N = 33)	p-value
SF3602-Social Functioning: NBS at Week 24					
Responder, n(%)	4 (14.8%)	1 (16.7%)	2 (5.1%)	4 (12.1%)	
Unadjusted Inverse Relative Risk (95% CI)	1.13 (0.15, 8.35)		2.36 (0.46, 12.10)		
p-value [1]	0.91		0.30		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	1.15 (0.10, 12.62)		2.55 (0.44, 14.92)		
p-value [1]	0.91		0.30		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.35, 0.31)		-0.07 (-0.20, 0.06)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Non-Responder, n(%)	23 (85.2%)	5 (83.3%)	37 (94.9%)	29 (87.9%)	
Non-missing	6 (22.2%)	1 (16.7%)	14 (35.9%)	17 (51.5%)	
Missing	17 (63.0%)	4 (66.7%)	23 (59.0%)	12 (36.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8107: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 27)	BAT (N = 6)	MMB (N = 39)	BAT (N = 33)	p-value
SF3602-Role Emotional: NBS at Week 24					
Responder, n(%)	2 (7.4%)	1 (16.7%)	3 (7.7%)	6 (18.2%)	
Unadjusted Inverse Relative Risk (95% CI)	2.25 (0.24, 20.96)		2.36 (0.64, 8.73)		
p-value [1]	0.48		0.20		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	2.50 (0.19, 33.17)		2.67 (0.61, 11.63)		
p-value [1]	0.49		0.19		
Unadjusted Absolute Risk Difference (95% CI)	-0.09 (-0.41, 0.22)		-0.10 (-0.26, 0.05)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Non-Responder, n(%)	25 (92.6%)	5 (83.3%)	36 (92.3%)	27 (81.8%)	
Non-missing	8 (29.6%)	1 (16.7%)	13 (33.3%)	15 (45.5%)	
Missing	17 (63.0%)	4 (66.7%)	23 (59.0%)	12 (36.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8107: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 27)	BAT (N = 6)	MMB (N = 39)	BAT (N = 33)	p-value
SF3602-Mental Health: NBS at Week 24					
Responder, n(%)	1 (3.7%)	1 (16.7%)	3 (7.7%)	3 (9.1%)	
Unadjusted Inverse Relative Risk (95% CI)	4.50 (0.33, 62.24)		1.18 (0.26, 5.47)		
p-value [1]	0.26		0.83		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	5.20 (0.28, 97.62)		1.20 (0.23, 6.39)		
p-value [1]	0.27		0.83		
Unadjusted Absolute Risk Difference (95% CI)	-0.13 (-0.44, 0.18)		-0.01 (-0.14, 0.11)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Non-Responder, n(%)	26 (96.3%)	5 (83.3%)	36 (92.3%)	30 (90.9%)	
Non-missing	9 (33.3%)	1 (16.7%)	13 (33.3%)	18 (54.5%)	
Missing	17 (63.0%)	4 (66.7%)	23 (59.0%)	12 (36.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8107: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 27)	BAT (N = 6)	MMB (N = 39)	BAT (N = 33)	p-value
SF3602-Physical Component Summary at Week 24					
Responder, n(%)	1 (3.7%)	0	3 (7.7%)	0	
Unadjusted Inverse Relative Risk (95% CI)	1.33 (0.06, 29.35)		0.17 (0.01, 3.14)		
p-value [1]	0.86		0.23		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	1.36 (0.05, 37.35)		0.16 (0.01, 3.13)		
p-value [1]	0.86		0.22		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.23, 0.19)		0.07 (-0.02, 0.17)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Non-Responder, n(%)	26 (96.3%)	6 (100.0%)	36 (92.3%)	33 (100.0%)	
Non-missing	9 (33.3%)	2 (33.3%)	13 (33.3%)	21 (63.6%)	
Missing	17 (63.0%)	4 (66.7%)	23 (59.0%)	12 (36.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8107: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Hemoglobin Level
Randomized Treatment Phase
ITT-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N = 27)	BAT (N = 6)	MMB (N = 39)	BAT (N = 33)	p-value
SF3602-Mental Component Summary at Week 24					
Responder, n(%)	1 (3.7%)	0	2 (5.1%)	4 (12.1%)	
Unadjusted Inverse Relative Risk (95% CI)	1.33 (0.06, 29.35)		2.36 (0.46, 12.10)		
p-value [1]	0.86		0.30		
Unadjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	1.36 (0.05, 37.35)		2.55 (0.44, 14.92)		
p-value [1]	0.86		0.30		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.23, 0.19)		-0.07 (-0.20, 0.06)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Non-Responder, n(%)	26 (96.3%)	6 (100.0%)	37 (94.9%)	29 (87.9%)	
Non-missing	9 (33.3%)	2 (33.3%)	14 (35.9%)	17 (51.5%)	
Missing	17 (63.0%)	4 (66.7%)	23 (59.0%)	12 (36.4%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8106: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 49)	BAT (N = 31)	MMB (N = 17)	BAT (N = 8)	p-value
SF3602-Physical Functioning: NBS at Week 24					
Responder, n(%)	8 (16.3%)	1 (3.2%)	4 (23.5%)	0	
Unadjusted Inverse Relative Risk (95% CI)	0.20 (0.03, 1.50)		0.22 (0.01, 3.69)		
p-value [1]	0.12		0.29		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.17 (0.02, 1.44)		0.18 (0.01, 3.71)		
p-value [1]	0.10		0.26		
Unadjusted Absolute Risk Difference (95% CI)	0.13 (0.01, 0.25)		0.19 (-0.06, 0.44)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Non-Responder, n(%)	41 (83.7%)	30 (96.8%)	13 (76.5%)	8 (100.0%)	
Non-missing	11 (22.4%)	17 (54.8%)	3 (17.6%)	5 (62.5%)	
Missing	30 (61.2%)	13 (41.9%)	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8106: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 49)	BAT (N = 31)	MMB (N = 17)	BAT (N = 8)	p-value
SF3602-Role Physical: NBS at Week 24					
Responder, n(%)	3 (6.1%)	0	3 (17.6%)	2 (25.0%)	
Unadjusted Inverse Relative Risk (95% CI)	0.22 (0.01, 4.18)		1.42 (0.29, 6.88)		
p-value [1]	0.32		0.67		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.21 (0.01, 4.23)		1.56 (0.20, 11.83)		
p-value [1]	0.31		0.67		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.03, 0.14)		-0.07 (-0.42, 0.28)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Non-Responder, n(%)	46 (93.9%)	31 (100.0%)	14 (82.4%)	6 (75.0%)	
Non-missing	16 (32.7%)	18 (58.1%)	4 (23.5%)	3 (37.5%)	
Missing	30 (61.2%)	13 (41.9%)	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8106: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 49)	BAT (N = 31)	MMB (N = 17)	BAT (N = 8)	p-value
SF3602-Bodily Pain: NBS at Week 24					
Responder, n(%)	3 (6.1%)	2 (6.5%)	3 (17.6%)	0	
Unadjusted Inverse Relative Risk (95% CI)	1.05 (0.19, 5.95)		0.29 (0.02, 4.96)		
p-value [1]	0.95		0.39		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	1.06 (0.17, 6.72)		0.24 (0.01, 5.31)		
p-value [1]	0.95		0.37		
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.11, 0.11)		0.14 (-0.10, 0.38)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Non-Responder, n(%)	46 (93.9%)	29 (93.5%)	14 (82.4%)	8 (100.0%)	
Non-missing	16 (32.7%)	16 (51.6%)	4 (23.5%)	5 (62.5%)	
Missing	30 (61.2%)	13 (41.9%)	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8106: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 49)	BAT (N = 31)	MMB (N = 17)	BAT (N = 8)	p-value
SF3602-General Health: NBS at Week 24					
Responder, n(%)	4 (8.2%)	3 (9.7%)	1 (5.9%)	0	
Unadjusted Inverse Relative Risk (95% CI)	1.19 (0.28, 4.94)		0.67 (0.03, 14.78)		
p-value [1]	0.82		0.80		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	1.21 (0.25, 5.79)		0.65 (0.02, 17.65)		
p-value [1]	0.82		0.80		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.14, 0.11)		0.03 (-0.17, 0.22)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Non-Responder, n(%)	45 (91.8%)	28 (90.3%)	16 (94.1%)	8 (100.0%)	
Non-missing	15 (30.6%)	15 (48.4%)	6 (35.3%)	5 (62.5%)	
Missing	30 (61.2%)	13 (41.9%)	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8106: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 49)	BAT (N = 31)	MMB (N = 17)	BAT (N = 8)	p-value
SF3602-Vitality: NBS at Week 24					
Responder, n(%)	3 (6.1%)	1 (3.2%)	1 (5.9%)	0	
Unadjusted Inverse Relative Risk (95% CI)	0.53 (0.06, 4.84)		0.67 (0.03, 14.78)		
p-value [1]	0.57		0.80		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.51 (0.05, 5.15)		0.65 (0.02, 17.65)		
p-value [1]	0.57		0.80		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.06, 0.12)		0.03 (-0.17, 0.22)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Non-Responder, n(%)	46 (93.9%)	30 (96.8%)	16 (94.1%)	8 (100.0%)	
Non-missing	16 (32.7%)	17 (54.8%)	6 (35.3%)	5 (62.5%)	
Missing	30 (61.2%)	13 (41.9%)	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8106: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 49)	BAT (N = 31)	MMB (N = 17)	BAT (N = 8)	p-value
SF3602-Social Functioning: NBS at Week 24					
Responder, n(%)	4 (8.2%)	3 (9.7%)	2 (11.8%)	2 (25.0%)	
Unadjusted Inverse Relative Risk (95% CI)	1.19 (0.28, 4.94)		2.13 (0.36, 12.48)		
p-value [1]	0.82		0.40		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	1.21 (0.25, 5.79)		2.50 (0.28, 22.04)		
p-value [1]	0.82		0.41		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.14, 0.11)		-0.13 (-0.47, 0.20)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Non-Responder, n(%)	45 (91.8%)	28 (90.3%)	15 (88.2%)	6 (75.0%)	
Non-missing	15 (30.6%)	15 (48.4%)	5 (29.4%)	3 (37.5%)	
Missing	30 (61.2%)	13 (41.9%)	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8106: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 49)	BAT (N = 31)	MMB (N = 17)	BAT (N = 8)	p-value
SF3602-Role Emotional: NBS at Week 24					
Responder, n(%)	3 (6.1%)	6 (19.4%)	2 (11.8%)	1 (12.5%)	
Unadjusted Inverse Relative Risk (95% CI)	3.16 (0.85, 11.73)		1.06 (0.11, 10.07)		
p-value [1]	0.085		0.96		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	3.68 (0.85, 15.99)		1.07 (0.08, 13.90)		
p-value [1]	0.082		0.96		
Unadjusted Absolute Risk Difference (95% CI)	-0.13 (-0.29, 0.02)		-0.01 (-0.28, 0.27)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Non-Responder, n(%)	46 (93.9%)	25 (80.6%)	15 (88.2%)	7 (87.5%)	
Non-missing	16 (32.7%)	12 (38.7%)	5 (29.4%)	4 (50.0%)	
Missing	30 (61.2%)	13 (41.9%)	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8106: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 49)	BAT (N = 31)	MMB (N = 17)	BAT (N = 8)	p-value
SF3602-Mental Health: NBS at Week 24					
Responder, n(%)	3 (6.1%)	4 (12.9%)	1 (5.9%)	0	
Unadjusted Inverse Relative Risk (95% CI)	2.11 (0.51, 8.79)		0.67 (0.03, 14.78)		
p-value [1]	0.31		0.80		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	2.27 (0.47, 10.93)		0.65 (0.02, 17.65)		
p-value [1]	0.31		0.80		
Unadjusted Absolute Risk Difference (95% CI)	-0.07 (-0.20, 0.07)		0.03 (-0.17, 0.22)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Non-Responder, n(%)	46 (93.9%)	27 (87.1%)	16 (94.1%)	8 (100.0%)	
Non-missing	16 (32.7%)	14 (45.2%)	6 (35.3%)	5 (62.5%)	
Missing	30 (61.2%)	13 (41.9%)	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8106: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 49)	BAT (N = 31)	MMB (N = 17)	BAT (N = 8)	p-value
SF3602-Physical Component Summary at Week 24					
Responder, n(%)	2 (4.1%)	0	2 (11.8%)	0	
Unadjusted Inverse Relative Risk (95% CI)	0.31 (0.02, 6.30)		0.40 (0.02, 7.48)		
p-value [1]	0.45		0.54		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.30 (0.01, 6.49)		0.36 (0.02, 8.51)		
p-value [1]	0.44		0.53		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.04, 0.11)		0.08 (-0.14, 0.30)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Non-Responder, n(%)	47 (95.9%)	31 (100.0%)	15 (88.2%)	8 (100.0%)	
Non-missing	17 (34.7%)	18 (58.1%)	5 (29.4%)	5 (62.5%)	
Missing	30 (61.2%)	13 (41.9%)	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8106: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Two-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N = 49)	BAT (N = 31)	MMB (N = 17)	BAT (N = 8)	p-value
SF3602-Mental Component Summary at Week 24					
Responder, n(%)	2 (4.1%)	4 (12.9%)	1 (5.9%)	0	
Unadjusted Inverse Relative Risk (95% CI)	3.16 (0.62, 16.24)		0.67 (0.03, 14.78)		
p-value [1]	0.17		0.80		
Unadjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	3.48 (0.60, 20.28)		0.65 (0.02, 17.65)		
p-value [1]	0.17		0.80		
Unadjusted Absolute Risk Difference (95% CI)	-0.09 (-0.22, 0.04)		0.03 (-0.17, 0.22)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*DIPSS 2-Level Risk [3]					NA
Non-Responder, n(%)	47 (95.9%)	27 (87.1%)	16 (94.1%)	8 (100.0%)	
Non-missing	17 (34.7%)	14 (45.2%)	6 (35.3%)	5 (62.5%)	
Missing	30 (61.2%)	13 (41.9%)	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8105: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 5)	BAT (N = 7)	MMB (N = 44)	BAT (N = 24)
SF3602-Physical Functioning: NBS at Week 24				
Responder, n(%)	0	0	8 (18.2%)	1 (4.2%)
Unadjusted Inverse Relative Risk (95% CI)	NA		0.23 (0.03, 1.72)	
p-value [1]	NA		0.15	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	NA		0.20 (0.02, 1.67)	
p-value [1]	NA		0.14	
Unadjusted Absolute Risk Difference (95% CI)	NA		0.14 (0.00, 0.28)	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Non-Responder, n(%)	5 (100.0%)	7 (100.0%)	36 (81.8%)	23 (95.8%)
Non-missing	1 (20.0%)	3 (42.9%)	10 (22.7%)	14 (58.3%)
Missing	4 (80.0%)	4 (57.1%)	26 (59.1%)	9 (37.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8105: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 17)	BAT (N = 8)	p-value
SF3602-Physical Functioning: NBS at Week 24			
Responder, n(%)	4 (23.5%)	0	
Unadjusted Inverse Relative Risk (95% CI)	0.22 (0.01, 3.69)		
p-value [1]	0.29		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	0.18 (0.01, 3.71)		
p-value [1]	0.26		
Unadjusted Absolute Risk Difference (95% CI)	0.19 (-0.06, 0.44)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	13 (76.5%)	8 (100.0%)	
Non-missing	3 (17.6%)	5 (62.5%)	
Missing	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8105: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 5)	BAT (N = 7)	MMB (N = 44)	BAT (N = 24)
SF3602-Role Physical: NBS at Week 24				
Responder, n(%)	0	0	3 (6.8%)	0
Unadjusted Inverse Relative Risk (95% CI)	NA		0.26 (0.01, 4.78)	
p-value [1]	NA		0.36	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	NA		0.24 (0.01, 4.88)	
p-value [1]	NA		0.35	
Unadjusted Absolute Risk Difference (95% CI)	NA		0.06 (-0.04, 0.15)	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Non-Responder, n(%)	5 (100.0%)	7 (100.0%)	41 (93.2%)	24 (100.0%)
Non-missing	1 (20.0%)	3 (42.9%)	15 (34.1%)	15 (62.5%)
Missing	4 (80.0%)	4 (57.1%)	26 (59.1%)	9 (37.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8105: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 17)	BAT (N = 8)	p-value
SF3602-Role Physical: NBS at Week 24			
Responder, n(%)	3 (17.6%)	2 (25.0%)	
Unadjusted Inverse Relative Risk (95% CI)	1.42 (0.29, 6.88)		
p-value [1]	0.67		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	1.56 (0.20, 11.83)		
p-value [1]	0.67		
Unadjusted Absolute Risk Difference (95% CI)	-0.07 (-0.42, 0.28)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	14 (82.4%)	6 (75.0%)	
Non-missing	4 (23.5%)	3 (37.5%)	
Missing	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8105: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 5)	BAT (N = 7)	MMB (N = 44)	BAT (N = 24)
SF3602-Bodily Pain: NBS at Week 24				
Responder, n(%)	0	0	3 (6.8%)	2 (8.3%)
Unadjusted Inverse Relative Risk (95% CI)	NA		1.22 (0.22, 6.82)	
p-value [1]	NA		0.82	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	NA		1.24 (0.19, 8.00)	
p-value [1]	NA		0.82	
Unadjusted Absolute Risk Difference (95% CI)	NA		-0.02 (-0.15, 0.12)	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Non-Responder, n(%)	5 (100.0%)	7 (100.0%)	41 (93.2%)	22 (91.7%)
Non-missing	1 (20.0%)	3 (42.9%)	15 (34.1%)	13 (54.2%)
Missing	4 (80.0%)	4 (57.1%)	26 (59.1%)	9 (37.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8105: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 17)	BAT (N = 8)	p-value
SF3602-Bodily Pain: NBS at Week 24			
Responder, n(%)	3 (17.6%)	0	
Unadjusted Inverse Relative Risk (95% CI)	0.29 (0.02, 4.96)		
p-value [1]	0.39		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	0.24 (0.01, 5.31)		
p-value [1]	0.37		
Unadjusted Absolute Risk Difference (95% CI)	0.14 (-0.10, 0.38)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	14 (82.4%)	8 (100.0%)	
Non-missing	4 (23.5%)	5 (62.5%)	
Missing	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8105: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 5)	BAT (N = 7)	MMB (N = 44)	BAT (N = 24)
SF3602-General Health: NBS at Week 24				
Responder, n(%)	0	1 (14.3%)	4 (9.1%)	2 (8.3%)
Unadjusted Inverse Relative Risk (95% CI)	2.25 (0.11, 46.13)		0.92 (0.18, 4.65)	
p-value [1]	0.60		0.92	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	2.54 (0.09, 75.77)		0.91 (0.15, 5.37)	
p-value [1]	0.59		0.92	
Unadjusted Absolute Risk Difference (95% CI)	-0.10 (-0.45, 0.25)		0.01 (-0.13, 0.15)	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Non-Responder, n(%)	5 (100.0%)	6 (85.7%)	40 (90.9%)	22 (91.7%)
Non-missing	1 (20.0%)	2 (28.6%)	14 (31.8%)	13 (54.2%)
Missing	4 (80.0%)	4 (57.1%)	26 (59.1%)	9 (37.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8105: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 17)	BAT (N = 8)	p-value
SF3602-General Health: NBS at Week 24			
Responder, n(%)	1 (5.9%)	0	
Unadjusted Inverse Relative Risk (95% CI)	0.67 (0.03, 14.78)		
p-value [1]	0.80		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	0.65 (0.02, 17.65)		
p-value [1]	0.80		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.17, 0.22)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	16 (94.1%)	8 (100.0%)	
Non-missing	6 (35.3%)	5 (62.5%)	
Missing	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8105: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 5)	BAT (N = 7)	MMB (N = 44)	BAT (N = 24)
SF3602-Vitality: NBS at Week 24				
Responder, n(%)	0	0	3 (6.8%)	1 (4.2%)
Unadjusted Inverse Relative Risk (95% CI)	NA		0.61 (0.07, 5.56)	
p-value [1]	NA		0.66	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	NA		0.59 (0.06, 6.05)	
p-value [1]	NA		0.66	
Unadjusted Absolute Risk Difference (95% CI)	NA		0.03 (-0.08, 0.14)	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Non-Responder, n(%)	5 (100.0%)	7 (100.0%)	41 (93.2%)	23 (95.8%)
Non-missing	1 (20.0%)	3 (42.9%)	15 (34.1%)	14 (58.3%)
Missing	4 (80.0%)	4 (57.1%)	26 (59.1%)	9 (37.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8105: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 17)	BAT (N = 8)	p-value
SF3602-Vitality: NBS at Week 24			
Responder, n(%)	1 (5.9%)	0	
Unadjusted Inverse Relative Risk (95% CI)	0.67 (0.03, 14.78)		
p-value [1]	0.80		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	0.65 (0.02, 17.65)		
p-value [1]	0.80		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.17, 0.22)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	16 (94.1%)	8 (100.0%)	
Non-missing	6 (35.3%)	5 (62.5%)	
Missing	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8105: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 5)	BAT (N = 7)	MMB (N = 44)	BAT (N = 24)
SF3602-Social Functioning: NBS at Week 24				
Responder, n(%)	0	1 (14.3%)	4 (9.1%)	2 (8.3%)
Unadjusted Inverse Relative Risk (95% CI)	2.25 (0.11, 46.13)		0.92 (0.18, 4.65)	
p-value [1]	0.60		0.92	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	2.54 (0.09, 75.77)		0.91 (0.15, 5.37)	
p-value [1]	0.59		0.92	
Unadjusted Absolute Risk Difference (95% CI)	-0.10 (-0.45, 0.25)		0.01 (-0.13, 0.15)	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Non-Responder, n(%)	5 (100.0%)	6 (85.7%)	40 (90.9%)	22 (91.7%)
Non-missing	1 (20.0%)	2 (28.6%)	14 (31.8%)	13 (54.2%)
Missing	4 (80.0%)	4 (57.1%)	26 (59.1%)	9 (37.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8105: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 17)	BAT (N = 8)	p-value
SF3602-Social Functioning: NBS at Week 24			
Responder, n(%)	2 (11.8%)	2 (25.0%)	
Unadjusted Inverse Relative Risk (95% CI)	2.13 (0.36, 12.48)		
p-value [1]	0.40		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	2.50 (0.28, 22.04)		
p-value [1]	0.41		
Unadjusted Absolute Risk Difference (95% CI)	-0.13 (-0.47, 0.20)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	15 (88.2%)	6 (75.0%)	
Non-missing	5 (29.4%)	3 (37.5%)	
Missing	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8105: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 5)	BAT (N = 7)	MMB (N = 44)	BAT (N = 24)
SF3602-Role Emotional: NBS at Week 24				
Responder, n(%)	0	0	3 (6.8%)	6 (25.0%)
Unadjusted Inverse Relative Risk (95% CI)	NA		3.67 (1.01, 13.37)	
p-value [1]	NA		0.049	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	NA		4.56 (1.02, 20.27)	
p-value [1]	NA		0.046	
Unadjusted Absolute Risk Difference (95% CI)	NA		-0.18 (-0.37, 0.01)	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Non-Responder, n(%)	5 (100.0%)	7 (100.0%)	41 (93.2%)	18 (75.0%)
Non-missing	1 (20.0%)	3 (42.9%)	15 (34.1%)	9 (37.5%)
Missing	4 (80.0%)	4 (57.1%)	26 (59.1%)	9 (37.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8105: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 17)	BAT (N = 8)	p-value
SF3602-Role Emotional: NBS at Week 24			
Responder, n(%)	2 (11.8%)	1 (12.5%)	
Unadjusted Inverse Relative Risk (95% CI)	1.06 (0.11, 10.07)		
p-value [1]	0.96		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	1.07 (0.08, 13.90)		
p-value [1]	0.96		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.28, 0.27)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	15 (88.2%)	7 (87.5%)	
Non-missing	5 (29.4%)	4 (50.0%)	
Missing	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8105: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 5)	BAT (N = 7)	MMB (N = 44)	BAT (N = 24)
SF3602-Mental Health: NBS at Week 24				
Responder, n(%)	0	1 (14.3%)	3 (6.8%)	3 (12.5%)
Unadjusted Inverse Relative Risk (95% CI)	2.25 (0.11, 46.13)		1.83 (0.40, 8.39)	
p-value [1]	0.60		0.43	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	2.54 (0.09, 75.77)		1.95 (0.36, 10.52)	
p-value [1]	0.59		0.44	
Unadjusted Absolute Risk Difference (95% CI)	-0.10 (-0.45, 0.25)		-0.06 (-0.21, 0.10)	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Non-Responder, n(%)	5 (100.0%)	6 (85.7%)	41 (93.2%)	21 (87.5%)
Non-missing	1 (20.0%)	2 (28.6%)	15 (34.1%)	12 (50.0%)
Missing	4 (80.0%)	4 (57.1%)	26 (59.1%)	9 (37.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8105: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 17)	BAT (N = 8)	p-value
SF3602-Mental Health: NBS at Week 24			
Responder, n(%)	1 (5.9%)	0	
Unadjusted Inverse Relative Risk (95% CI)	0.67 (0.03, 14.78)		
p-value [1]	0.80		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	0.65 (0.02, 17.65)		
p-value [1]	0.80		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.17, 0.22)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	16 (94.1%)	8 (100.0%)	
Non-missing	6 (35.3%)	5 (62.5%)	
Missing	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8105: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 5)	BAT (N = 7)	MMB (N = 44)	BAT (N = 24)
SF3602-Physical Component Summary at Week 24				
Responder, n(%)	0	0	2 (4.5%)	0
Unadjusted Inverse Relative Risk (95% CI)	NA		0.36 (0.02, 7.21)	
p-value [1]	NA		0.50	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	NA		0.35 (0.02, 7.53)	
p-value [1]	NA		0.50	
Unadjusted Absolute Risk Difference (95% CI)	NA		0.04 (-0.05, 0.12)	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Non-Responder, n(%)	5 (100.0%)	7 (100.0%)	42 (95.5%)	24 (100.0%)
Non-missing	1 (20.0%)	3 (42.9%)	16 (36.4%)	15 (62.5%)
Missing	4 (80.0%)	4 (57.1%)	26 (59.1%)	9 (37.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8105: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 17)	BAT (N = 8)	p-value
SF3602-Physical Component Summary at Week 24			
Responder, n(%)	2 (11.8%)	0	
Unadjusted Inverse Relative Risk (95% CI)	0.40 (0.02, 7.48)		
p-value [1]	0.54		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	0.36 (0.02, 8.51)		
p-value [1]	0.53		
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.14, 0.30)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	15 (88.2%)	8 (100.0%)	
Non-missing	5 (29.4%)	5 (62.5%)	
Missing	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8105: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N = 5)	BAT (N = 7)	MMB (N = 44)	BAT (N = 24)
SF3602-Mental Component Summary at Week 24				
Responder, n(%)	0	1 (14.3%)	2 (4.5%)	3 (12.5%)
Unadjusted Inverse Relative Risk (95% CI)	2.25 (0.11, 46.13)		2.75 (0.49, 15.34)	
p-value [1]	0.60		0.25	
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Unadjusted Inverse Odds Ratio (95% CI)	2.54 (0.09, 75.77)		3.00 (0.46, 19.35)	
p-value [1]	0.59		0.25	
Unadjusted Absolute Risk Difference (95% CI)	-0.10 (-0.45, 0.25)		-0.08 (-0.23, 0.07)	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]				
Non-Responder, n(%)	5 (100.0%)	6 (85.7%)	42 (95.5%)	21 (87.5%)
Non-missing	1 (20.0%)	2 (28.6%)	16 (36.4%)	12 (50.0%)
Missing	4 (80.0%)	4 (57.1%)	26 (59.1%)	9 (37.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8105: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline DIPSS Three-Level Risk
Randomized Treatment Phase
ITT-Anemic Analysis Set

	High Risk		
	MMB (N = 17)	BAT (N = 8)	p-value
SF3602-Mental Component Summary at Week 24			
Responder, n(%)	1 (5.9%)	0	
Unadjusted Inverse Relative Risk (95% CI)	0.67 (0.03, 14.78)		
p-value [1]	0.80		
Unadjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	0.65 (0.02, 17.65)		
p-value [1]	0.80		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.17, 0.22)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*DIPSS 3-Level Risk [3]			NA
Non-Responder, n(%)	16 (94.1%)	8 (100.0%)	
Non-missing	6 (35.3%)	5 (62.5%)	
Missing	10 (58.8%)	3 (37.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8108: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 45)	BAT (N = 23)	MMB (N = 13)	BAT (N = 8)
SF3602-Physical Functioning: NBS at Week 24				
Responder, n(%)	7 (15.6%)	0	3 (23.1%)	0
Unadjusted Inverse Relative Risk (95% CI)	0.13 (0.01, 2.14)		0.22 (0.01, 3.81)	
p-value [1]	0.15		0.30	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	0.11 (0.01, 2.00)		0.18 (0.01, 3.91)	
p-value [1]	0.14		0.27	
Unadjusted Absolute Risk Difference (95% CI)	0.14 (0.02, 0.26)		0.19 (-0.08, 0.47)	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	38 (84.4%)	23 (100.0%)	10 (76.9%)	8 (100.0%)
Non-missing	11 (24.4%)	13 (56.5%)	2 (15.4%)	3 (37.5%)
Missing	27 (60.0%)	10 (43.5%)	8 (61.5%)	5 (62.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8108: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 8)	BAT (N = 8)	p-value
SF3602-Physical Functioning: NBS at Week 24			
Responder, n(%)	2 (25.0%)	1 (12.5%)	
Unadjusted Inverse Relative Risk (95% CI)	0.50 (0.06, 4.47)		
p-value [1]	0.54		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	0.43 (0.03, 5.99)		
p-value [1]	0.53		
Unadjusted Absolute Risk Difference (95% CI)	0.13 (-0.25, 0.50)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Non-Responder, n(%)	6 (75.0%)	7 (87.5%)	
Non-missing	1 (12.5%)	6 (75.0%)	
Missing	5 (62.5%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8108: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 45)	BAT (N = 23)	MMB (N = 13)	BAT (N = 8)
SF3602-Role Physical: NBS at Week 24				
Responder, n(%)	3 (6.7%)	2 (8.7%)	2 (15.4%)	0
Unadjusted Inverse Relative Risk (95% CI)	1.30 (0.23, 7.26)		0.31 (0.02, 5.76)	
p-value [1]	0.76		0.43	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	1.33 (0.21, 8.60)		0.27 (0.01, 6.40)	
p-value [1]	0.76		0.42	
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.16, 0.12)		0.12 (-0.13, 0.37)	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	42 (93.3%)	21 (91.3%)	11 (84.6%)	8 (100.0%)
Non-missing	15 (33.3%)	11 (47.8%)	3 (23.1%)	3 (37.5%)
Missing	27 (60.0%)	10 (43.5%)	8 (61.5%)	5 (62.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8108: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 8)	BAT (N = 8)	p-value
SF3602-Role Physical: NBS at Week 24			
Responder, n(%)	1 (12.5%)	0	
Unadjusted Inverse Relative Risk (95% CI)	0.33 (0.02, 7.14)		
p-value [1]	0.48		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	0.29 (0.01, 8.37)		
p-value [1]	0.47		
Unadjusted Absolute Risk Difference (95% CI)	0.11 (-0.17, 0.40)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Non-Responder, n(%)	7 (87.5%)	8 (100.0%)	
Non-missing	2 (25.0%)	7 (87.5%)	
Missing	5 (62.5%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8108: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 45)	BAT (N = 23)	MMB (N = 13)	BAT (N = 8)
SF3602-Bodily Pain: NBS at Week 24				
Responder, n(%)	4 (8.9%)	1 (4.3%)	2 (15.4%)	0
Unadjusted Inverse Relative Risk (95% CI)	0.49 (0.06, 4.13)		0.31 (0.02, 5.76)	
p-value [1]	0.51		0.43	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	0.47 (0.05, 4.43)		0.27 (0.01, 6.40)	
p-value [1]	0.51		0.42	
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.07, 0.16)		0.12 (-0.13, 0.37)	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	41 (91.1%)	22 (95.7%)	11 (84.6%)	8 (100.0%)
Non-missing	14 (31.1%)	12 (52.2%)	3 (23.1%)	3 (37.5%)
Missing	27 (60.0%)	10 (43.5%)	8 (61.5%)	5 (62.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8108: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 8)	BAT (N = 8)	p-value
SF3602-Bodily Pain: NBS at Week 24			
Responder, n(%)	0	1 (12.5%)	
Unadjusted Inverse Relative Risk (95% CI)	3.00 (0.14, 64.27)		
p-value [1]	0.48		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	3.40 (0.12, 96.71)		
p-value [1]	0.47		
Unadjusted Absolute Risk Difference (95% CI)	-0.11 (-0.40, 0.17)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Non-Responder, n(%)	8 (100.0%)	7 (87.5%)	
Non-missing	3 (37.5%)	6 (75.0%)	
Missing	5 (62.5%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8108: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 45)	BAT (N = 23)	MMB (N = 13)	BAT (N = 8)
SF3602-General Health: NBS at Week 24				
Responder, n(%)	2 (4.4%)	1 (4.3%)	2 (15.4%)	1 (12.5%)
Unadjusted Inverse Relative Risk (95% CI)	0.98 (0.09, 10.23)		0.81 (0.09, 7.58)	
p-value [1]	0.99		0.86	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	0.98 (0.08, 11.38)		0.79 (0.06, 10.38)	
p-value [1]	0.99		0.85	
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.10, 0.10)		0.03 (-0.27, 0.33)	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	43 (95.6%)	22 (95.7%)	11 (84.6%)	7 (87.5%)
Non-missing	16 (35.6%)	12 (52.2%)	3 (23.1%)	2 (25.0%)
Missing	27 (60.0%)	10 (43.5%)	8 (61.5%)	5 (62.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8108: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 8)	BAT (N = 8)	p-value
SF3602-General Health: NBS at Week 24			
Responder, n(%)	1 (12.5%)	1 (12.5%)	
Unadjusted Inverse Relative Risk (95% CI)	1.00 (0.07, 13.37)		
p-value [1]	1.00		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	1.00 (0.05, 19.36)		
p-value [1]	1.00		
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.32, 0.32)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Non-Responder, n(%)	7 (87.5%)	7 (87.5%)	
Non-missing	2 (25.0%)	6 (75.0%)	
Missing	5 (62.5%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

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Table 2.8108: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 45)	BAT (N = 23)	MMB (N = 13)	BAT (N = 8)
SF3602-Vitality: NBS at Week 24				
Responder, n(%)	2 (4.4%)	0	2 (15.4%)	0
Unadjusted Inverse Relative Risk (95% CI)	0.38 (0.02, 7.67)		0.31 (0.02, 5.76)	
p-value [1]	0.53		0.43	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	0.37 (0.02, 8.04)		0.27 (0.01, 6.40)	
p-value [1]	0.53		0.42	
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.05, 0.12)		0.12 (-0.13, 0.37)	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	43 (95.6%)	23 (100.0%)	11 (84.6%)	8 (100.0%)
Non-missing	16 (35.6%)	13 (56.5%)	3 (23.1%)	3 (37.5%)
Missing	27 (60.0%)	10 (43.5%)	8 (61.5%)	5 (62.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8108: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 8)	BAT (N = 8)	p-value
SF3602-Vitality: NBS at Week 24			
Responder, n(%)	0	1 (12.5%)	
Unadjusted Inverse Relative Risk (95% CI)	3.00 (0.14, 64.27)		
p-value [1]	0.48		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	3.40 (0.12, 96.71)		
p-value [1]	0.47		
Unadjusted Absolute Risk Difference (95% CI)	-0.11 (-0.40, 0.17)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Non-Responder, n(%)	8 (100.0%)	7 (87.5%)	
Non-missing	3 (37.5%)	6 (75.0%)	
Missing	5 (62.5%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8108: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 45)	BAT (N = 23)	MMB (N = 13)	BAT (N = 8)
SF3602-Social Functioning: NBS at Week 24				
Responder, n(%)	4 (8.9%)	4 (17.4%)	2 (15.4%)	0
Unadjusted Inverse Relative Risk (95% CI)	1.96 (0.54, 7.12)		0.31 (0.02, 5.76)	
p-value [1]	0.31		0.43	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	2.16 (0.49, 9.56)		0.27 (0.01, 6.40)	
p-value [1]	0.31		0.42	
Unadjusted Absolute Risk Difference (95% CI)	-0.09 (-0.26, 0.09)		0.12 (-0.13, 0.37)	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	41 (91.1%)	19 (82.6%)	11 (84.6%)	8 (100.0%)
Non-missing	14 (31.1%)	9 (39.1%)	3 (23.1%)	3 (37.5%)
Missing	27 (60.0%)	10 (43.5%)	8 (61.5%)	5 (62.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8108: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 8)	BAT (N = 8)	p-value
SF3602-Social Functioning: NBS at Week 24			
Responder, n(%)	0	1 (12.5%)	
Unadjusted Inverse Relative Risk (95% CI)	3.00 (0.14, 64.27)		
p-value [1]	0.48		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	3.40 (0.12, 96.71)		
p-value [1]	0.47		
Unadjusted Absolute Risk Difference (95% CI)	-0.11 (-0.40, 0.17)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Non-Responder, n(%)	8 (100.0%)	7 (87.5%)	
Non-missing	3 (37.5%)	6 (75.0%)	
Missing	5 (62.5%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8108: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 45)	BAT (N = 23)	MMB (N = 13)	BAT (N = 8)
SF3602-Role Emotional: NBS at Week 24				
Responder, n(%)	4 (8.9%)	3 (13.0%)	1 (7.7%)	1 (12.5%)
Unadjusted Inverse Relative Risk (95% CI)	1.47 (0.36, 6.01)		1.63 (0.12, 22.50)	
p-value [1]	0.59		0.72	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	1.54 (0.31, 7.54)		1.71 (0.09, 31.93)	
p-value [1]	0.60		0.72	
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.20, 0.12)		-0.05 (-0.32, 0.22)	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	41 (91.1%)	20 (87.0%)	12 (92.3%)	7 (87.5%)
Non-missing	14 (31.1%)	10 (43.5%)	4 (30.8%)	2 (25.0%)
Missing	27 (60.0%)	10 (43.5%)	8 (61.5%)	5 (62.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8108: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 8)	BAT (N = 8)	p-value
SF3602-Role Emotional: NBS at Week 24			
Responder, n(%)	0	3 (37.5%)	
Unadjusted Inverse Relative Risk (95% CI)	7.00 (0.42, 116.91)		
p-value [1]	0.18		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	10.82 (0.46, 252.80		
p-value [1]	0.14		
Unadjusted Absolute Risk Difference (95% CI)	-0.33 (-0.69, 0.02)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Non-Responder, n(%)	8 (100.0%)	5 (62.5%)	
Non-missing	3 (37.5%)	4 (50.0%)	
Missing	5 (62.5%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8108: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 45)	BAT (N = 23)	MMB (N = 13)	BAT (N = 8)
SF3602-Mental Health: NBS at Week 24				
Responder, n(%)	3 (6.7%)	2 (8.7%)	1 (7.7%)	0
Unadjusted Inverse Relative Risk (95% CI)	1.30 (0.23, 7.26)		0.52 (0.02, 11.39)	
p-value [1]	0.76		0.68	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	1.33 (0.21, 8.60)		0.49 (0.02, 13.52)	
p-value [1]	0.76		0.67	
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.16, 0.12)		0.05 (-0.17, 0.27)	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	42 (93.3%)	21 (91.3%)	12 (92.3%)	8 (100.0%)
Non-missing	15 (33.3%)	11 (47.8%)	4 (30.8%)	3 (37.5%)
Missing	27 (60.0%)	10 (43.5%)	8 (61.5%)	5 (62.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8108: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 8)	BAT (N = 8)	p-value
SF3602-Mental Health: NBS at Week 24			
Responder, n(%)	0	2 (25.0%)	
Unadjusted Inverse Relative Risk (95% CI)	5.00 (0.28, 90.19)		
p-value [1]	0.28		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	6.54 (0.27, 160.98)		
p-value [1]	0.25		
Unadjusted Absolute Risk Difference (95% CI)	-0.22 (-0.55, 0.11)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Non-Responder, n(%)	8 (100.0%)	6 (75.0%)	
Non-missing	3 (37.5%)	5 (62.5%)	
Missing	5 (62.5%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-sf36-gba.sas V.03.05 Output file: t-subgrp-sf36-gba-improv-mf.pdf 24AUG2023:16:53

Table 2.8108: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 45)	BAT (N = 23)	MMB (N = 13)	BAT (N = 8)
SF3602-Physical Component Summary at Week 24				
Responder, n(%)	2 (4.4%)	0	2 (15.4%)	0
Unadjusted Inverse Relative Risk (95% CI)	0.38 (0.02, 7.67)		0.31 (0.02, 5.76)	
p-value [1]	0.53		0.43	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	0.37 (0.02, 8.04)		0.27 (0.01, 6.40)	
p-value [1]	0.53		0.42	
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.05, 0.12)		0.12 (-0.13, 0.37)	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	43 (95.6%)	23 (100.0%)	11 (84.6%)	8 (100.0%)
Non-missing	16 (35.6%)	13 (56.5%)	3 (23.1%)	3 (37.5%)
Missing	27 (60.0%)	10 (43.5%)	8 (61.5%)	5 (62.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8108: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 8)	BAT (N = 8)	p-value
SF3602-Physical Component Summary at Week 24			
Responder, n(%)	0	0	
Unadjusted Inverse Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Non-Responder, n(%)	8 (100.0%)	8 (100.0%)	
Non-missing	3 (37.5%)	7 (87.5%)	
Missing	5 (62.5%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8108: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N = 45)	BAT (N = 23)	MMB (N = 13)	BAT (N = 8)
SF3602-Mental Component Summary at Week 24				
Responder, n(%)	2 (4.4%)	2 (8.7%)	1 (7.7%)	0
Unadjusted Inverse Relative Risk (95% CI)	1.96 (0.29, 13.01)		0.52 (0.02, 11.39)	
p-value [1]	0.49		0.68	
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Unadjusted Inverse Odds Ratio (95% CI)	2.05 (0.27, 15.56)		0.49 (0.02, 13.52)	
p-value [1]	0.49		0.67	
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.17, 0.09)		0.05 (-0.17, 0.27)	
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Responder, n(%)	43 (95.6%)	21 (91.3%)	12 (92.3%)	8 (100.0%)
Non-missing	16 (35.6%)	11 (47.8%)	4 (30.8%)	3 (37.5%)
Missing	27 (60.0%)	10 (43.5%)	8 (61.5%)	5 (62.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8108: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline MF Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N = 8)	BAT (N = 8)	p-value
SF3602-Mental Component Summary at Week 24			
Responder, n(%)	0	2 (25.0%)	
Unadjusted Inverse Relative Risk (95% CI)	5.00 (0.28, 90.19)		
p-value [1]	0.28		
Unadjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Unadjusted Inverse Odds Ratio (95% CI)	6.54 (0.27, 160.98)		
p-value [1]	0.25		
Unadjusted Absolute Risk Difference (95% CI)	-0.22 (-0.55, 0.11)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Adjusted interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Non-Responder, n(%)	8 (100.0%)	6 (75.0%)	
Non-missing	3 (37.5%)	5 (62.5%)	
Missing	5 (62.5%)	1 (12.5%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8103: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 52)	BAT (N = 18)	MMB (N = 14)	BAT (N = 21)	p-value
SF3602-Physical Functioning: NBS at Week 24					
Responder, n(%)	11 (21.2%)	0	1 (7.1%)	1 (4.8%)	
Unadjusted Inverse Relative Risk (95% CI)	0.12 (0.01, 1.96)		0.67 (0.05, 9.80)		
p-value [1]	0.14		0.77		
Unadjusted interaction test for Treatment*Gender [3]					NE
Unadjusted Inverse Odds Ratio (95% CI)	0.10 (0.01, 1.74)		0.65 (0.04, 11.33)		
p-value [1]	0.11		0.77		
Unadjusted Absolute Risk Difference (95% CI)	0.19 (0.06, 0.32)		0.02 (-0.14, 0.19)		
Adjusted Inverse Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Adjusted interaction test for Treatment*Gender [3]					NE
Non-Responder, n(%)	41 (78.8%)	18 (100.0%)	13 (92.9%)	20 (95.2%)	
Non-missing	7 (13.5%)	8 (44.4%)	7 (50.0%)	14 (66.7%)	
Missing	34 (65.4%)	10 (55.6%)	6 (42.9%)	6 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8103: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 52)	BAT (N = 18)	MMB (N = 14)	BAT (N = 21)	p-value
SF3602-Role Physical: NBS at Week 24					
Responder, n(%)	5 (9.6%)	1 (5.6%)	1 (7.1%)	1 (4.8%)	
Unadjusted Inverse Relative Risk (95% CI)	0.58 (0.07, 4.62)		0.67 (0.05, 9.80)		
p-value [1]	0.61		0.77		
Unadjusted interaction test for Treatment*Gender [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.55 (0.06, 5.08)		0.65 (0.04, 11.33)		
p-value [1]	0.60		0.77		
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.09, 0.17)		0.02 (-0.14, 0.19)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Gender [3]					NA
Non-Responder, n(%)	47 (90.4%)	17 (94.4%)	13 (92.9%)	20 (95.2%)	
Non-missing	13 (25.0%)	7 (38.9%)	7 (50.0%)	14 (66.7%)	
Missing	34 (65.4%)	10 (55.6%)	6 (42.9%)	6 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8103: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 52)	BAT (N = 18)	MMB (N = 14)	BAT (N = 21)	p-value
SF3602-Bodily Pain: NBS at Week 24					
Responder, n(%)	5 (9.6%)	1 (5.6%)	1 (7.1%)	1 (4.8%)	
Unadjusted Inverse Relative Risk (95% CI)	0.58 (0.07, 4.62)		0.67 (0.05, 9.80)		
p-value [1]	0.61		0.77		
Unadjusted interaction test for Treatment*Gender [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.55 (0.06, 5.08)		0.65 (0.04, 11.33)		
p-value [1]	0.60		0.77		
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.09, 0.17)		0.02 (-0.14, 0.19)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Gender [3]					NA
Non-Responder, n(%)	47 (90.4%)	17 (94.4%)	13 (92.9%)	20 (95.2%)	
Non-missing	13 (25.0%)	7 (38.9%)	7 (50.0%)	14 (66.7%)	
Missing	34 (65.4%)	10 (55.6%)	6 (42.9%)	6 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8103: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 52)	BAT (N = 18)	MMB (N = 14)	BAT (N = 21)	p-value
SF3602-General Health: NBS at Week 24					
Responder, n(%)	4 (7.7%)	1 (5.6%)	1 (7.1%)	2 (9.5%)	
Unadjusted Inverse Relative Risk (95% CI)	0.72 (0.09, 6.05)		1.33 (0.13, 13.34)		
p-value [1]	0.76		0.81		
Unadjusted interaction test for Treatment*Gender [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.71 (0.07, 6.77)		1.37 (0.11, 16.70)		
p-value [1]	0.76		0.81		
Unadjusted Absolute Risk Difference (95% CI)	0.02 (-0.11, 0.15)		-0.02 (-0.21, 0.16)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Gender [3]					NA
Non-Responder, n(%)	48 (92.3%)	17 (94.4%)	13 (92.9%)	19 (90.5%)	
Non-missing	14 (26.9%)	7 (38.9%)	7 (50.0%)	13 (61.9%)	
Missing	34 (65.4%)	10 (55.6%)	6 (42.9%)	6 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8103: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 52)	BAT (N = 18)	MMB (N = 14)	BAT (N = 21)	p-value
SF3602-Vitality: NBS at Week 24					
Responder, n(%)	3 (5.8%)	0	1 (7.1%)	1 (4.8%)	
Unadjusted Inverse Relative Risk (95% CI)	0.40 (0.02, 7.36)		0.67 (0.05, 9.80)		
p-value [1]	0.54		0.77		
Unadjusted interaction test for Treatment*Gender [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.38 (0.02, 7.76)		0.65 (0.04, 11.33)		
p-value [1]	0.53		0.77		
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.06, 0.14)		0.02 (-0.14, 0.19)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Gender [3]					NA
Non-Responder, n(%)	49 (94.2%)	18 (100.0%)	13 (92.9%)	20 (95.2%)	
Non-missing	15 (28.8%)	8 (44.4%)	7 (50.0%)	14 (66.7%)	
Missing	34 (65.4%)	10 (55.6%)	6 (42.9%)	6 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8103: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 52)	BAT (N = 18)	MMB (N = 14)	BAT (N = 21)	p-value
SF3602-Social Functioning: NBS at Week 24					
Responder, n(%)	5 (9.6%)	3 (16.7%)	1 (7.1%)	2 (9.5%)	
Unadjusted Inverse Relative Risk (95% CI)	1.73 (0.46, 6.54)		1.33 (0.13, 13.34)		
p-value [1]	0.42		0.81		
Unadjusted interaction test for Treatment*Gender [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	1.88 (0.40, 8.81)		1.37 (0.11, 16.70)		
p-value [1]	0.42		0.81		
Unadjusted Absolute Risk Difference (95% CI)	-0.07 (-0.26, 0.12)		-0.02 (-0.21, 0.16)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Gender [3]					NA
Non-Responder, n(%)	47 (90.4%)	15 (83.3%)	13 (92.9%)	19 (90.5%)	
Non-missing	13 (25.0%)	5 (27.8%)	7 (50.0%)	13 (61.9%)	
Missing	34 (65.4%)	10 (55.6%)	6 (42.9%)	6 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8103: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 52)	BAT (N = 18)	MMB (N = 14)	BAT (N = 21)	p-value
SF3602-Role Emotional: NBS at Week 24					
Responder, n(%)	5 (9.6%)	3 (16.7%)	0	4 (19.0%)	
Unadjusted Inverse Relative Risk (95% CI)	1.73 (0.46, 6.54)		6.14 (0.36, 105.78)		
p-value [1]	0.42		0.21		
Unadjusted interaction test for Treatment*Gender [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	1.88 (0.40, 8.81)		7.46 (0.37, 150.31)		
p-value [1]	0.42		0.19		
Unadjusted Absolute Risk Difference (95% CI)	-0.07 (-0.26, 0.12)		-0.17 (-0.36, 0.02)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Gender [3]					NA
Non-Responder, n(%)	47 (90.4%)	15 (83.3%)	14 (100.0%)	17 (81.0%)	
Non-missing	13 (25.0%)	5 (27.8%)	8 (57.1%)	11 (52.4%)	
Missing	34 (65.4%)	10 (55.6%)	6 (42.9%)	6 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8103: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 52)	BAT (N = 18)	MMB (N = 14)	BAT (N = 21)	p-value
SF3602-Mental Health: NBS at Week 24					
Responder, n(%)	4 (7.7%)	2 (11.1%)	0	2 (9.5%)	
Unadjusted Inverse Relative Risk (95% CI)	1.44 (0.29, 7.23)		3.41 (0.18, 66.09)		
p-value [1]	0.65		0.42		
Unadjusted interaction test for Treatment*Gender [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	1.50 (0.25, 8.98)		3.72 (0.17, 83.49)		
p-value [1]	0.66		0.41		
Unadjusted Absolute Risk Difference (95% CI)	-0.03 (-0.20, 0.13)		-0.08 (-0.24, 0.08)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Gender [3]					NA
Non-Responder, n(%)	48 (92.3%)	16 (88.9%)	14 (100.0%)	19 (90.5%)	
Non-missing	14 (26.9%)	6 (33.3%)	8 (57.1%)	13 (61.9%)	
Missing	34 (65.4%)	10 (55.6%)	6 (42.9%)	6 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8103: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 52)	BAT (N = 18)	MMB (N = 14)	BAT (N = 21)	p-value
SF3602-Physical Component Summary at Week 24					
Responder, n(%)	4 (7.7%)	0	0	0	
Unadjusted Inverse Relative Risk (95% CI)	0.31 (0.02, 5.49)		NA		
p-value [1]	0.42		NA		
Unadjusted interaction test for Treatment*Gender [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.29 (0.01, 5.68)		NA		
p-value [1]	0.42		NA		
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.05, 0.16)		NA		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Gender [3]					NA
Non-Responder, n(%)	48 (92.3%)	18 (100.0%)	14 (100.0%)	21 (100.0%)	
Non-missing	14 (26.9%)	8 (44.4%)	8 (57.1%)	15 (71.4%)	
Missing	34 (65.4%)	10 (55.6%)	6 (42.9%)	6 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8103: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female		
	MMB (N = 52)	BAT (N = 18)	MMB (N = 14)	BAT (N = 21)	p-value
SF3602-Mental Component Summary at Week 24					
Responder, n(%)	3 (5.8%)	2 (11.1%)	0	2 (9.5%)	
Unadjusted Inverse Relative Risk (95% CI)	1.93 (0.35, 10.62)		3.41 (0.18, 66.09)		
p-value [1]	0.45		0.42		
Unadjusted interaction test for Treatment*Gender [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	2.04 (0.31, 13.33)		3.72 (0.17, 83.49)		
p-value [1]	0.46		0.41		
Unadjusted Absolute Risk Difference (95% CI)	-0.05 (-0.21, 0.10)		-0.08 (-0.24, 0.08)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Gender [3]					NA
Non-Responder, n(%)	49 (94.2%)	16 (88.9%)	14 (100.0%)	19 (90.5%)	
Non-missing	15 (28.8%)	6 (33.3%)	8 (57.1%)	13 (61.9%)	
Missing	34 (65.4%)	10 (55.6%)	6 (42.9%)	6 (28.6%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.
Modified Poisson regression model did not converge so these values are presented as NE. NE = Not Estimable.

Data Extracted: CRF data: 25JUN2019

Table 2.8110: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N = 28)	BAT (N = 24)	MMB (N = 38)	BAT (N = 15)	p-value
SF3602-Physical Functioning: NBS at Week 24					
Responder, n(%)	6 (21.4%)	1 (4.2%)	6 (15.8%)	0	
Unadjusted Inverse Relative Risk (95% CI)	0.19 (0.03, 1.50)		0.19 (0.01, 3.14)		
p-value [1]	0.12		0.24		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.16 (0.02, 1.43)		0.16 (0.01, 3.05)		
p-value [1]	0.10		0.22		
Unadjusted Absolute Risk Difference (95% CI)	0.17 (0.00, 0.34)		0.14 (-0.01, 0.28)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Non-Responder, n(%)	22 (78.6%)	23 (95.8%)	32 (84.2%)	15 (100.0%)	
Non-missing	6 (21.4%)	15 (62.5%)	8 (21.1%)	7 (46.7%)	
Missing	16 (57.1%)	8 (33.3%)	24 (63.2%)	8 (53.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8110: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N = 28)	BAT (N = 24)	MMB (N = 38)	BAT (N = 15)	p-value
SF3602-Role Physical: NBS at Week 24					
Responder, n(%)	4 (14.3%)	2 (8.3%)	2 (5.3%)	0	
Unadjusted Inverse Relative Risk (95% CI)	0.58 (0.12, 2.91)		0.49 (0.02, 9.60)		
p-value [1]	0.51		0.64		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.55 (0.09, 3.28)		0.47 (0.02, 10.39)		
p-value [1]	0.51		0.63		
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.11, 0.23)		0.03 (-0.08, 0.15)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Non-Responder, n(%)	24 (85.7%)	22 (91.7%)	36 (94.7%)	15 (100.0%)	
Non-missing	8 (28.6%)	14 (58.3%)	12 (31.6%)	7 (46.7%)	
Missing	16 (57.1%)	8 (33.3%)	24 (63.2%)	8 (53.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8110: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N = 28)	BAT (N = 24)	MMB (N = 38)	BAT (N = 15)	p-value
SF3602-Bodily Pain: NBS at Week 24					
Responder, n(%)	4 (14.3%)	1 (4.2%)	2 (5.3%)	1 (6.7%)	
Unadjusted Inverse Relative Risk (95% CI)	0.29 (0.03, 2.44)		1.27 (0.12, 12.95)		
p-value [1]	0.26		0.84		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.26 (0.03, 2.51)		1.29 (0.11, 15.33)		
p-value [1]	0.24		0.84		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.05, 0.25)		-0.01 (-0.16, 0.13)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Non-Responder, n(%)	24 (85.7%)	23 (95.8%)	36 (94.7%)	14 (93.3%)	
Non-missing	8 (28.6%)	15 (62.5%)	12 (31.6%)	6 (40.0%)	
Missing	16 (57.1%)	8 (33.3%)	24 (63.2%)	8 (53.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8110: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N = 28)	BAT (N = 24)	MMB (N = 38)	BAT (N = 15)	p-value
SF3602-General Health: NBS at Week 24					
Responder, n(%)	4 (14.3%)	1 (4.2%)	1 (2.6%)	2 (13.3%)	
Unadjusted Inverse Relative Risk (95% CI)	0.29 (0.03, 2.44)		5.07 (0.50, 51.81)		
p-value [1]	0.26		0.17		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.26 (0.03, 2.51)		5.69 (0.48, 68.13)		
p-value [1]	0.24		0.17		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.05, 0.25)		-0.11 (-0.29, 0.07)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Non-Responder, n(%)	24 (85.7%)	23 (95.8%)	37 (97.4%)	13 (86.7%)	
Non-missing	8 (28.6%)	15 (62.5%)	13 (34.2%)	5 (33.3%)	
Missing	16 (57.1%)	8 (33.3%)	24 (63.2%)	8 (53.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8110: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N = 28)	BAT (N = 24)	MMB (N = 38)	BAT (N = 15)	p-value
SF3602-Vitality: NBS at Week 24					
Responder, n(%)	2 (7.1%)	1 (4.2%)	2 (5.3%)	0	
Unadjusted Inverse Relative Risk (95% CI)	0.58 (0.06, 6.04)		0.49 (0.02, 9.60)		
p-value [1]	0.65		0.64		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.57 (0.05, 6.65)		0.47 (0.02, 10.39)		
p-value [1]	0.65		0.63		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.09, 0.15)		0.03 (-0.08, 0.15)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Non-Responder, n(%)	26 (92.9%)	23 (95.8%)	36 (94.7%)	15 (100.0%)	
Non-missing	10 (35.7%)	15 (62.5%)	12 (31.6%)	7 (46.7%)	
Missing	16 (57.1%)	8 (33.3%)	24 (63.2%)	8 (53.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8110: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N = 28)	BAT (N = 24)	MMB (N = 38)	BAT (N = 15)	p-value
SF3602-Social Functioning: NBS at Week 24					
Responder, n(%)	4 (14.3%)	4 (16.7%)	2 (5.3%)	1 (6.7%)	
Unadjusted Inverse Relative Risk (95% CI)	1.17 (0.33, 4.17)		1.27 (0.12, 12.95)		
p-value [1]	0.81		0.84		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	1.20 (0.27, 5.42)		1.29 (0.11, 15.33)		
p-value [1]	0.81		0.84		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.22, 0.17)		-0.01 (-0.16, 0.13)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Non-Responder, n(%)	24 (85.7%)	20 (83.3%)	36 (94.7%)	14 (93.3%)	
Non-missing	8 (28.6%)	12 (50.0%)	12 (31.6%)	6 (40.0%)	
Missing	16 (57.1%)	8 (33.3%)	24 (63.2%)	8 (53.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8110: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N = 28)	BAT (N = 24)	MMB (N = 38)	BAT (N = 15)	p-value
SF3602-Role Emotional: NBS at Week 24					
Responder, n(%)	3 (10.7%)	6 (25.0%)	2 (5.3%)	1 (6.7%)	
Unadjusted Inverse Relative Risk (95% CI)	2.33 (0.65, 8.34)		1.27 (0.12, 12.95)		
p-value [1]	0.19		0.84		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	2.78 (0.61, 12.61)		1.29 (0.11, 15.33)		
p-value [1]	0.19		0.84		
Unadjusted Absolute Risk Difference (95% CI)	-0.14 (-0.35, 0.06)		-0.01 (-0.16, 0.13)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Non-Responder, n(%)	25 (89.3%)	18 (75.0%)	36 (94.7%)	14 (93.3%)	
Non-missing	9 (32.1%)	10 (41.7%)	12 (31.6%)	6 (40.0%)	
Missing	16 (57.1%)	8 (33.3%)	24 (63.2%)	8 (53.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8110: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N = 28)	BAT (N = 24)	MMB (N = 38)	BAT (N = 15)	p-value
SF3602-Mental Health: NBS at Week 24					
Responder, n(%)	3 (10.7%)	3 (12.5%)	1 (2.6%)	1 (6.7%)	
Unadjusted Inverse Relative Risk (95% CI)	1.17 (0.26, 5.25)		2.53 (0.17, 37.95)		
p-value [1]	0.84		0.50		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	1.19 (0.22, 6.53)		2.64 (0.15, 45.20)		
p-value [1]	0.84		0.50		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.19, 0.16)		-0.04 (-0.18, 0.10)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Non-Responder, n(%)	25 (89.3%)	21 (87.5%)	37 (97.4%)	14 (93.3%)	
Non-missing	9 (32.1%)	13 (54.2%)	13 (34.2%)	6 (40.0%)	
Missing	16 (57.1%)	8 (33.3%)	24 (63.2%)	8 (53.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8110: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N = 28)	BAT (N = 24)	MMB (N = 38)	BAT (N = 15)	p-value
SF3602-Physical Component Summary at Week 24					
Responder, n(%)	3 (10.7%)	0	1 (2.6%)	0	
Unadjusted Inverse Relative Risk (95% CI)	0.17 (0.01, 3.06)		0.81 (0.03, 18.91)		
p-value [1]	0.23		0.90		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.15 (0.01, 3.03)		0.81 (0.03, 20.90)		
p-value [1]	0.22		0.90		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.03, 0.23)		0.01 (-0.10, 0.11)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Non-Responder, n(%)	25 (89.3%)	24 (100.0%)	37 (97.4%)	15 (100.0%)	
Non-missing	9 (32.1%)	16 (66.7%)	13 (34.2%)	7 (46.7%)	
Missing	16 (57.1%)	8 (33.3%)	24 (63.2%)	8 (53.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8110: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline Spleen Volume
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<Median 2329.91 cm^3		>=Median 2329.91 cm^3		
	MMB (N = 28)	BAT (N = 24)	MMB (N = 38)	BAT (N = 15)	p-value
SF3602-Mental Component Summary at Week 24					
Responder, n(%)	3 (10.7%)	3 (12.5%)	0	1 (6.7%)	
Unadjusted Inverse Relative Risk (95% CI)	1.17 (0.26, 5.25)		7.31 (0.31, 170.19)		
p-value [1]	0.84		0.22		
Unadjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	1.19 (0.22, 6.53)		7.97 (0.31, 206.91)		
p-value [1]	0.84		0.21		
Unadjusted Absolute Risk Difference (95% CI)	-0.02 (-0.19, 0.16)		-0.08 (-0.23, 0.07)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Non-Responder, n(%)	25 (89.3%)	21 (87.5%)	38 (100.0%)	14 (93.3%)	
Non-missing	9 (32.1%)	13 (54.2%)	14 (36.8%)	6 (40.0%)	
Missing	16 (57.1%)	8 (33.3%)	24 (63.2%)	8 (53.3%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8109: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 42)	BAT (N = 20)	MMB (N = 24)	BAT (N = 19)	p-value
SF3602-Physical Functioning: NBS at Week 24					
Responder, n(%)	7 (16.7%)	1 (5.0%)	5 (20.8%)	0	
Unadjusted Inverse Relative Risk (95% CI)	0.30 (0.04, 2.28)		0.11 (0.01, 1.93)		
p-value [1]	0.24		0.13		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.26 (0.03, 2.30)		0.09 (0.00, 1.76)		
p-value [1]	0.23		0.11		
Unadjusted Absolute Risk Difference (95% CI)	0.12 (-0.03, 0.26)		0.20 (0.02, 0.37)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Non-Responder, n(%)	35 (83.3%)	19 (95.0%)	19 (79.2%)	19 (100.0%)	
Non-missing	11 (26.2%)	10 (50.0%)	3 (12.5%)	12 (63.2%)	
Missing	24 (57.1%)	9 (45.0%)	16 (66.7%)	7 (36.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8109: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 42)	BAT (N = 20)	MMB (N = 24)	BAT (N = 19)	p-value
SF3602-Role Physical: NBS at Week 24					
Responder, n(%)	5 (11.9%)	1 (5.0%)	1 (4.2%)	1 (5.3%)	
Unadjusted Inverse Relative Risk (95% CI)	0.42 (0.05, 3.36)		1.26 (0.08, 18.90)		
p-value [1]	0.41		0.87		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.39 (0.04, 3.58)		1.28 (0.07, 21.86)		
p-value [1]	0.40		0.87		
Unadjusted Absolute Risk Difference (95% CI)	0.07 (-0.07, 0.21)		-0.01 (-0.14, 0.12)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Non-Responder, n(%)	37 (88.1%)	19 (95.0%)	23 (95.8%)	18 (94.7%)	
Non-missing	13 (31.0%)	10 (50.0%)	7 (29.2%)	11 (57.9%)	
Missing	24 (57.1%)	9 (45.0%)	16 (66.7%)	7 (36.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8109: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 42)	BAT (N = 20)	MMB (N = 24)	BAT (N = 19)	p-value
SF3602-Bodily Pain: NBS at Week 24					
Responder, n(%)	4 (9.5%)	1 (5.0%)	2 (8.3%)	1 (5.3%)	
Unadjusted Inverse Relative Risk (95% CI)	0.53 (0.06, 4.40)		0.63 (0.06, 6.45)		
p-value [1]	0.55		0.70		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.50 (0.05, 4.79)		0.61 (0.05, 7.30)		
p-value [1]	0.55		0.70		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.09, 0.18)		0.03 (-0.12, 0.18)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Non-Responder, n(%)	38 (90.5%)	19 (95.0%)	22 (91.7%)	18 (94.7%)	
Non-missing	14 (33.3%)	10 (50.0%)	6 (25.0%)	11 (57.9%)	
Missing	24 (57.1%)	9 (45.0%)	16 (66.7%)	7 (36.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8109: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 42)	BAT (N = 20)	MMB (N = 24)	BAT (N = 19)	p-value
SF3602-General Health: NBS at Week 24					
Responder, n(%)	3 (7.1%)	0	2 (8.3%)	3 (15.8%)	
Unadjusted Inverse Relative Risk (95% CI)	0.29 (0.02, 5.41)		1.89 (0.35, 10.22)		
p-value [1]	0.41		0.46		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.28 (0.01, 5.59)		2.06 (0.31, 13.81)		
p-value [1]	0.40		0.46		
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.05, 0.16)		-0.07 (-0.27, 0.12)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Non-Responder, n(%)	39 (92.9%)	20 (100.0%)	22 (91.7%)	16 (84.2%)	
Non-missing	15 (35.7%)	11 (55.0%)	6 (25.0%)	9 (47.4%)	
Missing	24 (57.1%)	9 (45.0%)	16 (66.7%)	7 (36.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8109: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 42)	BAT (N = 20)	MMB (N = 24)	BAT (N = 19)	p-value
SF3602-Vitality: NBS at Week 24					
Responder, n(%)	4 (9.5%)	1 (5.0%)	0	0	
Unadjusted Inverse Relative Risk (95% CI)	0.53 (0.06, 4.40)		NA		
p-value [1]	0.55		NA		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.50 (0.05, 4.79)		NA		
p-value [1]	0.55		NA		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.09, 0.18)		NA		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Non-Responder, n(%)	38 (90.5%)	19 (95.0%)	24 (100.0%)	19 (100.0%)	
Non-missing	14 (33.3%)	10 (50.0%)	8 (33.3%)	12 (63.2%)	
Missing	24 (57.1%)	9 (45.0%)	16 (66.7%)	7 (36.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8109: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 42)	BAT (N = 20)	MMB (N = 24)	BAT (N = 19)	p-value
SF3602-Social Functioning: NBS at Week 24					
Responder, n(%)	4 (9.5%)	3 (15.0%)	2 (8.3%)	2 (10.5%)	
Unadjusted Inverse Relative Risk (95% CI)	1.58 (0.39, 6.38)		1.26 (0.20, 8.16)		
p-value [1]	0.52		0.81		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	1.68 (0.34, 8.32)		1.29 (0.16, 10.15)		
p-value [1]	0.53		0.81		
Unadjusted Absolute Risk Difference (95% CI)	-0.05 (-0.23, 0.13)		-0.02 (-0.20, 0.15)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Non-Responder, n(%)	38 (90.5%)	17 (85.0%)	22 (91.7%)	17 (89.5%)	
Non-missing	14 (33.3%)	8 (40.0%)	6 (25.0%)	10 (52.6%)	
Missing	24 (57.1%)	9 (45.0%)	16 (66.7%)	7 (36.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8109: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 42)	BAT (N = 20)	MMB (N = 24)	BAT (N = 19)	p-value
SF3602-Role Emotional: NBS at Week 24					
Responder, n(%)	3 (7.1%)	4 (20.0%)	2 (8.3%)	3 (15.8%)	
Unadjusted Inverse Relative Risk (95% CI)	2.80 (0.69, 11.34)		1.89 (0.35, 10.22)		
p-value [1]	0.15		0.46		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	3.25 (0.65, 16.20)		2.06 (0.31, 13.81)		
p-value [1]	0.15		0.46		
Unadjusted Absolute Risk Difference (95% CI)	-0.13 (-0.32, 0.06)		-0.07 (-0.27, 0.12)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Non-Responder, n(%)	39 (92.9%)	16 (80.0%)	22 (91.7%)	16 (84.2%)	
Non-missing	15 (35.7%)	7 (35.0%)	6 (25.0%)	9 (47.4%)	
Missing	24 (57.1%)	9 (45.0%)	16 (66.7%)	7 (36.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8109: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 42)	BAT (N = 20)	MMB (N = 24)	BAT (N = 19)	p-value
SF3602-Mental Health: NBS at Week 24					
Responder, n(%)	2 (4.8%)	3 (15.0%)	2 (8.3%)	1 (5.3%)	
Unadjusted Inverse Relative Risk (95% CI)	3.15 (0.57, 17.38)		0.63 (0.06, 6.45)		
p-value [1]	0.19		0.70		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	3.53 (0.54, 23.06)		0.61 (0.05, 7.30)		
p-value [1]	0.19		0.70		
Unadjusted Absolute Risk Difference (95% CI)	-0.10 (-0.27, 0.07)		0.03 (-0.12, 0.18)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Non-Responder, n(%)	40 (95.2%)	17 (85.0%)	22 (91.7%)	18 (94.7%)	
Non-missing	16 (38.1%)	8 (40.0%)	6 (25.0%)	11 (57.9%)	
Missing	24 (57.1%)	9 (45.0%)	16 (66.7%)	7 (36.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8109: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 42)	BAT (N = 20)	MMB (N = 24)	BAT (N = 19)	p-value
SF3602-Physical Component Summary at Week 24					
Responder, n(%)	3 (7.1%)	0	1 (4.2%)	0	
Unadjusted Inverse Relative Risk (95% CI)	0.29 (0.02, 5.41)		0.42 (0.02, 9.69)		
p-value [1]	0.41		0.59		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	0.28 (0.01, 5.59)		0.40 (0.02, 10.43)		
p-value [1]	0.40		0.58		
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.05, 0.16)		0.04 (-0.08, 0.15)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Non-Responder, n(%)	39 (92.9%)	20 (100.0%)	23 (95.8%)	19 (100.0%)	
Non-missing	15 (35.7%)	11 (55.0%)	7 (29.2%)	12 (63.2%)	
Missing	24 (57.1%)	9 (45.0%)	16 (66.7%)	7 (36.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 2.8109: Analysis of Response Rate (improvement) in SF-36v2 (for PCS, MCS and all 8 domains) at Week 24 by Baseline TSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18		
	MMB (N = 42)	BAT (N = 20)	MMB (N = 24)	BAT (N = 19)	p-value
SF3602-Mental Component Summary at Week 24					
Responder, n(%)	2 (4.8%)	2 (10.0%)	1 (4.2%)	2 (10.5%)	
Unadjusted Inverse Relative Risk (95% CI)	2.10 (0.32, 13.85)		2.53 (0.25, 25.81)		
p-value [1]	0.44		0.43		
Unadjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Unadjusted Inverse Odds Ratio (95% CI)	2.22 (0.29, 17.05)		2.71 (0.23, 32.34)		
p-value [1]	0.44		0.43		
Unadjusted Absolute Risk Difference (95% CI)	-0.05 (-0.20, 0.09)		-0.06 (-0.22, 0.10)		
Adjusted Inverse Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Adjusted interaction test for Treatment*Baseline TSS Group [3]					NA
Non-Responder, n(%)	40 (95.2%)	18 (90.0%)	23 (95.8%)	17 (89.5%)	
Non-missing	16 (38.1%)	9 (45.0%)	7 (29.2%)	10 (52.6%)	
Missing	24 (57.1%)	9 (45.0%)	16 (66.7%)	7 (36.8%)	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment and baseline TD (yes, no) as covariates.
[3] The interaction test p-value was obtained for the treatment by subgroup interaction term from the corresponding modified Poisson regression which additionally includes subgroup as covariate and the treatment by subgroup interaction term.

Data Extracted: CRF data: 25JUN2019

Table 3.0202: TEAEs: Overall Summary by Age
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
TEAE					
Number of subjects, n(%)	24 (100.0%)	7 (77.8%)	42 (100.0%)	28 (93.3%)	
Unadjusted Relative Risk (95% CI)	1.31 (0.91, 1.88)		1.08 (0.96, 1.20)		
p-value [1]	0.15		0.19		
Unadjusted Odds Ratio (95% CI)	16.33 (0.70, 379.12)		7.46 (0.34, 161.15)		
p-value [1]	0.082		0.20		
Unadjusted Absolute Risk Difference (95% CI)	0.23 (-0.04, 0.50)		0.07 (-0.03, 0.17)		
Adjusted Relative Risk (95% CI) [2]	1.24 (0.91, 1.69)		1.07 (0.97, 1.17)		
p-value [2]	0.16		0.17		
Interaction test for Treatment*Age Group [3]					0.30
TEAE with Grade >=3					
Number of subjects, n(%)	16 (66.7%)	2 (22.2%)	24 (57.1%)	16 (53.3%)	
Unadjusted Relative Risk (95% CI)	3.00 (0.86, 10.52)		1.07 (0.70, 1.64)		
p-value [1]	0.086		0.75		
Unadjusted Odds Ratio (95% CI)	7.00 (1.17, 41.76)		1.17 (0.45, 2.99)		
p-value [1]	0.033		0.75		
Unadjusted Absolute Risk Difference (95% CI)	0.44 (0.11, 0.78)		0.04 (-0.19, 0.27)		
Adjusted Relative Risk (95% CI) [2]	2.77 (0.77, 10.02)		1.07 (0.70, 1.62)		
p-value [2]	0.12		0.76		
Interaction test for Treatment*Age Group [3]					0.061

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0202: TEAEs: Overall Summary by Age
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
TEAE with Grade 3 or 4					
Number of subjects, n(%)	16 (66.7%)	2 (22.2%)	23 (54.8%)	16 (53.3%)	
Unadjusted Relative Risk (95% CI)	3.00 (0.86, 10.52)		1.03 (0.67, 1.58)		
p-value [1]	0.086		0.90		
Unadjusted Odds Ratio (95% CI)	7.00 (1.17, 41.76)		1.06 (0.41, 2.71)		
p-value [1]	0.033		0.90		
Unadjusted Absolute Risk Difference (95% CI)	0.44 (0.11, 0.78)		0.01 (-0.22, 0.25)		
Adjusted Relative Risk (95% CI) [2]	2.77 (0.77, 10.02)		1.03 (0.67, 1.57)		
p-value [2]	0.12		0.91		
Interaction test for Treatment*Age Group [3]					0.051
TEAE Related to Study Drug					
Number of subjects, n(%)	16 (66.7%)	4 (44.4%)	33 (78.6%)	11 (36.7%)	
Unadjusted Relative Risk (95% CI)	1.50 (0.69, 3.28)		2.14 (1.30, 3.52)		
p-value [1]	0.31		0.003		
Unadjusted Odds Ratio (95% CI)	2.50 (0.52, 11.96)		6.33 (2.22, 18.03)		
p-value [1]	0.25		<0.001		
Unadjusted Absolute Risk Difference (95% CI)	0.22 (-0.15, 0.60)		0.42 (0.21, 0.63)		
Adjusted Relative Risk (95% CI) [2]	1.72 (0.85, 3.46)		2.16 (1.30, 3.59)		
p-value [2]	0.13		0.003		
Interaction test for Treatment*Age Group [3]					0.49

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0202: TEAEs: Overall Summary by Age
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
TEAE Related to Study Drug with Grade >=3					
Number of subjects, n(%)	8 (33.3%)	2 (22.2%)	12 (28.6%)	6 (20.0%)	
Unadjusted Relative Risk (95% CI)	1.50 (0.39, 5.77)		1.43 (0.60, 3.38)		
p-value [1]	0.56		0.42		
Unadjusted Odds Ratio (95% CI)	1.75 (0.29, 10.44)		1.60 (0.52, 4.89)		
p-value [1]	0.54		0.41		
Unadjusted Absolute Risk Difference (95% CI)	0.11 (-0.22, 0.44)		0.09 (-0.11, 0.28)		
Adjusted Relative Risk (95% CI) [2]	NE		1.37 (0.54, 3.48)		
p-value [2]	NE		0.50		
Interaction test for Treatment*Age Group [3]					0.95
Serious TEAE					
Number of subjects, n(%)	8 (33.3%)	2 (22.2%)	15 (35.7%)	7 (23.3%)	
Unadjusted Relative Risk (95% CI)	1.50 (0.39, 5.77)		1.53 (0.71, 3.29)		
p-value [1]	0.56		0.28		
Unadjusted Odds Ratio (95% CI)	1.75 (0.29, 10.44)		1.83 (0.64, 5.25)		
p-value [1]	0.54		0.26		
Unadjusted Absolute Risk Difference (95% CI)	0.11 (-0.22, 0.44)		0.12 (-0.09, 0.33)		
Adjusted Relative Risk (95% CI) [2]	1.26 (0.32, 5.04)		NE		
p-value [2]	0.74		NE		
Interaction test for Treatment*Age Group [3]					0.98

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0202: TEAEs: Overall Summary by Age
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Serious TEAE Related to Study Drug					
Number of subjects, n(%)	2 (8.3%)	1 (11.1%)	5 (11.9%)	1 (3.3%)	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Age Group [3]					NA
Non-Fatal SAEs					
Number of subjects, n(%)	8 (33.3%)	2 (22.2%)	15 (35.7%)	6 (20.0%)	
Unadjusted Relative Risk (95% CI)	1.50 (0.39, 5.77)		1.79 (0.78, 4.07)		
p-value [1]	0.56		0.17		
Unadjusted Odds Ratio (95% CI)	1.75 (0.29, 10.44)		2.22 (0.74, 6.64)		
p-value [1]	0.54		0.15		
Unadjusted Absolute Risk Difference (95% CI)	0.11 (-0.22, 0.44)		0.16 (-0.05, 0.36)		
Adjusted Relative Risk (95% CI) [2]	1.26 (0.32, 5.04)		NE		
p-value [2]	0.74		NE		
Interaction test for Treatment*Age Group [3]					0.83

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0202: TEAEs: Overall Summary by Age
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
TEAE Leading to Premature Discontinuation of Study Drug					
Number of subjects, n(%)	11 (45.8%)	0	3 (7.1%)	1 (3.3%)	
Unadjusted Relative Risk (95% CI)	9.20 (0.60, 141.75)		2.14 (0.23, 19.62)		
p-value [1]	0.11		0.50		
Unadjusted Odds Ratio (95% CI)	16.19 (0.85, 309.43)		2.23 (0.22, 22.56)		
p-value [1]	0.064		0.50		
Unadjusted Absolute Risk Difference (95% CI)	0.41 (0.17, 0.65)		0.04 (-0.06, 0.14)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Interaction test for Treatment*Age Group [3]					NE
TEAE Leading to Dose Reduction or Temporary Interruption of Study Drug					
Number of subjects, n(%)	4 (16.7%)	3 (33.3%)	5 (11.9%)	5 (16.7%)	
Unadjusted Relative Risk (95% CI)	0.50 (0.14, 1.81)		0.71 (0.23, 2.25)		
p-value [1]	0.29		0.57		
Unadjusted Odds Ratio (95% CI)	0.40 (0.07, 2.31)		0.68 (0.18, 2.58)		
p-value [1]	0.31		0.57		
Unadjusted Absolute Risk Difference (95% CI)	-0.17 (-0.51, 0.18)		-0.05 (-0.21, 0.12)		
Adjusted Relative Risk (95% CI) [2]	0.48 (0.15, 1.47)		0.78 (0.20, 2.96)		
p-value [2]	0.20		0.71		
Interaction test for Treatment*Age Group [3]					0.69

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-rt-sub-gba.sas V.03.05 Output file: t-aesum-rt-gba-age.pdf 24AUG2023:16:51

Table 3.0202: TEAEs: Overall Summary by Age
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
TEAE Leading to Death					
Number of subjects, n(%)	2 (8.3%)	1 (11.1%)	2 (4.8%)	3 (10.0%)	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Age Group [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0204: TEAEs: Overall Summary by Region
Randomized Treatment Phase
SAF-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
TEAE					
Number of subjects, n(%)	29 (100.0%)	6 (85.7%)	37 (100.0%)	29 (90.6%)	
Unadjusted Relative Risk (95% CI)	1.21 (0.86, 1.69)		1.10 (0.98, 1.25)		
p-value [1]	0.27		0.12		
Unadjusted Odds Ratio (95% CI)	13.62 (0.50, 373.39)		8.90 (0.44, 179.13)		
p-value [1]	0.12		0.15		
Unadjusted Absolute Risk Difference (95% CI)	0.17 (-0.10, 0.45)		0.09 (-0.02, 0.20)		
Adjusted Relative Risk (95% CI) [2]	1.19 (0.86, 1.64)		1.09 (0.99, 1.20)		
p-value [2]	0.29		0.083		
Interaction test for Treatment*Region [3]					0.73
TEAE with Grade >=3					
Number of subjects, n(%)	15 (51.7%)	2 (28.6%)	25 (67.6%)	16 (50.0%)	
Unadjusted Relative Risk (95% CI)	1.81 (0.53, 6.15)		1.35 (0.89, 2.04)		
p-value [1]	0.34		0.15		
Unadjusted Odds Ratio (95% CI)	2.68 (0.45, 16.11)		2.08 (0.78, 5.53)		
p-value [1]	0.28		0.14		
Unadjusted Absolute Risk Difference (95% CI)	0.23 (-0.15, 0.61)		0.18 (-0.05, 0.41)		
Adjusted Relative Risk (95% CI) [2]	1.69 (0.52, 5.52)		1.40 (0.93, 2.10)		
p-value [2]	0.38		0.11		
Interaction test for Treatment*Region [3]					0.63

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0204: TEAEs: Overall Summary by Region
Randomized Treatment Phase
SAF-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
TEAE with Grade 3 or 4					
Number of subjects, n(%)	15 (51.7%)	2 (28.6%)	24 (64.9%)	16 (50.0%)	
Unadjusted Relative Risk (95% CI)	1.81 (0.53, 6.15)		1.30 (0.85, 1.97)		
p-value [1]	0.34		0.22		
Unadjusted Odds Ratio (95% CI)	2.68 (0.45, 16.11)		1.85 (0.70, 4.86)		
p-value [1]	0.28		0.21		
Unadjusted Absolute Risk Difference (95% CI)	0.23 (-0.15, 0.61)		0.15 (-0.08, 0.38)		
Adjusted Relative Risk (95% CI) [2]	1.69 (0.52, 5.52)		1.34 (0.88, 2.04)		
p-value [2]	0.38		0.17		
Interaction test for Treatment*Region [3]					0.58
TEAE Related to Study Drug					
Number of subjects, n(%)	21 (72.4%)	3 (42.9%)	28 (75.7%)	12 (37.5%)	
Unadjusted Relative Risk (95% CI)	1.69 (0.70, 4.09)		2.02 (1.24, 3.27)		
p-value [1]	0.25		0.004		
Unadjusted Odds Ratio (95% CI)	3.50 (0.64, 19.24)		5.19 (1.84, 14.63)		
p-value [1]	0.15		0.002		
Unadjusted Absolute Risk Difference (95% CI)	0.30 (-0.11, 0.70)		0.38 (0.16, 0.60)		
Adjusted Relative Risk (95% CI) [2]	1.82 (0.89, 3.71)		2.03 (1.26, 3.27)		
p-value [2]	0.10		0.004		
Interaction test for Treatment*Region [3]					0.74

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0204: TEAEs: Overall Summary by Region
Randomized Treatment Phase
SAF-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
TEAE Related to Study Drug with Grade >=3					
Number of subjects, n(%)	7 (24.1%)	0	13 (35.1%)	8 (25.0%)	
Unadjusted Relative Risk (95% CI)	4.00 (0.25, 62.85)		1.41 (0.67, 2.95)		
p-value [1]	0.32		0.37		
Unadjusted Odds Ratio (95% CI)	5.00 (0.25, 98.41)		1.63 (0.57, 4.63)		
p-value [1]	0.29		0.36		
Unadjusted Absolute Risk Difference (95% CI)	0.19 (-0.04, 0.42)		0.10 (-0.11, 0.32)		
Adjusted Relative Risk (95% CI) [2]	NE		1.36 (0.65, 2.88)		
p-value [2]	NE		0.41		
Interaction test for Treatment*Region [3]					NE
Serious TEAE					
Number of subjects, n(%)	5 (17.2%)	0	18 (48.6%)	9 (28.1%)	
Unadjusted Relative Risk (95% CI)	2.93 (0.18, 47.67)		1.73 (0.91, 3.30)		
p-value [1]	0.45		0.096		
Unadjusted Odds Ratio (95% CI)	3.37 (0.17, 68.21)		2.42 (0.89, 6.61)		
p-value [1]	0.43		0.085		
Unadjusted Absolute Risk Difference (95% CI)	0.12 (-0.10, 0.34)		0.21 (-0.02, 0.43)		
Adjusted Relative Risk (95% CI) [2]	NE		1.64 (0.86, 3.14)		
p-value [2]	NE		0.13		
Interaction test for Treatment*Region [3]					NE

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0204: TEAEs: Overall Summary by Region
Randomized Treatment Phase
SAF-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Serious TEAE Related to Study Drug					
Number of subjects, n(%)	1 (3.4%)	0	6 (16.2%)	2 (6.3%)	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Region [3]					NA
Non-Fatal SAEs					
Number of subjects, n(%)	5 (17.2%)	0	18 (48.6%)	8 (25.0%)	
Unadjusted Relative Risk (95% CI)	2.93 (0.18, 47.67)		1.95 (0.98, 3.86)		
p-value [1]	0.45		0.057		
Unadjusted Odds Ratio (95% CI)	3.37 (0.17, 68.21)		2.84 (1.02, 7.94)		
p-value [1]	0.43		0.046		
Unadjusted Absolute Risk Difference (95% CI)	0.12 (-0.10, 0.34)		0.24 (0.02, 0.46)		
Adjusted Relative Risk (95% CI) [2]	NE		1.87 (0.94, 3.72)		
p-value [2]	NE		0.073		
Interaction test for Treatment*Region [3]					NE

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0204: TEAEs: Overall Summary by Region
Randomized Treatment Phase
SAF-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
TEAE Leading to Premature Discontinuation of Study Drug					
Number of subjects, n(%)	4 (13.8%)	0	10 (27.0%)	1 (3.1%)	
Unadjusted Relative Risk (95% CI)	2.40 (0.14, 40.10)		8.65 (1.17, 63.94)		
p-value [1]	0.54		0.035		
Unadjusted Odds Ratio (95% CI)	2.65 (0.13, 54.96)		11.48 (1.38, 95.60)		
p-value [1]	0.53		0.024		
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.12, 0.30)		0.24 (0.08, 0.39)		
Adjusted Relative Risk (95% CI) [2]	NE		9.21 (1.24, 68.72)		
p-value [2]	NE		0.030		
Interaction test for Treatment*Region [3]					NE
TEAE Leading to Dose Reduction or Temporary Interruption of Study Drug					
Number of subjects, n(%)	3 (10.3%)	1 (14.3%)	6 (16.2%)	7 (21.9%)	
Unadjusted Relative Risk (95% CI)	0.72 (0.09, 5.96)		0.74 (0.28, 1.98)		
p-value [1]	0.76		0.55		
Unadjusted Odds Ratio (95% CI)	0.69 (0.06, 7.87)		0.69 (0.21, 2.32)		
p-value [1]	0.77		0.55		
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.32, 0.24)		-0.06 (-0.24, 0.13)		
Adjusted Relative Risk (95% CI) [2]	NE		0.81 (0.30, 2.19)		
p-value [2]	NE		0.67		
Interaction test for Treatment*Region [3]					0.98

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-rt-sub-gba.sas V.03.05 Output file: t-aesum-rt-gba-geo.pdf 24AUG2023:16:51

Table 3.0204: TEAEs: Overall Summary by Region
Randomized Treatment Phase
SAF-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
TEAE Leading to Death					
Number of subjects, n(%)	1 (3.4%)	0	3 (8.1%)	4 (12.5%)	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Region [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0207: TEAEs: Overall Summary by Baseline Hemoglobin Level
Randomized Treatment Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
TEAE					
Number of subjects, n(%)	27 (100.0%)	5 (83.3%)	39 (100.0%)	30 (90.9%)	
Unadjusted Relative Risk (95% CI)	1.25 (0.85, 1.85)		1.10 (0.98, 1.24)		
p-value [1]	0.26		0.11		
Unadjusted Odds Ratio (95% CI)	15.00 (0.54, 418.67)		9.07 (0.45, 182.21)		
p-value [1]	0.11		0.15		
Unadjusted Absolute Risk Difference (95% CI)	0.20 (-0.11, 0.50)		0.09 (-0.02, 0.20)		
Adjusted Relative Risk (95% CI) [2]	1.19 (0.85, 1.67)		1.10 (0.99, 1.23)		
p-value [2]	0.31		0.083		
Interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.64
TEAE with Grade >=3					
Number of subjects, n(%)	17 (63.0%)	3 (50.0%)	23 (59.0%)	15 (45.5%)	
Unadjusted Relative Risk (95% CI)	1.26 (0.54, 2.95)		1.30 (0.82, 2.05)		
p-value [1]	0.60		0.26		
Unadjusted Odds Ratio (95% CI)	1.70 (0.29, 10.09)		1.73 (0.68, 4.40)		
p-value [1]	0.56		0.25		
Unadjusted Absolute Risk Difference (95% CI)	0.13 (-0.31, 0.57)		0.14 (-0.09, 0.36)		
Adjusted Relative Risk (95% CI) [2]	1.32 (0.59, 2.95)		1.32 (0.84, 2.08)		
p-value [2]	0.50		0.24		
Interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.95

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0207: TEAEs: Overall Summary by Baseline Hemoglobin Level
Randomized Treatment Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
TEAE with Grade 3 or 4					
Number of subjects, n(%)	16 (59.3%)	3 (50.0%)	23 (59.0%)	15 (45.5%)	
Unadjusted Relative Risk (95% CI)	1.19 (0.50, 2.80)		1.30 (0.82, 2.05)		
p-value [1]	0.70		0.26		
Unadjusted Odds Ratio (95% CI)	1.45 (0.25, 8.58)		1.73 (0.68, 4.40)		
p-value [1]	0.68		0.25		
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.35, 0.53)		0.14 (-0.09, 0.36)		
Adjusted Relative Risk (95% CI) [2]	1.23 (0.54, 2.80)		1.32 (0.84, 2.08)		
p-value [2]	0.62		0.24		
Interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.86
TEAE Related to Study Drug					
Number of subjects, n(%)	19 (70.4%)	0	30 (76.9%)	15 (45.5%)	
Unadjusted Relative Risk (95% CI)	9.75 (0.67, 142.52)		1.69 (1.12, 2.55)		
p-value [1]	0.096		0.012		
Unadjusted Odds Ratio (95% CI)	29.82 (1.50, 591.38)		4.00 (1.45, 11.01)		
p-value [1]	0.026		0.007		
Unadjusted Absolute Risk Difference (95% CI)	0.63 (0.37, 0.88)		0.31 (0.10, 0.53)		
Adjusted Relative Risk (95% CI) [2]	NE		1.74 (1.17, 2.60)		
p-value [2]	NE		0.007		
Interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-rt-sub-gba.sas V.03.05 Output file: t-aesum-rt-gba-hgb.pdf 24AUG2023:16:51

Table 3.0207: TEAEs: Overall Summary by Baseline Hemoglobin Level
Randomized Treatment Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
TEAE Related to Study Drug with Grade >=3					
Number of subjects, n(%)	7 (25.9%)	0	13 (33.3%)	8 (24.2%)	
Unadjusted Relative Risk (95% CI)	3.75 (0.24, 58.10)		1.38 (0.65, 2.91)		
p-value [1]	0.34		0.40		
Unadjusted Odds Ratio (95% CI)	4.76 (0.24, 95.11)		1.56 (0.55, 4.41)		
p-value [1]	0.31		0.40		
Unadjusted Absolute Risk Difference (95% CI)	0.20 (-0.06, 0.45)		0.09 (-0.12, 0.30)		
Adjusted Relative Risk (95% CI) [2]	NE		1.27 (0.60, 2.69)		
p-value [2]	NE		0.53		
Interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE
Serious TEAE					
Number of subjects, n(%)	9 (33.3%)	1 (16.7%)	14 (35.9%)	8 (24.2%)	
Unadjusted Relative Risk (95% CI)	2.00 (0.31, 12.94)		1.48 (0.71, 3.09)		
p-value [1]	0.47		0.29		
Unadjusted Odds Ratio (95% CI)	2.50 (0.25, 24.72)		1.75 (0.62, 4.90)		
p-value [1]	0.43		0.29		
Unadjusted Absolute Risk Difference (95% CI)	0.17 (-0.18, 0.51)		0.12 (-0.09, 0.33)		
Adjusted Relative Risk (95% CI) [2]	1.99 (0.30, 13.09)		1.45 (0.69, 3.02)		
p-value [2]	0.48		0.32		
Interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.75

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0207: TEAEs: Overall Summary by Baseline Hemoglobin Level
Randomized Treatment Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Serious TEAE Related to Study Drug					
Number of subjects, n(%)	2 (7.4%)	0	5 (12.8%)	2 (6.1%)	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA
Non-Fatal SAEs					
Number of subjects, n(%)	9 (33.3%)	1 (16.7%)	14 (35.9%)	7 (21.2%)	
Unadjusted Relative Risk (95% CI)	2.00 (0.31, 12.94)		1.69 (0.78, 3.69)		
p-value [1]	0.47		0.19		
Unadjusted Odds Ratio (95% CI)	2.50 (0.25, 24.72)		2.08 (0.72, 6.01)		
p-value [1]	0.43		0.18		
Unadjusted Absolute Risk Difference (95% CI)	0.17 (-0.18, 0.51)		0.15 (-0.06, 0.35)		
Adjusted Relative Risk (95% CI) [2]	1.99 (0.30, 13.09)		1.69 (0.78, 3.65)		
p-value [2]	0.48		0.18		
Interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.87

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0207: TEAEs: Overall Summary by Baseline Hemoglobin Level
Randomized Treatment Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
TEAE Leading to Premature Discontinuation of Study Drug					
Number of subjects, n(%)	5 (18.5%)	0	9 (23.1%)	1 (3.0%)	
Unadjusted Relative Risk (95% CI)	2.75 (0.17, 44.07)		7.62 (1.02, 57.03)		
p-value [1]	0.47		0.048		
Unadjusted Odds Ratio (95% CI)	3.18 (0.15, 65.37)		9.60 (1.15, 80.40)		
p-value [1]	0.45		0.037		
Unadjusted Absolute Risk Difference (95% CI)	0.13 (-0.12, 0.37)		0.20 (0.06, 0.35)		
Adjusted Relative Risk (95% CI) [2]	NE		7.99 (1.15, 55.48)		
p-value [2]	NE		0.036		
Interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE
TEAE Leading to Dose Reduction or Temporary Interruption of Study Drug					
Number of subjects, n(%)	2 (7.4%)	2 (33.3%)	7 (17.9%)	6 (18.2%)	
Unadjusted Relative Risk (95% CI)	0.22 (0.04, 1.28)		0.99 (0.37, 2.65)		
p-value [1]	0.092		0.98		
Unadjusted Odds Ratio (95% CI)	0.16 (0.02, 1.48)		0.98 (0.30, 3.28)		
p-value [1]	0.11		0.98		
Unadjusted Absolute Risk Difference (95% CI)	-0.26 (-0.65, 0.13)		0.00 (-0.18, 0.18)		
Adjusted Relative Risk (95% CI) [2]	0.23 (0.04, 1.14)		1.02 (0.37, 2.80)		
p-value [2]	0.071		0.97		
Interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.23

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0207: TEAEs: Overall Summary by Baseline Hemoglobin Level
Randomized Treatment Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
TEAE Leading to Death					
Number of subjects, n(%)	4 (14.8%)	1 (16.7%)	0	3 (9.1%)	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0206: TEAEs: Overall Summary by Baseline DIPSS Two-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
TEAE					
Number of subjects, n(%)	49 (100.0%)	28 (90.3%)	17 (100.0%)	7 (87.5%)	
Unadjusted Relative Risk (95% CI)	1.11 (0.98, 1.26)		1.17 (0.86, 1.58)		
p-value [1]	0.096		0.32		
Unadjusted Odds Ratio (95% CI)	12.16 (0.61, 243.92)		7.00 (0.25, 192.27)		
p-value [1]	0.10		0.25		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.01, 0.21)		0.14 (-0.12, 0.39)		
Adjusted Relative Risk (95% CI) [2]	1.09 (0.99, 1.20)		1.13 (0.90, 1.42)		
p-value [2]	0.091		0.31		
Interaction test for Treatment*Baseline DIPSS 2-Level Risk [3]					0.83
TEAE with Grade >=3					
Number of subjects, n(%)	29 (59.2%)	11 (35.5%)	11 (64.7%)	7 (87.5%)	
Unadjusted Relative Risk (95% CI)	1.67 (0.98, 2.83)		0.74 (0.48, 1.15)		
p-value [1]	0.058		0.18		
Unadjusted Odds Ratio (95% CI)	2.64 (1.04, 6.69)		0.26 (0.03, 2.66)		
p-value [1]	0.041		0.26		
Unadjusted Absolute Risk Difference (95% CI)	0.24 (0.02, 0.45)		-0.23 (-0.55, 0.09)		
Adjusted Relative Risk (95% CI) [2]	1.76 (1.04, 2.98)		0.69 (0.45, 1.08)		
p-value [2]	0.036		0.11		
Interaction test for Treatment*Baseline DIPSS 2-Level Risk [3]					0.023

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0206: TEAEs: Overall Summary by Baseline DIPSS Two-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
TEAE with Grade 3 or 4					
Number of subjects, n(%)	29 (59.2%)	11 (35.5%)	10 (58.8%)	7 (87.5%)	
Unadjusted Relative Risk (95% CI)	1.67 (0.98, 2.83)		0.67 (0.42, 1.08)		
p-value [1]	0.058		0.10		
Unadjusted Odds Ratio (95% CI)	2.64 (1.04, 6.69)		0.20 (0.02, 2.05)		
p-value [1]	0.041		0.18		
Unadjusted Absolute Risk Difference (95% CI)	0.24 (0.02, 0.45)		-0.29 (-0.61, 0.04)		
Adjusted Relative Risk (95% CI) [2]	1.76 (1.04, 2.98)		0.62 (0.37, 1.02)		
p-value [2]	0.036		0.062		
Interaction test for Treatment*Baseline DIPSS 2-Level Risk [3]					0.015
TEAE Related to Study Drug					
Number of subjects, n(%)	35 (71.4%)	11 (35.5%)	14 (82.4%)	4 (50.0%)	
Unadjusted Relative Risk (95% CI)	2.01 (1.21, 3.34)		1.65 (0.80, 3.41)		
p-value [1]	0.007		0.18		
Unadjusted Odds Ratio (95% CI)	4.55 (1.74, 11.90)		4.67 (0.72, 30.11)		
p-value [1]	0.002		0.11		
Unadjusted Absolute Risk Difference (95% CI)	0.36 (0.15, 0.57)		0.32 (-0.07, 0.71)		
Adjusted Relative Risk (95% CI) [2]	2.13 (1.29, 3.49)		1.70 (0.82, 3.52)		
p-value [2]	0.003		0.15		
Interaction test for Treatment*Baseline DIPSS 2-Level Risk [3]					0.67

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0206: TEAEs: Overall Summary by Baseline DIPSS Two-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
TEAE Related to Study Drug with Grade >=3					
Number of subjects, n(%)	13 (26.5%)	5 (16.1%)	7 (41.2%)	3 (37.5%)	
Unadjusted Relative Risk (95% CI)	1.64 (0.65, 4.16)		1.10 (0.38, 3.17)		
p-value [1]	0.29		0.86		
Unadjusted Odds Ratio (95% CI)	1.88 (0.60, 5.92)		1.17 (0.21, 6.56)		
p-value [1]	0.28		0.86		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.07, 0.28)		0.04 (-0.37, 0.45)		
Adjusted Relative Risk (95% CI) [2]	1.51 (0.62, 3.66)		1.09 (0.37, 3.24)		
p-value [2]	0.36		0.88		
Interaction test for Treatment*Baseline DIPSS 2-Level Risk [3]					0.58
Serious TEAE					
Number of subjects, n(%)	16 (32.7%)	7 (22.6%)	7 (41.2%)	2 (25.0%)	
Unadjusted Relative Risk (95% CI)	1.45 (0.67, 3.11)		1.65 (0.44, 6.21)		
p-value [1]	0.35		0.46		
Unadjusted Odds Ratio (95% CI)	1.66 (0.59, 4.67)		2.10 (0.32, 13.61)		
p-value [1]	0.33		0.44		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.10, 0.30)		0.16 (-0.22, 0.54)		
Adjusted Relative Risk (95% CI) [2]	1.36 (0.61, 3.03)		NE		
p-value [2]	0.45		NE		
Interaction test for Treatment*Baseline DIPSS 2-Level Risk [3]					0.87

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-rt-sub-gba.sas V.03.05 Output file: t-aesum-rt-gba-ipss2.pdf 24AUG2023:16:51

Table 3.0206: TEAEs: Overall Summary by Baseline DIPSS Two-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Serious TEAE Related to Study Drug					
Number of subjects, n(%)	4 (8.2%)	1 (3.2%)	3 (17.6%)	1 (12.5%)	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Baseline DIPSS 2-Level Risk [3]					NA
Non-Fatal SAEs					
Number of subjects, n(%)	16 (32.7%)	6 (19.4%)	7 (41.2%)	2 (25.0%)	
Unadjusted Relative Risk (95% CI)	1.69 (0.74, 3.84)		1.65 (0.44, 6.21)		
p-value [1]	0.21		0.46		
Unadjusted Odds Ratio (95% CI)	2.02 (0.69, 5.90)		2.10 (0.32, 13.61)		
p-value [1]	0.20		0.44		
Unadjusted Absolute Risk Difference (95% CI)	0.13 (-0.06, 0.32)		0.16 (-0.22, 0.54)		
Adjusted Relative Risk (95% CI) [2]	1.65 (0.71, 3.84)		NE		
p-value [2]	0.24		NE		
Interaction test for Treatment*Baseline DIPSS 2-Level Risk [3]					0.98

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0206: TEAEs: Overall Summary by Baseline DIPSS Two-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
TEAE Leading to Premature Discontinuation of Study Drug					
Number of subjects, n(%)	11 (22.4%)	1 (3.2%)	3 (17.6%)	0	
Unadjusted Relative Risk (95% CI)	6.96 (0.94, 51.27)		3.50 (0.20, 60.70)		
p-value [1]	0.057		0.39		
Unadjusted Odds Ratio (95% CI)	8.68 (1.06, 71.09)		4.10 (0.19, 89.45)		
p-value [1]	0.044		0.37		
Unadjusted Absolute Risk Difference (95% CI)	0.19 (0.06, 0.32)		0.14 (-0.10, 0.38)		
Adjusted Relative Risk (95% CI) [2]	6.82 (0.86, 53.89)		NE		
p-value [2]	0.069		NE		
Interaction test for Treatment*Baseline DIPSS 2-Level Risk [3]					NE
TEAE Leading to Dose Reduction or Temporary Interruption of Study Drug					
Number of subjects, n(%)	5 (10.2%)	7 (22.6%)	4 (23.5%)	1 (12.5%)	
Unadjusted Relative Risk (95% CI)	0.45 (0.16, 1.30)		1.88 (0.25, 14.24)		
p-value [1]	0.14		0.54		
Unadjusted Odds Ratio (95% CI)	0.39 (0.11, 1.36)		2.15 (0.20, 23.18)		
p-value [1]	0.14		0.53		
Unadjusted Absolute Risk Difference (95% CI)	-0.12 (-0.29, 0.05)		0.11 (-0.19, 0.42)		
Adjusted Relative Risk (95% CI) [2]	0.50 (0.16, 1.59)		1.56 (0.19, 12.99)		
p-value [2]	0.24		0.68		
Interaction test for Treatment*Baseline DIPSS 2-Level Risk [3]					0.18

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-rt-sub-gba.sas V.03.05 Output file: t-aesum-rt-gba-ipss2.pdf 24AUG2023:16:51

Table 3.0206: TEAEs: Overall Summary by Baseline DIPSS Two-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
TEAE Leading to Death					
Number of subjects, n(%)	2 (4.1%)	4 (12.9%)	2 (11.8%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Baseline DIPSS 2-Level Risk [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0205: TEAEs: Overall Summary by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
TEAE				
Number of subjects, n(%)	5 (100.0%)	6 (85.7%)	44 (100.0%)	22 (91.7%)
Unadjusted Relative Risk (95% CI)	1.13 (0.75, 1.70)		1.10 (0.96, 1.26)	
p-value [1]	0.57		0.17	
Unadjusted Odds Ratio (95% CI)	2.54 (0.09, 75.77)		9.89 (0.46, 214.83)	
p-value [1]	0.59		0.14	
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.25, 0.45)		0.09 (-0.03, 0.21)	
Adjusted Relative Risk (95% CI) [2]	1.00 (1.00, 1.00)		1.05 (0.98, 1.14)	
p-value [2]	>0.99		0.17	
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]				
TEAE with Grade >=3				
Number of subjects, n(%)	2 (40.0%)	1 (14.3%)	27 (61.4%)	10 (41.7%)
Unadjusted Relative Risk (95% CI)	2.80 (0.34, 23.06)		1.47 (0.87, 2.50)	
p-value [1]	0.34		0.15	
Unadjusted Odds Ratio (95% CI)	4.00 (0.25, 63.95)		2.22 (0.81, 6.13)	
p-value [1]	0.33		0.12	
Unadjusted Absolute Risk Difference (95% CI)	0.26 (-0.24, 0.76)		0.20 (-0.05, 0.44)	
Adjusted Relative Risk (95% CI) [2]	NE		1.59 (0.94, 2.71)	
p-value [2]	NE		0.086	
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0205: TEAEs: Overall Summary by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=17)	BAT (N=8)	p-value
TEAE			
Number of subjects, n(%)	17 (100.0%)	7 (87.5%)	
Unadjusted Relative Risk (95% CI)	1.17 (0.86, 1.58)		
p-value [1]	0.32		
Unadjusted Odds Ratio (95% CI)	7.00 (0.25, 192.27)		
p-value [1]	0.25		
Unadjusted Absolute Risk Difference (95% CI)	0.14 (-0.12, 0.39)		
Adjusted Relative Risk (95% CI) [2]	1.13 (0.90, 1.42)		
p-value [2]	0.31		
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]			0.89
TEAE with Grade >=3			
Number of subjects, n(%)	11 (64.7%)	7 (87.5%)	
Unadjusted Relative Risk (95% CI)	0.74 (0.48, 1.15)		
p-value [1]	0.18		
Unadjusted Odds Ratio (95% CI)	0.26 (0.03, 2.66)		
p-value [1]	0.26		
Unadjusted Absolute Risk Difference (95% CI)	-0.23 (-0.55, 0.09)		
Adjusted Relative Risk (95% CI) [2]	0.69 (0.45, 1.08)		
p-value [2]	0.11		
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]			0.097

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0205: TEAEs: Overall Summary by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
TEAE with Grade 3 or 4				
Number of subjects, n(%)	2 (40.0%)	1 (14.3%)	27 (61.4%)	10 (41.7%)
Unadjusted Relative Risk (95% CI)	2.80 (0.34, 23.06)		1.47 (0.87, 2.50)	
p-value [1]	0.34		0.15	
Unadjusted Odds Ratio (95% CI)	4.00 (0.25, 63.95)		2.22 (0.81, 6.13)	
p-value [1]	0.33		0.12	
Unadjusted Absolute Risk Difference (95% CI)	0.26 (-0.24, 0.76)		0.20 (-0.05, 0.44)	
Adjusted Relative Risk (95% CI) [2]	NE		1.59 (0.94, 2.71)	
p-value [2]	NE		0.086	
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]				
TEAE Related to Study Drug				
Number of subjects, n(%)	1 (20.0%)	2 (28.6%)	34 (77.3%)	9 (37.5%)
Unadjusted Relative Risk (95% CI)	0.70 (0.09, 5.76)		2.06 (1.20, 3.54)	
p-value [1]	0.74		0.009	
Unadjusted Odds Ratio (95% CI)	0.63 (0.04, 9.65)		5.67 (1.91, 16.79)	
p-value [1]	0.74		0.002	
Unadjusted Absolute Risk Difference (95% CI)	-0.09 (-0.57, 0.40)		0.40 (0.17, 0.63)	
Adjusted Relative Risk (95% CI) [2]	NE		2.13 (1.21, 3.75)	
p-value [2]	NE		0.009	
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0205: TEAEs: Overall Summary by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=17)	BAT (N=8)	p-value
TEAE with Grade 3 or 4			
Number of subjects, n(%)	10 (58.8%)	7 (87.5%)	
Unadjusted Relative Risk (95% CI)	0.67 (0.42, 1.08)		
p-value [1]	0.10		
Unadjusted Odds Ratio (95% CI)	0.20 (0.02, 2.05)		
p-value [1]	0.18		
Unadjusted Absolute Risk Difference (95% CI)	-0.29 (-0.61, 0.04)		
Adjusted Relative Risk (95% CI) [2]	0.62 (0.37, 1.02)		
p-value [2]	0.062		
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]			0.066
TEAE Related to Study Drug			
Number of subjects, n(%)	14 (82.4%)	4 (50.0%)	
Unadjusted Relative Risk (95% CI)	1.65 (0.80, 3.41)		
p-value [1]	0.18		
Unadjusted Odds Ratio (95% CI)	4.67 (0.72, 30.11)		
p-value [1]	0.11		
Unadjusted Absolute Risk Difference (95% CI)	0.32 (-0.07, 0.71)		
Adjusted Relative Risk (95% CI) [2]	1.70 (0.82, 3.52)		
p-value [2]	0.15		
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]			0.60

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0205: TEAEs: Overall Summary by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
TEAE Related to Study Drug with Grade >=3				
Number of subjects, n(%)	0	0	13 (29.5%)	5 (20.8%)
Unadjusted Relative Risk (95% CI)	NE		1.42 (0.57, 3.50)	
p-value [1]	NE		0.45	
Unadjusted Odds Ratio (95% CI)	NE		1.59 (0.49, 5.18)	
p-value [1]	NE		0.44	
Unadjusted Absolute Risk Difference (95% CI)	NE		0.09 (-0.12, 0.30)	
Adjusted Relative Risk (95% CI) [2]	NE		1.28 (0.51, 3.20)	
p-value [2]	NE		0.60	
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]				
Serious TEAE				
Number of subjects, n(%)	2 (40.0%)	1 (14.3%)	14 (31.8%)	6 (25.0%)
Unadjusted Relative Risk (95% CI)	2.80 (0.34, 23.06)		1.27 (0.56, 2.88)	
p-value [1]	0.34		0.56	
Unadjusted Odds Ratio (95% CI)	4.00 (0.25, 63.95)		1.40 (0.46, 4.29)	
p-value [1]	0.33		0.56	
Unadjusted Absolute Risk Difference (95% CI)	0.26 (-0.24, 0.76)		0.07 (-0.15, 0.29)	
Adjusted Relative Risk (95% CI) [2]	NE		1.25 (0.50, 3.10)	
p-value [2]	NE		0.63	
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0205: TEAEs: Overall Summary by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=17)	BAT (N=8)	p-value
TEAE Related to Study Drug with Grade >=3			
Number of subjects, n(%)	7 (41.2%)	3 (37.5%)	
Unadjusted Relative Risk (95% CI)	1.10 (0.38, 3.17)		
p-value [1]	0.86		
Unadjusted Odds Ratio (95% CI)	1.17 (0.21, 6.56)		
p-value [1]	0.86		
Unadjusted Absolute Risk Difference (95% CI)	0.04 (-0.37, 0.45)		
Adjusted Relative Risk (95% CI) [2]	1.09 (0.37, 3.24)		
p-value [2]	0.88		
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]			NE
Serious TEAE			
Number of subjects, n(%)	7 (41.2%)	2 (25.0%)	
Unadjusted Relative Risk (95% CI)	1.65 (0.44, 6.21)		
p-value [1]	0.46		
Unadjusted Odds Ratio (95% CI)	2.10 (0.32, 13.61)		
p-value [1]	0.44		
Unadjusted Absolute Risk Difference (95% CI)	0.16 (-0.22, 0.54)		
Adjusted Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]			0.76

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0205: TEAEs: Overall Summary by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Serious TEAE Related to Study Drug				
Number of subjects, n(%)	0	0	4 (9.1%)	1 (4.2%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]				
Non-Fatal SAEs				
Number of subjects, n(%)	2 (40.0%)	1 (14.3%)	14 (31.8%)	5 (20.8%)
Unadjusted Relative Risk (95% CI)	2.80 (0.34, 23.06)		1.53 (0.63, 3.73)	
p-value [1]	0.34		0.35	
Unadjusted Odds Ratio (95% CI)	4.00 (0.25, 63.95)		1.77 (0.55, 5.72)	
p-value [1]	0.33		0.34	
Unadjusted Absolute Risk Difference (95% CI)	0.26 (-0.24, 0.76)		0.11 (-0.10, 0.32)	
Adjusted Relative Risk (95% CI) [2]	NE		1.62 (0.62, 4.21)	
p-value [2]	NE		0.32	
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0205: TEAEs: Overall Summary by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=17)	BAT (N=8)	p-value
Serious TEAE Related to Study Drug			
Number of subjects, n(%)	3 (17.6%)	1 (12.5%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]			NA
Non-Fatal SAEs			
Number of subjects, n(%)	7 (41.2%)	2 (25.0%)	
Unadjusted Relative Risk (95% CI)	1.65 (0.44, 6.21)		
p-value [1]	0.46		
Unadjusted Odds Ratio (95% CI)	2.10 (0.32, 13.61)		
p-value [1]	0.44		
Unadjusted Absolute Risk Difference (95% CI)	0.16 (-0.22, 0.54)		
Adjusted Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]			0.86

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0205: TEAEs: Overall Summary by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
TEAE Leading to Premature Discontinuation of Study Drug				
Number of subjects, n(%)	1 (20.0%)	0	10 (22.7%)	1 (4.2%)
Unadjusted Relative Risk (95% CI)	4.00 (0.20, 82.01)		5.45 (0.74, 40.09)	
p-value [1]	0.37		0.096	
Unadjusted Odds Ratio (95% CI)	5.00 (0.17, 150.93)		6.76 (0.81, 56.51)	
p-value [1]	0.35		0.078	
Unadjusted Absolute Risk Difference (95% CI)	0.19 (-0.20, 0.57)		0.19 (0.04, 0.33)	
Adjusted Relative Risk (95% CI) [2]	NE		5.64 (0.55, 57.64)	
p-value [2]	NE		0.14	
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]				
TEAE Leading to Dose Reduction or Temporary Interruption of Study Drug				
Number of subjects, n(%)	1 (20.0%)	1 (14.3%)	4 (9.1%)	6 (25.0%)
Unadjusted Relative Risk (95% CI)	1.40 (0.11, 17.45)		0.36 (0.11, 1.16)	
p-value [1]	0.79		0.088	
Unadjusted Odds Ratio (95% CI)	1.50 (0.07, 31.58)		0.30 (0.08, 1.19)	
p-value [1]	0.79		0.088	
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.38, 0.49)		-0.16 (-0.35, 0.03)	
Adjusted Relative Risk (95% CI) [2]	NE		0.46 (0.10, 2.14)	
p-value [2]	NE		0.32	
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0205: TEAEs: Overall Summary by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=17)	BAT (N=8)	p-value
TEAE Leading to Premature Discontinuation of Study Drug			
Number of subjects, n(%)	3 (17.6%)	0	
Unadjusted Relative Risk (95% CI)	3.50 (0.20, 60.70)		
p-value [1]	0.39		
Unadjusted Odds Ratio (95% CI)	4.10 (0.19, 89.45)		
p-value [1]	0.37		
Unadjusted Absolute Risk Difference (95% CI)	0.14 (-0.10, 0.38)		
Adjusted Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]			NE
TEAE Leading to Dose Reduction or Temporary Interruption of Study Drug			
Number of subjects, n(%)	4 (23.5%)	1 (12.5%)	
Unadjusted Relative Risk (95% CI)	1.88 (0.25, 14.24)		
p-value [1]	0.54		
Unadjusted Odds Ratio (95% CI)	2.15 (0.20, 23.18)		
p-value [1]	0.53		
Unadjusted Absolute Risk Difference (95% CI)	0.11 (-0.19, 0.42)		
Adjusted Relative Risk (95% CI) [2]	1.56 (0.19, 12.99)		
p-value [2]	0.68		
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]			0.27

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0205: TEAEs: Overall Summary by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
TEAE Leading to Death				
Number of subjects, n(%)	1 (20.0%)	1 (14.3%)	1 (2.3%)	3 (12.5%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0205: TEAEs: Overall Summary by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=17)	BAT (N=8)	p-value
TEAE Leading to Death			
Number of subjects, n(%)	2 (11.8%)	0	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0208: TEAEs: Overall Summary by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
TEAE				
Number of subjects, n(%)	45 (100.0%)	22 (95.7%)	13 (100.0%)	6 (75.0%)
Unadjusted Relative Risk (95% CI)	1.06 (0.95, 1.17)		1.34 (0.88, 2.03)	
p-value [1]	0.33		0.17	
Unadjusted Odds Ratio (95% CI)	6.07 (0.24, 154.95)		10.38 (0.43, 249.05)	
p-value [1]	0.28		0.15	
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.05, 0.15)		0.24 (-0.07, 0.55)	
Adjusted Relative Risk (95% CI) [2]	1.04 (0.96, 1.13)		1.31 (0.88, 1.95)	
p-value [2]	0.31		0.19	
Interaction test for Treatment*Myelofibrosis Disease Type [3]				
TEAE with Grade >=3				
Number of subjects, n(%)	25 (55.6%)	12 (52.2%)	9 (69.2%)	2 (25.0%)
Unadjusted Relative Risk (95% CI)	1.06 (0.67, 1.70)		2.77 (0.79, 9.70)	
p-value [1]	0.79		0.11	
Unadjusted Odds Ratio (95% CI)	1.15 (0.42, 3.14)		6.75 (0.93, 49.23)	
p-value [1]	0.79		0.060	
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.22, 0.28)		0.44 (0.05, 0.83)	
Adjusted Relative Risk (95% CI) [2]	1.07 (0.67, 1.72)		NE	
p-value [2]	0.78		NE	
Interaction test for Treatment*Myelofibrosis Disease Type [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-rt-sub-gba.sas V.03.05 Output file: t-aesum-rt-gba-mf.pdf 24AUG2023:16:51

Table 3.0208: TEAEs: Overall Summary by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=8)	BAT (N=8)	p-value
TEAE			
Number of subjects, n(%)	8 (100.0%)	7 (87.5%)	
Unadjusted Relative Risk (95% CI)	1.13 (0.81, 1.58)		
p-value [1]	0.46		
Unadjusted Odds Ratio (95% CI)	3.40 (0.12, 96.71)		
p-value [1]	0.47		
Unadjusted Absolute Risk Difference (95% CI)	0.11 (-0.17, 0.40)		
Adjusted Relative Risk (95% CI) [2]	1.00 (1.00, 1.00)		
p-value [2]	>0.99		
Interaction test for Treatment*Myelofibrosis Disease Type [3]			0.40
TEAE with Grade >=3			
Number of subjects, n(%)	6 (75.0%)	4 (50.0%)	
Unadjusted Relative Risk (95% CI)	1.50 (0.67, 3.34)		
p-value [1]	0.32		
Unadjusted Odds Ratio (95% CI)	3.00 (0.36, 24.92)		
p-value [1]	0.31		
Unadjusted Absolute Risk Difference (95% CI)	0.25 (-0.21, 0.71)		
Adjusted Relative Risk (95% CI) [2]	2.09 (0.87, 5.05)		
p-value [2]	0.10		
Interaction test for Treatment*Myelofibrosis Disease Type [3]			0.25

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0208: TEAEs: Overall Summary by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
TEAE with Grade 3 or 4				
Number of subjects, n(%)	25 (55.6%)	12 (52.2%)	8 (61.5%)	2 (25.0%)
Unadjusted Relative Risk (95% CI)	1.06 (0.67, 1.70)		2.46 (0.69, 8.81)	
p-value [1]	0.79		0.17	
Unadjusted Odds Ratio (95% CI)	1.15 (0.42, 3.14)		4.80 (0.68, 33.80)	
p-value [1]	0.79		0.12	
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.22, 0.28)		0.37 (-0.03, 0.77)	
Adjusted Relative Risk (95% CI) [2]	1.07 (0.67, 1.72)		NE	
p-value [2]	0.78		NE	
Interaction test for Treatment*Myelofibrosis Disease Type [3]				
TEAE Related to Study Drug				
Number of subjects, n(%)	32 (71.1%)	9 (39.1%)	10 (76.9%)	3 (37.5%)
Unadjusted Relative Risk (95% CI)	1.82 (1.06, 3.13)		2.05 (0.80, 5.27)	
p-value [1]	0.031		0.14	
Unadjusted Odds Ratio (95% CI)	3.83 (1.33, 11.02)		5.56 (0.81, 38.16)	
p-value [1]	0.013		0.081	
Unadjusted Absolute Risk Difference (95% CI)	0.32 (0.08, 0.56)		0.39 (-0.01, 0.80)	
Adjusted Relative Risk (95% CI) [2]	1.82 (1.05, 3.13)		2.15 (0.92, 5.06)	
p-value [2]	0.031		0.079	
Interaction test for Treatment*Myelofibrosis Disease Type [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0208: TEAEs: Overall Summary by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=8)	BAT (N=8)	p-value
TEAE with Grade 3 or 4			
Number of subjects, n(%)	6 (75.0%)	4 (50.0%)	
Unadjusted Relative Risk (95% CI)	1.50 (0.67, 3.34)		
p-value [1]	0.32		
Unadjusted Odds Ratio (95% CI)	3.00 (0.36, 24.92)		
p-value [1]	0.31		
Unadjusted Absolute Risk Difference (95% CI)	0.25 (-0.21, 0.71)		
Adjusted Relative Risk (95% CI) [2]	2.09 (0.87, 5.05)		
p-value [2]	0.10		
Interaction test for Treatment*Myelofibrosis Disease Type [3]			0.35
TEAE Related to Study Drug			
Number of subjects, n(%)	7 (87.5%)	3 (37.5%)	
Unadjusted Relative Risk (95% CI)	2.33 (0.92, 5.93)		
p-value [1]	0.075		
Unadjusted Odds Ratio (95% CI)	11.67 (0.92, 147.57)		
p-value [1]	0.058		
Unadjusted Absolute Risk Difference (95% CI)	0.50 (0.09, 0.91)		
Adjusted Relative Risk (95% CI) [2]	4.49 (0.86, 23.38)		
p-value [2]	0.074		
Interaction test for Treatment*Myelofibrosis Disease Type [3]			0.89

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0208: TEAEs: Overall Summary by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
TEAE Related to Study Drug with Grade >=3				
Number of subjects, n(%)	11 (24.4%)	5 (21.7%)	6 (46.2%)	2 (25.0%)
Unadjusted Relative Risk (95% CI)	1.12 (0.44, 2.85)		1.85 (0.49, 7.02)	
p-value [1]	0.80		0.37	
Unadjusted Odds Ratio (95% CI)	1.16 (0.35, 3.87)		2.57 (0.37, 17.83)	
p-value [1]	0.80		0.34	
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.18, 0.24)		0.21 (-0.19, 0.62)	
Adjusted Relative Risk (95% CI) [2]	1.09 (0.43, 2.79)		NE	
p-value [2]	0.85		NE	
Interaction test for Treatment*Myelofibrosis Disease Type [3]				
Serious TEAE				
Number of subjects, n(%)	17 (37.8%)	7 (30.4%)	3 (23.1%)	1 (12.5%)
Unadjusted Relative Risk (95% CI)	1.24 (0.60, 2.56)		1.85 (0.23, 14.85)	
p-value [1]	0.56		0.56	
Unadjusted Odds Ratio (95% CI)	1.39 (0.47, 4.06)		2.10 (0.18, 24.60)	
p-value [1]	0.55		0.55	
Unadjusted Absolute Risk Difference (95% CI)	0.07 (-0.16, 0.31)		0.11 (-0.22, 0.43)	
Adjusted Relative Risk (95% CI) [2]	1.16 (0.57, 2.38)		NE	
p-value [2]	0.68		NE	
Interaction test for Treatment*Myelofibrosis Disease Type [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0208: TEAEs: Overall Summary by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=8)	BAT (N=8)	p-value
TEAE Related to Study Drug with Grade >=3			
Number of subjects, n(%)	3 (37.5%)	1 (12.5%)	
Unadjusted Relative Risk (95% CI)	3.00 (0.39, 23.07)		
p-value [1]	0.29		
Unadjusted Odds Ratio (95% CI)	4.20 (0.33, 53.13)		
p-value [1]	0.27		
Unadjusted Absolute Risk Difference (95% CI)	0.25 (-0.16, 0.66)		
Adjusted Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Interaction test for Treatment*Myelofibrosis Disease Type [3]			0.62
Serious TEAE			
Number of subjects, n(%)	3 (37.5%)	1 (12.5%)	
Unadjusted Relative Risk (95% CI)	3.00 (0.39, 23.07)		
p-value [1]	0.29		
Unadjusted Odds Ratio (95% CI)	4.20 (0.33, 53.13)		
p-value [1]	0.27		
Unadjusted Absolute Risk Difference (95% CI)	0.25 (-0.16, 0.66)		
Adjusted Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Interaction test for Treatment*Myelofibrosis Disease Type [3]			0.66

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0208: TEAEs: Overall Summary by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
Serious TEAE Related to Study Drug				
Number of subjects, n(%)	5 (11.1%)	1 (4.3%)	2 (15.4%)	0
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Interaction test for Treatment*Myelofibrosis Disease Type [3]				
Non-Fatal SAEs				
Number of subjects, n(%)	17 (37.8%)	6 (26.1%)	3 (23.1%)	1 (12.5%)
Unadjusted Relative Risk (95% CI)	1.45 (0.66, 3.17)		1.85 (0.23, 14.85)	
p-value [1]	0.35		0.56	
Unadjusted Odds Ratio (95% CI)	1.72 (0.57, 5.21)		2.10 (0.18, 24.60)	
p-value [1]	0.34		0.55	
Unadjusted Absolute Risk Difference (95% CI)	0.12 (-0.11, 0.35)		0.11 (-0.22, 0.43)	
Adjusted Relative Risk (95% CI) [2]	1.37 (0.63, 2.99)		NE	
p-value [2]	0.43		NE	
Interaction test for Treatment*Myelofibrosis Disease Type [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0208: TEAEs: Overall Summary by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=8)	BAT (N=8)	p-value
Serious TEAE Related to Study Drug			
Number of subjects, n(%)	0	1 (12.5%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
Non-Fatal SAEs			
Number of subjects, n(%)	3 (37.5%)	1 (12.5%)	
Unadjusted Relative Risk (95% CI)	3.00 (0.39, 23.07)		
p-value [1]	0.29		
Unadjusted Odds Ratio (95% CI)	4.20 (0.33, 53.13)		
p-value [1]	0.27		
Unadjusted Absolute Risk Difference (95% CI)	0.25 (-0.16, 0.66)		
Adjusted Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Interaction test for Treatment*Myelofibrosis Disease Type [3]			0.77

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0208: TEAEs: Overall Summary by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
TEAE Leading to Premature Discontinuation of Study Drug				
Number of subjects, n(%)	9 (20.0%)	0	3 (23.1%)	1 (12.5%)
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Interaction test for Treatment*Myelofibrosis Disease Type [3]				
TEAE Leading to Dose Reduction or Temporary Interruption of Study Drug				
Number of subjects, n(%)	6 (13.3%)	5 (21.7%)	2 (15.4%)	1 (12.5%)
Unadjusted Relative Risk (95% CI)	0.61 (0.21, 1.80)		1.23 (0.13, 11.48)	
p-value [1]	0.37		0.86	
Unadjusted Odds Ratio (95% CI)	0.55 (0.15, 2.06)		1.27 (0.10, 16.81)	
p-value [1]	0.38		0.85	
Unadjusted Absolute Risk Difference (95% CI)	-0.08 (-0.28, 0.11)		0.03 (-0.27, 0.33)	
Adjusted Relative Risk (95% CI) [2]	0.65 (0.23, 1.88)		NE	
p-value [2]	0.43		NE	
Interaction test for Treatment*Myelofibrosis Disease Type [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0208: TEAEs: Overall Summary by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=8)	BAT (N=8)	p-value
TEAE Leading to Premature Discontinuation of Study Drug			
Number of subjects, n(%)	2 (25.0%)	0	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Interaction test for Treatment*Myelofibrosis Disease Type [3]			NA
TEAE Leading to Dose Reduction or Temporary Interruption of Study Drug			
Number of subjects, n(%)	1 (12.5%)	2 (25.0%)	
Unadjusted Relative Risk (95% CI)	0.50 (0.06, 4.47)		
p-value [1]	0.54		
Unadjusted Odds Ratio (95% CI)	0.43 (0.03, 5.99)		
p-value [1]	0.53		
Unadjusted Absolute Risk Difference (95% CI)	-0.13 (-0.50, 0.25)		
Adjusted Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Interaction test for Treatment*Myelofibrosis Disease Type [3]			0.82

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0208: TEAEs: Overall Summary by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
TEAE Leading to Death				
Number of subjects, n(%)	2 (4.4%)	3 (13.0%)	2 (15.4%)	0
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Interaction test for Treatment*Myelofibrosis Disease Type [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0208: TEAEs: Overall Summary by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=8)	BAT (N=8)	p-value
TEAE Leading to Death			
Number of subjects, n(%)	0	1 (12.5%)	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Interaction test for Treatment*Myelofibrosis Disease Type [3]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0203: TEAEs: Overall Summary by Gender
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
TEAE					
Number of subjects, n(%)	52 (100.0%)	16 (88.9%)	14 (100.0%)	19 (90.5%)	
Unadjusted Relative Risk (95% CI)	1.14 (0.96, 1.36)		1.09 (0.91, 1.30)		
p-value [1]	0.15		0.34		
Unadjusted Odds Ratio (95% CI)	15.91 (0.73, 348.38)		3.72 (0.17, 83.49)		
p-value [1]	0.079		0.41		
Unadjusted Absolute Risk Difference (95% CI)	0.12 (-0.03, 0.28)		0.08 (-0.08, 0.24)		
Adjusted Relative Risk (95% CI) [2]	1.13 (0.96, 1.33)		1.03 (0.97, 1.09)		
p-value [2]	0.15		0.40		
Interaction test for Treatment*Gender [3]					0.87
TEAE with Grade >=3					
Number of subjects, n(%)	33 (63.5%)	10 (55.6%)	7 (50.0%)	8 (38.1%)	
Unadjusted Relative Risk (95% CI)	1.14 (0.72, 1.81)		1.31 (0.62, 2.80)		
p-value [1]	0.57		0.48		
Unadjusted Odds Ratio (95% CI)	1.39 (0.47, 4.12)		1.63 (0.41, 6.39)		
p-value [1]	0.55		0.49		
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.19, 0.34)		0.12 (-0.22, 0.45)		
Adjusted Relative Risk (95% CI) [2]	1.15 (0.73, 1.81)		1.41 (0.68, 2.92)		
p-value [2]	0.56		0.36		
Interaction test for Treatment*Gender [3]					0.76

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0203: TEAEs: Overall Summary by Gender
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
TEAE with Grade 3 or 4					
Number of subjects, n(%)	33 (63.5%)	10 (55.6%)	6 (42.9%)	8 (38.1%)	
Unadjusted Relative Risk (95% CI)	1.14 (0.72, 1.81)		1.13 (0.50, 2.54)		
p-value [1]	0.57		0.78		
Unadjusted Odds Ratio (95% CI)	1.39 (0.47, 4.12)		1.22 (0.31, 4.83)		
p-value [1]	0.55		0.78		
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.19, 0.34)		0.05 (-0.28, 0.38)		
Adjusted Relative Risk (95% CI) [2]	1.15 (0.73, 1.81)		1.18 (0.52, 2.66)		
p-value [2]	0.56		0.70		
Interaction test for Treatment*Gender [3]					0.97
TEAE Related to Study Drug					
Number of subjects, n(%)	37 (71.2%)	7 (38.9%)	12 (85.7%)	8 (38.1%)	
Unadjusted Relative Risk (95% CI)	1.83 (1.00, 3.35)		2.25 (1.25, 4.04)		
p-value [1]	0.050		0.007		
Unadjusted Odds Ratio (95% CI)	3.88 (1.26, 11.90)		9.75 (1.72, 55.37)		
p-value [1]	0.018		0.010		
Unadjusted Absolute Risk Difference (95% CI)	0.32 (0.07, 0.58)		0.48 (0.20, 0.75)		
Adjusted Relative Risk (95% CI) [2]	1.81 (1.00, 3.30)		2.26 (1.11, 4.62)		
p-value [2]	0.052		0.025		
Interaction test for Treatment*Gender [3]					0.63

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0203: TEAEs: Overall Summary by Gender
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
TEAE Related to Study Drug with Grade >=3					
Number of subjects, n(%)	17 (32.7%)	5 (27.8%)	3 (21.4%)	3 (14.3%)	
Unadjusted Relative Risk (95% CI)	1.18 (0.51, 2.73)		1.50 (0.35, 6.40)		
p-value [1]	0.70		0.58		
Unadjusted Odds Ratio (95% CI)	1.26 (0.39, 4.12)		1.64 (0.28, 9.58)		
p-value [1]	0.70		0.58		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.19, 0.29)		0.07 (-0.19, 0.33)		
Adjusted Relative Risk (95% CI) [2]	1.18 (0.51, 2.74)		NE		
p-value [2]	0.70		NE		
Interaction test for Treatment*Gender [3]					0.78
Serious TEAE					
Number of subjects, n(%)	18 (34.6%)	6 (33.3%)	5 (35.7%)	3 (14.3%)	
Unadjusted Relative Risk (95% CI)	1.04 (0.49, 2.20)		2.50 (0.71, 8.83)		
p-value [1]	0.92		0.15		
Unadjusted Odds Ratio (95% CI)	1.06 (0.34, 3.29)		3.33 (0.65, 17.18)		
p-value [1]	0.92		0.15		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.24, 0.27)		0.21 (-0.08, 0.51)		
Adjusted Relative Risk (95% CI) [2]	1.01 (0.48, 2.14)		NE		
p-value [2]	0.97		NE		
Interaction test for Treatment*Gender [3]					0.24

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0203: TEAEs: Overall Summary by Gender
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Serious TEAE Related to Study Drug					
Number of subjects, n(%)	7 (13.5%)	0	0	2 (9.5%)	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Gender [3]					NA
Non-Fatal SAEs					
Number of subjects, n(%)	18 (34.6%)	5 (27.8%)	5 (35.7%)	3 (14.3%)	
Unadjusted Relative Risk (95% CI)	1.25 (0.54, 2.87)		2.50 (0.71, 8.83)		
p-value [1]	0.60		0.15		
Unadjusted Odds Ratio (95% CI)	1.38 (0.42, 4.48)		3.33 (0.65, 17.18)		
p-value [1]	0.60		0.15		
Unadjusted Absolute Risk Difference (95% CI)	0.07 (-0.18, 0.31)		0.21 (-0.08, 0.51)		
Adjusted Relative Risk (95% CI) [2]	1.22 (0.53, 2.78)		NE		
p-value [2]	0.64		NE		
Interaction test for Treatment*Gender [3]					0.37

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0203: TEAEs: Overall Summary by Gender
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
TEAE Leading to Premature Discontinuation of Study Drug					
Number of subjects, n(%)	11 (21.2%)	0	3 (21.4%)	1 (4.8%)	
Unadjusted Relative Risk (95% CI)	8.25 (0.51, 133.25)		4.50 (0.52, 39.01)		
p-value [1]	0.14		0.17		
Unadjusted Odds Ratio (95% CI)	10.25 (0.57, 183.38)		5.45 (0.50, 58.92)		
p-value [1]	0.11		0.16		
Unadjusted Absolute Risk Difference (95% CI)	0.19 (0.06, 0.32)		0.17 (-0.07, 0.40)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Interaction test for Treatment*Gender [3]					NE
TEAE Leading to Dose Reduction or Temporary Interruption of Study Drug					
Number of subjects, n(%)	8 (15.4%)	4 (22.2%)	1 (7.1%)	4 (19.0%)	
Unadjusted Relative Risk (95% CI)	0.69 (0.24, 2.03)		0.38 (0.05, 3.01)		
p-value [1]	0.50		0.36		
Unadjusted Odds Ratio (95% CI)	0.64 (0.17, 2.44)		0.33 (0.03, 3.28)		
p-value [1]	0.51		0.34		
Unadjusted Absolute Risk Difference (95% CI)	-0.07 (-0.28, 0.15)		-0.12 (-0.33, 0.10)		
Adjusted Relative Risk (95% CI) [2]	0.71 (0.25, 2.06)		NE		
p-value [2]	0.53		NE		
Interaction test for Treatment*Gender [3]					0.57

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0203: TEAEs: Overall Summary by Gender
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
TEAE Leading to Death					
Number of subjects, n(%)	3 (5.8%)	3 (16.7%)	1 (7.1%)	1 (4.8%)	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Gender [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0210: TEAEs: Overall Summary by Baseline Spleen Volume
Randomized Treatment Phase
SAF-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
TEAE					
Number of subjects, n(%)	28 (100.0%)	22 (91.7%)	38 (100.0%)	13 (86.7%)	
Unadjusted Relative Risk (95% CI)	1.09 (0.95, 1.26)		1.17 (0.94, 1.45)		
p-value [1]	0.22		0.15		
Unadjusted Odds Ratio (95% CI)	6.33 (0.29, 138.68)		14.26 (0.64, 316.23)		
p-value [1]	0.24		0.093		
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.04, 0.21)		0.14 (-0.04, 0.32)		
Adjusted Relative Risk (95% CI) [2]	1.08 (0.97, 1.21)		1.13 (0.94, 1.35)		
p-value [2]	0.17		0.19		
Interaction test for Treatment*Baseline Spleen Volume Group [3]					0.63
TEAE with Grade >=3					
Number of subjects, n(%)	16 (57.1%)	10 (41.7%)	24 (63.2%)	8 (53.3%)	
Unadjusted Relative Risk (95% CI)	1.37 (0.77, 2.43)		1.18 (0.70, 2.02)		
p-value [1]	0.28		0.53		
Unadjusted Odds Ratio (95% CI)	1.87 (0.62, 5.63)		1.50 (0.45, 5.03)		
p-value [1]	0.27		0.51		
Unadjusted Absolute Risk Difference (95% CI)	0.15 (-0.11, 0.42)		0.10 (-0.20, 0.39)		
Adjusted Relative Risk (95% CI) [2]	1.50 (0.85, 2.64)		1.12 (0.64, 1.94)		
p-value [2]	0.16		0.69		
Interaction test for Treatment*Baseline Spleen Volume Group [3]					0.71

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0210: TEAEs: Overall Summary by Baseline Spleen Volume
Randomized Treatment Phase
SAF-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
TEAE with Grade 3 or 4					
Number of subjects, n(%)	16 (57.1%)	10 (41.7%)	23 (60.5%)	8 (53.3%)	
Unadjusted Relative Risk (95% CI)	1.37 (0.77, 2.43)		1.13 (0.66, 1.94)		
p-value [1]	0.28		0.65		
Unadjusted Odds Ratio (95% CI)	1.87 (0.62, 5.63)		1.34 (0.40, 4.48)		
p-value [1]	0.27		0.63		
Unadjusted Absolute Risk Difference (95% CI)	0.15 (-0.11, 0.42)		0.07 (-0.22, 0.37)		
Adjusted Relative Risk (95% CI) [2]	1.50 (0.85, 2.64)		1.06 (0.60, 1.86)		
p-value [2]	0.16		0.84		
Interaction test for Treatment*Baseline Spleen Volume Group [3]					0.64
TEAE Related to Study Drug					
Number of subjects, n(%)	24 (85.7%)	10 (41.7%)	25 (65.8%)	5 (33.3%)	
Unadjusted Relative Risk (95% CI)	2.06 (1.25, 3.38)		1.97 (0.93, 4.18)		
p-value [1]	0.004		0.076		
Unadjusted Odds Ratio (95% CI)	8.40 (2.21, 31.88)		3.85 (1.08, 13.63)		
p-value [1]	0.002		0.037		
Unadjusted Absolute Risk Difference (95% CI)	0.44 (0.20, 0.68)		0.32 (0.04, 0.61)		
Adjusted Relative Risk (95% CI) [2]	2.19 (1.34, 3.58)		1.91 (0.88, 4.12)		
p-value [2]	0.002		0.10		
Interaction test for Treatment*Baseline Spleen Volume Group [3]					0.93

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0210: TEAEs: Overall Summary by Baseline Spleen Volume
Randomized Treatment Phase
SAF-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
TEAE Related to Study Drug with Grade >=3					
Number of subjects, n(%)	11 (39.3%)	5 (20.8%)	9 (23.7%)	3 (20.0%)	
Unadjusted Relative Risk (95% CI)	1.89 (0.76, 4.66)		1.18 (0.37, 3.79)		
p-value [1]	0.17		0.78		
Unadjusted Odds Ratio (95% CI)	2.46 (0.71, 8.52)		1.24 (0.29, 5.40)		
p-value [1]	0.16		0.77		
Unadjusted Absolute Risk Difference (95% CI)	0.18 (-0.06, 0.43)		0.04 (-0.21, 0.28)		
Adjusted Relative Risk (95% CI) [2]	2.08 (0.86, 5.03)		1.00 (0.31, 3.20)		
p-value [2]	0.10		>0.99		
Interaction test for Treatment*Baseline Spleen Volume Group [3]					0.56
Serious TEAE					
Number of subjects, n(%)	6 (21.4%)	6 (25.0%)	17 (44.7%)	3 (20.0%)	
Unadjusted Relative Risk (95% CI)	0.86 (0.32, 2.31)		2.24 (0.77, 6.53)		
p-value [1]	0.76		0.14		
Unadjusted Odds Ratio (95% CI)	0.82 (0.22, 2.98)		3.24 (0.78, 13.36)		
p-value [1]	0.76		0.10		
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.27, 0.19)		0.25 (-0.01, 0.50)		
Adjusted Relative Risk (95% CI) [2]	0.89 (0.34, 2.34)		1.93 (0.67, 5.60)		
p-value [2]	0.81		0.22		
Interaction test for Treatment*Baseline Spleen Volume Group [3]					0.18

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0210: TEAEs: Overall Summary by Baseline Spleen Volume
Randomized Treatment Phase
SAF-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Serious TEAE Related to Study Drug					
Number of subjects, n(%)	2 (7.1%)	2 (8.3%)	5 (13.2%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Baseline Spleen Volume Group [3]					NA
Non-Fatal SAEs					
Number of subjects, n(%)	6 (21.4%)	5 (20.8%)	17 (44.7%)	3 (20.0%)	
Unadjusted Relative Risk (95% CI)	1.03 (0.36, 2.95)		2.24 (0.77, 6.53)		
p-value [1]	0.96		0.14		
Unadjusted Odds Ratio (95% CI)	1.04 (0.27, 3.94)		3.24 (0.78, 13.36)		
p-value [1]	0.96		0.10		
Unadjusted Absolute Risk Difference (95% CI)	0.01 (-0.22, 0.23)		0.25 (-0.01, 0.50)		
Adjusted Relative Risk (95% CI) [2]	1.10 (0.40, 3.05)		1.93 (0.67, 5.60)		
p-value [2]	0.86		0.22		
Interaction test for Treatment*Baseline Spleen Volume Group [3]					0.30

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0210: TEAEs: Overall Summary by Baseline Spleen Volume
Randomized Treatment Phase
SAF-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
TEAE Leading to Premature Discontinuation of Study Drug					
Number of subjects, n(%)	4 (14.3%)	0	10 (26.3%)	1 (6.7%)	
Unadjusted Relative Risk (95% CI)	7.76 (0.44, 137.17)		3.95 (0.55, 28.22)		
p-value [1]	0.16		0.17		
Unadjusted Odds Ratio (95% CI)	9.00 (0.46, 176.30)		5.00 (0.58, 43.07)		
p-value [1]	0.15		0.14		
Unadjusted Absolute Risk Difference (95% CI)	0.14 (-0.01, 0.28)		0.20 (0.01, 0.39)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Interaction test for Treatment*Baseline Spleen Volume Group [3]					NE
TEAE Leading to Dose Reduction or Temporary Interruption of Study Drug					
Number of subjects, n(%)	3 (10.7%)	5 (20.8%)	6 (15.8%)	3 (20.0%)	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Baseline Spleen Volume Group [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-rt-sub-gba.sas V.03.05 Output file: t-aesum-rt-gba-svb.pdf 24AUG2023:16:51

Table 3.0210: TEAEs: Overall Summary by Baseline Spleen Volume
Randomized Treatment Phase
SAF-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
TEAE Leading to Death					
Number of subjects, n(%)	0	1 (4.2%)	4 (10.5%)	3 (20.0%)	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Baseline Spleen Volume Group [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0209: TEAEs: Overall Summary by Baseline TSS
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
TEAE					
Number of subjects, n(%)	42 (100.0%)	18 (90.0%)	24 (100.0%)	17 (89.5%)	
Unadjusted Relative Risk (95% CI)	1.12 (0.96, 1.32)		1.12 (0.94, 1.33)		
p-value [1]	0.16		0.20		
Unadjusted Odds Ratio (95% CI)	11.49 (0.53, 251.21)		7.00 (0.32, 155.04)		
p-value [1]	0.12		0.22		
Unadjusted Absolute Risk Difference (95% CI)	0.11 (-0.03, 0.25)		0.11 (-0.05, 0.26)		
Adjusted Relative Risk (95% CI) [2]	1.10 (0.96, 1.27)		1.12 (0.96, 1.30)		
p-value [2]	0.16		0.16		
Interaction test for Treatment*Baseline TSS Group [3]					0.96
TEAE with Grade >=3					
Number of subjects, n(%)	23 (54.8%)	9 (45.0%)	17 (70.8%)	9 (47.4%)	
Unadjusted Relative Risk (95% CI)	1.22 (0.70, 2.12)		1.50 (0.87, 2.56)		
p-value [1]	0.49		0.14		
Unadjusted Odds Ratio (95% CI)	1.48 (0.51, 4.31)		2.70 (0.77, 9.51)		
p-value [1]	0.47		0.12		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.17, 0.36)		0.23 (-0.05, 0.52)		
Adjusted Relative Risk (95% CI) [2]	1.26 (0.73, 2.20)		1.44 (0.84, 2.46)		
p-value [2]	0.41		0.18		
Interaction test for Treatment*Baseline TSS Group [3]					0.60

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-rt-sub-gba.sas V.03.05 Output file: t-aesum-rt-gba-tss.pdf 24AUG2023:16:51

Table 3.0209: TEAEs: Overall Summary by Baseline TSS
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
TEAE with Grade 3 or 4					
Number of subjects, n(%)	23 (54.8%)	9 (45.0%)	16 (66.7%)	9 (47.4%)	
Unadjusted Relative Risk (95% CI)	1.22 (0.70, 2.12)		1.41 (0.81, 2.44)		
p-value [1]	0.49		0.22		
Unadjusted Odds Ratio (95% CI)	1.48 (0.51, 4.31)		2.22 (0.64, 7.66)		
p-value [1]	0.47		0.21		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.17, 0.36)		0.19 (-0.10, 0.49)		
Adjusted Relative Risk (95% CI) [2]	1.26 (0.73, 2.20)		1.36 (0.78, 2.36)		
p-value [2]	0.41		0.27		
Interaction test for Treatment*Baseline TSS Group [3]					0.72
TEAE Related to Study Drug					
Number of subjects, n(%)	29 (69.0%)	8 (40.0%)	20 (83.3%)	7 (36.8%)	
Unadjusted Relative Risk (95% CI)	1.73 (0.97, 3.06)		2.26 (1.22, 4.19)		
p-value [1]	0.062		0.009		
Unadjusted Odds Ratio (95% CI)	3.35 (1.10, 10.14)		8.57 (2.07, 35.52)		
p-value [1]	0.033		0.003		
Unadjusted Absolute Risk Difference (95% CI)	0.29 (0.03, 0.55)		0.46 (0.20, 0.73)		
Adjusted Relative Risk (95% CI) [2]	1.80 (1.03, 3.15)		2.17 (1.18, 4.01)		
p-value [2]	0.041		0.013		
Interaction test for Treatment*Baseline TSS Group [3]					0.53

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.0209: TEAEs: Overall Summary by Baseline TSS
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
TEAE Related to Study Drug with Grade >=3					
Number of subjects, n(%)	13 (31.0%)	5 (25.0%)	7 (29.2%)	3 (15.8%)	
Unadjusted Relative Risk (95% CI)	1.24 (0.51, 2.99)		1.85 (0.55, 6.20)		
p-value [1]	0.64		0.32		
Unadjusted Odds Ratio (95% CI)	1.34 (0.40, 4.49)		2.20 (0.48, 9.99)		
p-value [1]	0.63		0.31		
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.18, 0.30)		0.13 (-0.11, 0.38)		
Adjusted Relative Risk (95% CI) [2]	1.26 (0.52, 3.04)		1.81 (0.53, 6.19)		
p-value [2]	0.61		0.34		
Interaction test for Treatment*Baseline TSS Group [3]					0.60
Serious TEAE					
Number of subjects, n(%)	15 (35.7%)	6 (30.0%)	8 (33.3%)	3 (15.8%)	
Unadjusted Relative Risk (95% CI)	1.19 (0.54, 2.60)		2.11 (0.65, 6.89)		
p-value [1]	0.66		0.22		
Unadjusted Odds Ratio (95% CI)	1.30 (0.41, 4.08)		2.67 (0.60, 11.92)		
p-value [1]	0.66		0.20		
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.19, 0.30)		0.18 (-0.07, 0.43)		
Adjusted Relative Risk (95% CI) [2]	1.22 (0.55, 2.70)		1.93 (0.60, 6.21)		
p-value [2]	0.62		0.27		
Interaction test for Treatment*Baseline TSS Group [3]					0.42

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.0209: TEAEs: Overall Summary by Baseline TSS
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Serious TEAE Related to Study Drug					
Number of subjects, n(%)	6 (14.3%)	2 (10.0%)	1 (4.2%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Baseline TSS Group [3]					NA
Non-Fatal SAEs					
Number of subjects, n(%)	15 (35.7%)	5 (25.0%)	8 (33.3%)	3 (15.8%)	
Unadjusted Relative Risk (95% CI)	1.43 (0.60, 3.38)		2.11 (0.65, 6.89)		
p-value [1]	0.42		0.22		
Unadjusted Odds Ratio (95% CI)	1.67 (0.51, 5.49)		2.67 (0.60, 11.92)		
p-value [1]	0.40		0.20		
Unadjusted Absolute Risk Difference (95% CI)	0.11 (-0.13, 0.35)		0.18 (-0.07, 0.43)		
Adjusted Relative Risk (95% CI) [2]	1.49 (0.63, 3.53)		1.93 (0.60, 6.21)		
p-value [2]	0.36		0.27		
Interaction test for Treatment*Baseline TSS Group [3]					0.60

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.0209: TEAEs: Overall Summary by Baseline TSS
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
TEAE Leading to Premature Discontinuation of Study Drug					
Number of subjects, n(%)	9 (21.4%)	0	5 (20.8%)	1 (5.3%)	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Baseline TSS Group [3]					NA
TEAE Leading to Dose Reduction or Temporary Interruption of Study Drug					
Number of subjects, n(%)	6 (14.3%)	4 (20.0%)	3 (12.5%)	4 (21.1%)	
Unadjusted Relative Risk (95% CI)	0.71 (0.23, 2.25)		0.59 (0.15, 2.34)		
p-value [1]	0.57		0.46		
Unadjusted Odds Ratio (95% CI)	0.67 (0.17, 2.69)		0.54 (0.10, 2.75)		
p-value [1]	0.57		0.45		
Unadjusted Absolute Risk Difference (95% CI)	-0.06 (-0.26, 0.15)		-0.09 (-0.31, 0.14)		
Adjusted Relative Risk (95% CI) [2]	0.82 (0.26, 2.60)		0.62 (0.14, 2.66)		
p-value [2]	0.74		0.52		
Interaction test for Treatment*Baseline TSS Group [3]					0.84

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.0209: TEAEs: Overall Summary by Baseline TSS
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
TEAE Leading to Death					
Number of subjects, n(%)	2 (4.8%)	2 (10.0%)	2 (8.3%)	2 (10.5%)	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Baseline TSS Group [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.1102: TEAEs of Grade 2 or less by Age
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Number of subjects, n(%)	23 (95.8%)	7 (77.8%)	41 (97.6%)	27 (90.0%)	
Unadjusted Relative Risk (95% CI)	1.23 (0.86, 1.76)		1.08 (0.95, 1.23)		
p-value [1]	0.25		0.21		
Unadjusted Odds Ratio (95% CI)	6.57 (0.52, 83.76)		4.56 (0.45, 46.11)		
p-value [1]	0.15		0.20		
Unadjusted Absolute Risk Difference (95% CI)	0.18 (-0.10, 0.46)		0.08 (-0.04, 0.19)		
Adjusted Relative Risk (95% CI) [2]	1.21 (0.88, 1.67)		1.07 (0.92, 1.24)		
p-value [2]	0.23		0.40		
Interaction test for Treatment*Age Group [3]					0.50

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-gle2-sub-gba.sas V.03.05 Output file: t-aesum-gle2-gba-age.pdf 24AUG2023:16:50

Table 3.1104: TEAEs of Grade 2 or less by Region
Randomized Treatment Phase
SAF-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Number of subjects, n(%)	28 (96.6%)	5 (71.4%)	36 (97.3%)	29 (90.6%)	
Unadjusted Relative Risk (95% CI)	1.35 (0.84, 2.17)		1.07 (0.95, 1.22)		
p-value [1]	0.21		0.26		
Unadjusted Odds Ratio (95% CI)	11.20 (0.85, 148.14)		3.72 (0.37, 37.72)		
p-value [1]	0.067		0.27		
Unadjusted Absolute Risk Difference (95% CI)	0.25 (-0.09, 0.59)		0.07 (-0.05, 0.18)		
Adjusted Relative Risk (95% CI) [2]	1.34 (0.81, 2.22)		1.07 (0.96, 1.19)		
p-value [2]	0.25		0.25		
Interaction test for Treatment*Region [3]					0.33

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-gle2-sub-gba.sas V.03.05 Output file: t-aesum-gle2-gba-geo.pdf 24AUG2023:16:50

Table 3.1107: TEAEs of Grade 2 or less by Baseline Hemoglobin Level
Randomized Treatment Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Number of subjects, n(%)	26 (96.3%)	4 (66.7%)	38 (97.4%)	30 (90.9%)	
Unadjusted Relative Risk (95% CI)	1.44 (0.82, 2.56)		1.07 (0.95, 1.21)		
p-value [1]	0.21		0.25		
Unadjusted Odds Ratio (95% CI)	13.00 (0.95, 178.77)		3.80 (0.38, 38.41)		
p-value [1]	0.055		0.26		
Unadjusted Absolute Risk Difference (95% CI)	0.30 (-0.09, 0.68)		0.07 (-0.04, 0.18)		
Adjusted Relative Risk (95% CI) [2]	1.45 (0.82, 2.57)		1.07 (0.94, 1.21)		
p-value [2]	0.20		0.29		
Interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.28

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.1106: TEAEs of Grade 2 or less by Baseline DIPSS Two-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Number of subjects, n(%)	48 (98.0%)	28 (90.3%)	16 (94.1%)	6 (75.0%)	
Unadjusted Relative Risk (95% CI)	1.08 (0.96, 1.23)		1.25 (0.83, 1.90)		
p-value [1]	0.19		0.29		
Unadjusted Odds Ratio (95% CI)	5.14 (0.51, 51.85)		5.33 (0.41, 70.20)		
p-value [1]	0.16		0.20		
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.03, 0.19)		0.19 (-0.13, 0.51)		
Adjusted Relative Risk (95% CI) [2]	1.07 (0.97, 1.18)		1.23 (0.85, 1.78)		
p-value [2]	0.19		0.27		
Interaction test for Treatment*Baseline DIPSS 2-Level Risk [3]					0.50

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.1105: TEAEs of Grade 2 or less by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Number of subjects, n(%)	5 (100.0%)	6 (85.7%)	43 (97.7%)	22 (91.7%)
Unadjusted Relative Risk (95% CI)	1.13 (0.75, 1.70)		1.07 (0.94, 1.21)	
p-value [1]	0.57		0.33	
Unadjusted Odds Ratio (95% CI)	2.54 (0.09, 75.77)		3.91 (0.34, 45.52)	
p-value [1]	0.59		0.28	
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.25, 0.45)		0.06 (-0.06, 0.18)	
Adjusted Relative Risk (95% CI) [2]	1.00 (1.00, 1.00)		1.04 (0.95, 1.13)	
p-value [2]	>0.99		0.40	
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.1105: TEAEs of Grade 2 or less by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=17)	BAT (N=8)	p-value
Number of subjects, n(%)	16 (94.1%)	6 (75.0%)	
Unadjusted Relative Risk (95% CI)	1.25 (0.83, 1.90)		
p-value [1]	0.29		
Unadjusted Odds Ratio (95% CI)	5.33 (0.41, 70.20)		
p-value [1]	0.20		
Unadjusted Absolute Risk Difference (95% CI)	0.19 (-0.13, 0.51)		
Adjusted Relative Risk (95% CI) [2]	1.23 (0.85, 1.78)		
p-value [2]	0.27		
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]			0.68

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.1108: TEAEs of Grade 2 or less by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
Number of subjects, n(%)	45 (100.0%)	21 (91.3%)	11 (84.6%)	6 (75.0%)
Unadjusted Relative Risk (95% CI)	1.10 (0.96, 1.27)		1.13 (0.71, 1.79)	
p-value [1]	0.16		0.61	
Unadjusted Odds Ratio (95% CI)	10.58 (0.49, 230.11)		1.83 (0.20, 16.51)	
p-value [1]	0.13		0.59	
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.03, 0.22)		0.10 (-0.26, 0.45)	
Adjusted Relative Risk (95% CI) [2]	1.10 (0.97, 1.25)		0.99 (0.62, 1.57)	
p-value [2]	0.15		0.95	
Interaction test for Treatment*Myelofibrosis Disease Type [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.1108: TEAEs of Grade 2 or less by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=8)	BAT (N=8)	p-value
Number of subjects, n(%)	8 (100.0%)	7 (87.5%)	
Unadjusted Relative Risk (95% CI)	1.13 (0.81, 1.58)		
p-value [1]	0.46		
Unadjusted Odds Ratio (95% CI)	3.40 (0.12, 96.71)		
p-value [1]	0.47		
Unadjusted Absolute Risk Difference (95% CI)	0.11 (-0.17, 0.40)		
Adjusted Relative Risk (95% CI) [2]	1.00 (1.00, 1.00)		
p-value [2]	>0.99		
Interaction test for Treatment*Myelofibrosis Disease Type [3]			0.96

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.1103: TEAEs of Grade 2 or less by Gender
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Number of subjects, n(%)	50 (96.2%)	15 (83.3%)	14 (100.0%)	19 (90.5%)	
Unadjusted Relative Risk (95% CI)	1.15 (0.93, 1.43)		1.09 (0.91, 1.30)		
p-value [1]	0.19		0.34		
Unadjusted Odds Ratio (95% CI)	5.00 (0.76, 32.77)		3.72 (0.17, 83.49)		
p-value [1]	0.093		0.41		
Unadjusted Absolute Risk Difference (95% CI)	0.13 (-0.05, 0.31)		0.08 (-0.08, 0.24)		
Adjusted Relative Risk (95% CI) [2]	1.15 (0.93, 1.43)		1.03 (0.97, 1.09)		
p-value [2]	0.21		0.40		
Interaction test for Treatment*Gender [3]					0.74

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.1110: TEAEs of Grade 2 or less by Baseline Spleen Volume
Randomized Treatment Phase
SAF-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Number of subjects, n(%)	27 (96.4%)	21 (87.5%)	37 (97.4%)	13 (86.7%)	
Unadjusted Relative Risk (95% CI)	1.10 (0.93, 1.30)		1.12 (0.91, 1.38)		
p-value [1]	0.25		0.27		
Unadjusted Odds Ratio (95% CI)	3.86 (0.37, 39.80)		5.69 (0.48, 68.13)		
p-value [1]	0.26		0.17		
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.06, 0.24)		0.11 (-0.07, 0.29)		
Adjusted Relative Risk (95% CI) [2]	1.10 (0.94, 1.30)		1.11 (0.92, 1.33)		
p-value [2]	0.23		0.27		
Interaction test for Treatment*Baseline Spleen Volume Group [3]					0.89

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.1109: TEAEs of Grade 2 or less by Baseline TSS
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Number of subjects, n(%)	41 (97.6%)	17 (85.0%)	23 (95.8%)	17 (89.5%)	
Unadjusted Relative Risk (95% CI)	1.15 (0.95, 1.39)		1.07 (0.90, 1.28)		
p-value [1]	0.15		0.44		
Unadjusted Odds Ratio (95% CI)	7.24 (0.70, 74.57)		2.71 (0.23, 32.34)		
p-value [1]	0.096		0.43		
Unadjusted Absolute Risk Difference (95% CI)	0.13 (-0.04, 0.29)		0.06 (-0.10, 0.22)		
Adjusted Relative Risk (95% CI) [2]	1.15 (0.95, 1.39)		1.06 (0.88, 1.27)		
p-value [2]	0.15		0.54		
Interaction test for Treatment*Baseline TSS Group [3]					0.60

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.0902: TEAEs by SOC and PT by Age
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Nervous system disorders					
Any Event	12 (50.0%)	5 (55.6%)	20 (47.6%)	3 (10.0%)	
Unadjusted Relative Risk (95% CI)	0.90 (0.44, 1.83)		4.76 (1.55, 14.59)		
p-value [1]	0.77		0.006		
Unadjusted Odds Ratio (95% CI)	0.80 (0.17, 3.73)		8.18 (2.15, 31.18)		
p-value [1]	0.78		0.002		
Unadjusted Absolute Risk Difference (95% CI)	-0.06 (-0.44, 0.33)		0.38 (0.19, 0.56)		
Adjusted Relative Risk (95% CI) [2]	1.10 (0.55, 2.22)		4.55 (1.45, 14.27)		
p-value [2]	0.79		0.009		
Interaction test for Treatment*Age Group [3]					0.023
Gastrointestinal disorders					
Diarrhoea	8 (33.3%)	1 (11.1%)	13 (31.0%)	4 (13.3%)	
Unadjusted Relative Risk (95% CI)	3.00 (0.43, 20.72)		2.32 (0.84, 6.43)		
p-value [1]	0.27		0.10		
Unadjusted Odds Ratio (95% CI)	4.00 (0.42, 37.78)		2.91 (0.84, 10.06)		
p-value [1]	0.23		0.091		
Unadjusted Absolute Risk Difference (95% CI)	0.22 (-0.06, 0.50)		0.18 (-0.01, 0.36)		
Adjusted Relative Risk (95% CI) [2]	3.76 (0.70, 20.33)		NE		
p-value [2]	0.12		NE		
Interaction test for Treatment*Age Group [3]					0.81

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE. [3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0902: TEAEs by SOC and PT by Age
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Investigations					
Any Event	8 (33.3%)	1 (11.1%)	9 (21.4%)	2 (6.7%)	
Unadjusted Relative Risk (95% CI)	3.00 (0.43, 20.72)		3.21 (0.75, 13.82)		
p-value [1]	0.27		0.12		
Unadjusted Odds Ratio (95% CI)	4.00 (0.42, 37.78)		3.82 (0.76, 19.16)		
p-value [1]	0.23		0.10		
Unadjusted Absolute Risk Difference (95% CI)	0.22 (-0.06, 0.50)		0.15 (-0.01, 0.30)		
Adjusted Relative Risk (95% CI) [2]	NE		3.34 (0.76, 14.66)		
p-value [2]	NE		0.11		
Interaction test for Treatment*Age Group [3]					0.96

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE. [3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0904: TEAEs by SOC and PT by Region
Randomized Treatment Phase
SAF-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Nervous system disorders					
Any Event	17 (58.6%)	2 (28.6%)	15 (40.5%)	6 (18.8%)	
Unadjusted Relative Risk (95% CI)	2.05 (0.61, 6.88)		2.16 (0.95, 4.91)		
p-value [1]	0.24		0.065		
Unadjusted Odds Ratio (95% CI)	3.54 (0.59, 21.40)		2.95 (0.98, 8.91)		
p-value [1]	0.17		0.054		
Unadjusted Absolute Risk Difference (95% CI)	0.30 (-0.08, 0.68)		0.22 (0.01, 0.43)		
Adjusted Relative Risk (95% CI) [2]	1.88 (0.64, 5.53)		2.32 (1.02, 5.28)		
p-value [2]	0.25		0.045		
Interaction test for Treatment*Region [3]					0.94
Gastrointestinal disorders					
Diarrhoea	11 (37.9%)	1 (14.3%)	10 (27.0%)	4 (12.5%)	
Unadjusted Relative Risk (95% CI)	2.66 (0.41, 17.29)		2.16 (0.75, 6.23)		
p-value [1]	0.31		0.15		
Unadjusted Odds Ratio (95% CI)	3.67 (0.39, 34.65)		2.59 (0.72, 9.27)		
p-value [1]	0.26		0.14		
Unadjusted Absolute Risk Difference (95% CI)	0.24 (-0.08, 0.55)		0.15 (-0.04, 0.33)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Interaction test for Treatment*Region [3]					0.85

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE. [3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-socpt-sub-gba.sas V.03.05 Output file: t-ae-socpt-gba-geo.pdf 24AUG2023:16:57

Table 3.0904: TEAEs by SOC and PT by Region
Randomized Treatment Phase
SAF-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Investigations					
Any Event	11 (37.9%)	1 (14.3%)	6 (16.2%)	2 (6.3%)	
Unadjusted Relative Risk (95% CI)	2.66 (0.41, 17.29)		2.59 (0.56, 11.97)		
p-value [1]	0.31		0.22		
Unadjusted Odds Ratio (95% CI)	3.67 (0.39, 34.65)		2.90 (0.54, 15.53)		
p-value [1]	0.26		0.21		
Unadjusted Absolute Risk Difference (95% CI)	0.24 (-0.08, 0.55)		0.10 (-0.05, 0.25)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Interaction test for Treatment*Region [3]					0.99

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE. [3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0907: TEAEs by SOC and PT by Baseline Hemoglobin Level
Randomized Treatment Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Nervous system disorders					
Any Event	14 (51.9%)	0	18 (46.2%)	8 (24.2%)	
Unadjusted Relative Risk (95% CI)	7.25 (0.49, 107.32)		1.90 (0.95, 3.80)		
p-value [1]	0.15		0.068		
Unadjusted Odds Ratio (95% CI)	13.96 (0.72, 272.29)		2.68 (0.97, 7.39)		
p-value [1]	0.082		0.057		
Unadjusted Absolute Risk Difference (95% CI)	0.45 (0.18, 0.71)		0.22 (0.00, 0.43)		
Adjusted Relative Risk (95% CI) [2]	NE		1.99 (1.00, 3.96)		
p-value [2]	NE		0.051		
Interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE
Gastrointestinal disorders					
Diarrhoea	12 (44.4%)	0	9 (23.1%)	5 (15.2%)	
Unadjusted Relative Risk (95% CI)	6.25 (0.42, 93.25)		1.52 (0.57, 4.10)		
p-value [1]	0.18		0.40		
Unadjusted Odds Ratio (95% CI)	10.48 (0.54, 204.64)		1.68 (0.50, 5.63)		
p-value [1]	0.12		0.40		
Unadjusted Absolute Risk Difference (95% CI)	0.38 (0.11, 0.64)		0.08 (-0.10, 0.26)		
Adjusted Relative Risk (95% CI) [2]	NE		1.41 (0.52, 3.78)		
p-value [2]	NE		0.50		
Interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE. [3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0907: TEAEs by SOC and PT by Baseline Hemoglobin Level
Randomized Treatment Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Investigations					
Any Event	3 (11.1%)	0	14 (35.9%)	3 (9.1%)	
Unadjusted Relative Risk (95% CI)	1.75 (0.10, 30.11)		3.95 (1.24, 12.57)		
p-value [1]	0.70		0.020		
Unadjusted Odds Ratio (95% CI)	1.86 (0.08, 40.69)		5.60 (1.44, 21.71)		
p-value [1]	0.69		0.013		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.17, 0.28)		0.27 (0.09, 0.45)		
Adjusted Relative Risk (95% CI) [2]	NE		3.77 (1.16, 12.21)		
p-value [2]	NE		0.027		
Interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE. [3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0906: TEAEs by SOC and PT by Baseline DIPSS Two-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Nervous system disorders					
Any Event	23 (46.9%)	6 (19.4%)	9 (52.9%)	2 (25.0%)	
Unadjusted Relative Risk (95% CI)	2.43 (1.11, 5.28)		2.12 (0.59, 7.63)		
p-value [1]	0.026		0.25		
Unadjusted Odds Ratio (95% CI)	3.69 (1.29, 10.56)		3.38 (0.52, 21.73)		
p-value [1]	0.015		0.20		
Unadjusted Absolute Risk Difference (95% CI)	0.28 (0.08, 0.47)		0.28 (-0.10, 0.66)		
Adjusted Relative Risk (95% CI) [2]	2.78 (1.28, 6.04)		2.62 (0.73, 9.33)		
p-value [2]	0.010		0.14		
Interaction test for Treatment*Baseline DIPSS 2-Level Risk [3]					0.86
Gastrointestinal disorders					
Diarrhoea	14 (28.6%)	3 (9.7%)	7 (41.2%)	2 (25.0%)	
Unadjusted Relative Risk (95% CI)	2.95 (0.92, 9.45)		1.65 (0.44, 6.21)		
p-value [1]	0.068		0.46		
Unadjusted Odds Ratio (95% CI)	3.73 (0.98, 14.29)		2.10 (0.32, 13.61)		
p-value [1]	0.054		0.44		
Unadjusted Absolute Risk Difference (95% CI)	0.19 (0.03, 0.35)		0.16 (-0.22, 0.54)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Interaction test for Treatment*Baseline DIPSS 2-Level Risk [3]					0.55

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE. [3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0906: TEAEs by SOC and PT by Baseline DIPSS Two-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Investigations					
Any Event	12 (24.5%)	3 (9.7%)	5 (29.4%)	0	
Unadjusted Relative Risk (95% CI)	2.53 (0.78, 8.26)		5.50 (0.34, 88.86)		
p-value [1]	0.12		0.23		
Unadjusted Odds Ratio (95% CI)	3.03 (0.78, 11.76)		7.48 (0.36, 153.80)		
p-value [1]	0.11		0.19		
Unadjusted Absolute Risk Difference (95% CI)	0.15 (-0.01, 0.31)		0.25 (-0.01, 0.51)		
Adjusted Relative Risk (95% CI) [2]	2.00 (0.60, 6.63)		NE		
p-value [2]	0.26		NE		
Interaction test for Treatment*Baseline DIPSS 2-Level Risk [3]					NE

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE. [3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0905: TEAEs by SOC and PT by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Nervous system disorders				
Any Event	3 (60.0%)	2 (28.6%)	20 (45.5%)	4 (16.7%)
Unadjusted Relative Risk (95% CI)	2.10 (0.53, 8.29)		2.73 (1.05, 7.06)	
p-value [1]	0.29		0.039	
Unadjusted Odds Ratio (95% CI)	3.75 (0.33, 42.47)		4.17 (1.22, 14.21)	
p-value [1]	0.29		0.023	
Unadjusted Absolute Risk Difference (95% CI)	0.31 (-0.23, 0.86)		0.29 (0.08, 0.50)	
Adjusted Relative Risk (95% CI) [2]	NE		3.52 (1.36, 9.12)	
p-value [2]	NE		0.010	
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]				
Gastrointestinal disorders				
Diarrhoea	3 (60.0%)	1 (14.3%)	11 (25.0%)	2 (8.3%)
Unadjusted Relative Risk (95% CI)	4.20 (0.60, 29.54)		3.00 (0.72, 12.44)	
p-value [1]	0.15		0.13	
Unadjusted Odds Ratio (95% CI)	9.00 (0.56, 143.89)		3.67 (0.74, 18.17)	
p-value [1]	0.12		0.11	
Unadjusted Absolute Risk Difference (95% CI)	0.46 (-0.04, 0.96)		0.17 (0.00, 0.34)	
Adjusted Relative Risk (95% CI) [2]	NE		NE	
p-value [2]	NE		NE	
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE. [3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-socpt-sub-gba.sas V.03.05 Output file: t-ae-socpt-gba-ipss3.pdf 24AUG2023:16:57

Table 3.0905: TEAEs by SOC and PT by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=17)	BAT (N=8)	p-value
Nervous system disorders			
Any Event	9 (52.9%)	2 (25.0%)	
Unadjusted Relative Risk (95% CI)	2.12 (0.59, 7.63)		
p-value [1]	0.25		
Unadjusted Odds Ratio (95% CI)	3.38 (0.52, 21.73)		
p-value [1]	0.20		
Unadjusted Absolute Risk Difference (95% CI)	0.28 (-0.10, 0.66)		
Adjusted Relative Risk (95% CI) [2]	2.62 (0.73, 9.33)		
p-value [2]	0.14		
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]			0.93
Gastrointestinal disorders			
Diarrhoea	7 (41.2%)	2 (25.0%)	
Unadjusted Relative Risk (95% CI)	1.65 (0.44, 6.21)		
p-value [1]	0.46		
Unadjusted Odds Ratio (95% CI)	2.10 (0.32, 13.61)		
p-value [1]	0.44		
Unadjusted Absolute Risk Difference (95% CI)	0.16 (-0.22, 0.54)		
Adjusted Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]			0.73

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE. [3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-socpt-sub-gba.sas V.03.05 Output file: t-ae-socpt-gba-ipss3.pdf 24AUG2023:16:57

Table 3.0905: TEAEs by SOC and PT by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Investigations				
Any Event	2 (40.0%)	1 (14.3%)	10 (22.7%)	2 (8.3%)
Unadjusted Relative Risk (95% CI)	2.80 (0.34, 23.06)		2.73 (0.65, 11.45)	
p-value [1]	0.34		0.17	
Unadjusted Odds Ratio (95% CI)	4.00 (0.25, 63.95)		3.24 (0.65, 16.19)	
p-value [1]	0.33		0.15	
Unadjusted Absolute Risk Difference (95% CI)	0.26 (-0.24, 0.76)		0.14 (-0.02, 0.31)	
Adjusted Relative Risk (95% CI) [2]	NE		2.33 (0.50, 10.77)	
p-value [2]	NE		0.28	
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE. [3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0905: TEAEs by SOC and PT by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=17)	BAT (N=8)	p-value
Investigations			
Any Event	5 (29.4%)	0	
Unadjusted Relative Risk (95% CI)	5.50 (0.34, 88.86)		
p-value [1]	0.23		
Unadjusted Odds Ratio (95% CI)	7.48 (0.36, 153.80)		
p-value [1]	0.19		
Unadjusted Absolute Risk Difference (95% CI)	0.25 (-0.01, 0.51)		
Adjusted Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]			NE

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE. [3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0908: TEAEs by SOC and PT by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
Nervous system disorders				
Any Event	23 (51.1%)	4 (17.4%)	5 (38.5%)	1 (12.5%)
Unadjusted Relative Risk (95% CI)	2.94 (1.15, 7.49)		3.08 (0.43, 21.80)	
p-value [1]	0.024		0.26	
Unadjusted Odds Ratio (95% CI)	4.97 (1.46, 16.93)		4.38 (0.41, 47.02)	
p-value [1]	0.010		0.22	
Unadjusted Absolute Risk Difference (95% CI)	0.34 (0.12, 0.55)		0.26 (-0.09, 0.61)	
Adjusted Relative Risk (95% CI) [2]	3.02 (1.19, 7.66)		NE	
p-value [2]	0.020		NE	
Interaction test for Treatment*Myelofibrosis Disease Type [3]				
Gastrointestinal disorders				
Diarrhoea	20 (44.4%)	2 (8.7%)	0	2 (25.0%)
Unadjusted Relative Risk (95% CI)	5.11 (1.31, 19.99)		0.13 (0.01, 2.38)	
p-value [1]	0.019		0.17	
Unadjusted Odds Ratio (95% CI)	8.40 (1.76, 40.18)		0.10 (0.00, 2.31)	
p-value [1]	0.008		0.15	
Unadjusted Absolute Risk Difference (95% CI)	0.36 (0.17, 0.54)		-0.24 (-0.55, 0.07)	
Adjusted Relative Risk (95% CI) [2]	4.73 (1.22, 18.26)		NE	
p-value [2]	0.024		NE	
Interaction test for Treatment*Myelofibrosis Disease Type [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE. [3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0908: TEAEs by SOC and PT by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=8)	BAT (N=8)	p-value
Nervous system disorders			
Any Event	4 (50.0%)	3 (37.5%)	
Unadjusted Relative Risk (95% CI)	1.33 (0.43, 4.13)		
p-value [1]	0.62		
Unadjusted Odds Ratio (95% CI)	1.67 (0.23, 12.22)		
p-value [1]	0.62		
Unadjusted Absolute Risk Difference (95% CI)	0.13 (-0.36, 0.61)		
Adjusted Relative Risk (95% CI) [2]	1.25 (0.34, 4.58)		
p-value [2]	0.74		
Interaction test for Treatment*Myelofibrosis Disease Type [3]			0.60
Gastrointestinal disorders			
Diarrhoea	1 (12.5%)	1 (12.5%)	
Unadjusted Relative Risk (95% CI)	1.00 (0.07, 13.37)		
p-value [1]	>0.99		
Unadjusted Odds Ratio (95% CI)	1.00 (0.05, 19.36)		
p-value [1]	>0.99		
Unadjusted Absolute Risk Difference (95% CI)	0.00 (-0.32, 0.32)		
Adjusted Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Interaction test for Treatment*Myelofibrosis Disease Type [3]			NE

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE. [3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0908: TEAEs by SOC and PT by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
Investigations				
Any Event	11 (24.4%)	3 (13.0%)	3 (23.1%)	0
Unadjusted Relative Risk (95% CI)	1.87 (0.58, 6.06)		4.50 (0.26, 77.21)	
p-value [1]	0.29		0.30	
Unadjusted Odds Ratio (95% CI)	2.16 (0.54, 8.67)		5.67 (0.26, 125.56)	
p-value [1]	0.28		0.27	
Unadjusted Absolute Risk Difference (95% CI)	0.11 (-0.07, 0.30)		0.19 (-0.08, 0.47)	
Adjusted Relative Risk (95% CI) [2]	1.71 (0.51, 5.69)		NE	
p-value [2]	0.38		NE	
Interaction test for Treatment*Myelofibrosis Disease Type [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE. [3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-socpt-sub-gba.sas V.03.05 Output file: t-ae-socpt-gba-mf.pdf 24AUG2023:16:58

Table 3.0908: TEAEs by SOC and PT by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=8)	BAT (N=8)	p-value
Investigations			
Any Event	3 (37.5%)	0	
Unadjusted Relative Risk (95% CI)	7.00 (0.42, 116.91)		
p-value [1]	0.18		
Unadjusted Odds Ratio (95% CI)	10.82 (0.46, 252.80)		
p-value [1]	0.14		
Unadjusted Absolute Risk Difference (95% CI)	0.33 (-0.02, 0.69)		
Adjusted Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Interaction test for Treatment*Myelofibrosis Disease Type [3]			NE

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE. [3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0903: TEAEs by SOC and PT by Gender
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Nervous system disorders					
Any Event	26 (50.0%)	1 (5.6%)	6 (42.9%)	7 (33.3%)	
Unadjusted Relative Risk (95% CI)	9.00 (1.31, 61.64)		1.29 (0.55, 3.02)		
p-value [1]	0.025		0.56		
Unadjusted Odds Ratio (95% CI)	17.00 (2.11, 137.28)		1.50 (0.37, 6.05)		
p-value [1]	0.008		0.57		
Unadjusted Absolute Risk Difference (95% CI)	0.44 (0.27, 0.62)		0.10 (-0.23, 0.42)		
Adjusted Relative Risk (95% CI) [2]	8.96 (1.31, 61.41)		1.21 (0.46, 3.17)		
p-value [2]	0.026		0.70		
Interaction test for Treatment*Gender [3]					0.018
Gastrointestinal disorders					
Diarrhoea	16 (30.8%)	2 (11.1%)	5 (35.7%)	3 (14.3%)	
Unadjusted Relative Risk (95% CI)	2.77 (0.70, 10.88)		2.50 (0.71, 8.83)		
p-value [1]	0.14		0.15		
Unadjusted Odds Ratio (95% CI)	3.56 (0.73, 17.32)		3.33 (0.65, 17.18)		
p-value [1]	0.12		0.15		
Unadjusted Absolute Risk Difference (95% CI)	0.20 (0.00, 0.39)		0.21 (-0.08, 0.51)		
Adjusted Relative Risk (95% CI) [2]	2.69 (0.71, 10.19)		NE		
p-value [2]	0.14		NE		
Interaction test for Treatment*Gender [3]					0.91

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE. [3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0903: TEAEs by SOC and PT by Gender
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Investigations					
Any Event	16 (30.8%)	2 (11.1%)	1 (7.1%)	1 (4.8%)	
Unadjusted Relative Risk (95% CI)	2.77 (0.70, 10.88)		1.50 (0.10, 22.06)		
p-value [1]	0.14		0.77		
Unadjusted Odds Ratio (95% CI)	3.56 (0.73, 17.32)		1.54 (0.09, 26.82)		
p-value [1]	0.12		0.77		
Unadjusted Absolute Risk Difference (95% CI)	0.20 (0.00, 0.39)		0.02 (-0.14, 0.19)		
Adjusted Relative Risk (95% CI) [2]	2.86 (0.69, 11.85)		NE		
p-value [2]	0.15		NE		
Interaction test for Treatment*Gender [3]					0.70

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE. [3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0910: TEAEs by SOC and PT by Baseline Spleen Volume
Randomized Treatment Phase
SAF-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Nervous system disorders					
Any Event	14 (50.0%)	7 (29.2%)	18 (47.4%)	1 (6.7%)	
Unadjusted Relative Risk (95% CI)	1.71 (0.83, 3.54)		7.11 (1.04, 48.61)		
p-value [1]	0.15		0.046		
Unadjusted Odds Ratio (95% CI)	2.43 (0.77, 7.67)		12.60 (1.50, 105.64)		
p-value [1]	0.13		0.020		
Unadjusted Absolute Risk Difference (95% CI)	0.21 (-0.05, 0.47)		0.41 (0.20, 0.61)		
Adjusted Relative Risk (95% CI) [2]	1.84 (0.89, 3.79)		8.39 (1.03, 68.22)		
p-value [2]	0.099		0.047		
Interaction test for Treatment*Baseline Spleen Volume Group [3]					0.078
Gastrointestinal disorders					
Diarrhoea	6 (21.4%)	2 (8.3%)	15 (39.5%)	3 (20.0%)	
Unadjusted Relative Risk (95% CI)	2.57 (0.57, 11.58)		1.97 (0.67, 5.85)		
p-value [1]	0.22		0.22		
Unadjusted Odds Ratio (95% CI)	3.00 (0.54, 16.52)		2.61 (0.63, 10.82)		
p-value [1]	0.21		0.19		
Unadjusted Absolute Risk Difference (95% CI)	0.13 (-0.06, 0.32)		0.19 (-0.06, 0.45)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Interaction test for Treatment*Baseline Spleen Volume Group [3]					0.78

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE. [3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-socpt-sub-gba.sas V.03.05 Output file: t-ae-socpt-gba-svb.pdf 24AUG2023:16:58

Table 3.0910: TEAEs by SOC and PT by Baseline Spleen Volume
Randomized Treatment Phase
SAF-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Investigations					
Any Event	5 (17.9%)	3 (12.5%)	12 (31.6%)	0	
Unadjusted Relative Risk (95% CI)	1.43 (0.38, 5.37)		10.26 (0.65, 163.06)		
p-value [1]	0.60		0.099		
Unadjusted Odds Ratio (95% CI)	1.52 (0.32, 7.16)		14.62 (0.81, 264.53)		
p-value [1]	0.60		0.069		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.14, 0.25)		0.29 (0.12, 0.46)		
Adjusted Relative Risk (95% CI) [2]	1.37 (0.40, 4.71)		NE		
p-value [2]	0.61		NE		
Interaction test for Treatment*Baseline Spleen Volume Group [3]					NE

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE. [3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.0909: TEAEs by SOC and PT by Baseline TSS
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Nervous system disorders					
Any Event	20 (47.6%)	4 (20.0%)	12 (50.0%)	4 (21.1%)	
Unadjusted Relative Risk (95% CI)	2.38 (0.94, 6.05)		2.38 (0.91, 6.19)		
p-value [1]	0.068		0.077		
Unadjusted Odds Ratio (95% CI)	3.64 (1.04, 12.72)		3.75 (0.96, 14.65)		
p-value [1]	0.043		0.057		
Unadjusted Absolute Risk Difference (95% CI)	0.28 (0.04, 0.51)		0.29 (0.02, 0.56)		
Adjusted Relative Risk (95% CI) [2]	2.42 (0.97, 6.07)		2.36 (0.89, 6.26)		
p-value [2]	0.059		0.085		
Interaction test for Treatment*Baseline TSS Group [3]					>0.99
Gastrointestinal disorders					
Diarrhoea	15 (35.7%)	3 (15.0%)	6 (25.0%)	2 (10.5%)	
Unadjusted Relative Risk (95% CI)	2.38 (0.78, 7.29)		2.38 (0.54, 10.46)		
p-value [1]	0.13		0.25		
Unadjusted Odds Ratio (95% CI)	3.15 (0.79, 12.52)		2.83 (0.50, 16.02)		
p-value [1]	0.10		0.24		
Unadjusted Absolute Risk Difference (95% CI)	0.21 (-0.01, 0.42)		0.14 (-0.08, 0.37)		
Adjusted Relative Risk (95% CI) [2]	2.22 (0.72, 6.89)		2.10 (0.48, 9.30)		
p-value [2]	0.17		0.33		
Interaction test for Treatment*Baseline TSS Group [3]					>0.99

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, and baseline TD (yes, no) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-socpt-sub-gba.sas V.03.05 Output file: t-ae-socpt-gba-tss.pdf 24AUG2023:16:58

Table 3.0909: TEAEs by SOC and PT by Baseline TSS
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Investigations					
Any Event	12 (28.6%)	2 (10.0%)	5 (20.8%)	1 (5.3%)	
Unadjusted Relative Risk (95% CI)	2.86 (0.71, 11.58)		3.96 (0.50, 31.09)		
p-value [1]	0.14		0.19		
Unadjusted Odds Ratio (95% CI)	3.60 (0.72, 17.96)		4.74 (0.50, 44.57)		
p-value [1]	0.12		0.17		
Unadjusted Absolute Risk Difference (95% CI)	0.19 (0.00, 0.38)		0.16 (-0.04, 0.35)		
Adjusted Relative Risk (95% CI) [2]	2.57 (0.66, 10.02)		4.42 (0.49, 39.65)		
p-value [2]	0.17		0.18		
Interaction test for Treatment*Baseline TSS Group [3]					0.79

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, and baseline TD (yes, no) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.1202: TEAEs of Grade 3 or more by SOC and PT by Age
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.

Data Extracted: CRF data: 25JUN2019

Table 3.1204: TEAEs of Grade 3 or more by SOC and PT by Region
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.

Data Extracted: CRF data: 25JUN2019

Table 3.1207: TEAEs of Grade 3 or more by SOC and PT by Baseline Hemoglobin Level
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.

Data Extracted: CRF data: 25JUN2019

Table 3.1206: TEAEs of Grade 3 or more by SOC and PT by Baseline DIPSS Two-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.

Data Extracted: CRF data: 25JUN2019

Table 3.1205: TEAEs of Grade 3 or more by SOC and PT by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.

Data Extracted: CRF data: 25JUN2019

Table 3.1208: TEAEs of Grade 3 or more by SOC and PT by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.

Data Extracted: CRF data: 25JUN2019

Table 3.1203: TEAEs of Grade 3 or more by SOC and PT by Gender
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.

Table 3.1210: TEAEs of Grade 3 or more by SOC and PT by Baseline Spleen Volume
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.

Data Extracted: CRF data: 25JUN2019

Table 3.1209: TEAEs of Grade 3 or more by SOC and PT by Baseline TSS
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.

Data Extracted: CRF data: 25JUN2019

Table 3.1002: TEAEs of Grade 2 or less by SOC and PT by Age
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Nervous system disorders					
Any Event	12 (50.0%)	4 (44.4%)	20 (47.6%)	3 (10.0%)	
Unadjusted Relative Risk (95% CI)	1.13 (0.49, 2.59)		4.76 (1.55, 14.59)		
p-value [1]	0.78		0.006		
Unadjusted Odds Ratio (95% CI)	1.25 (0.27, 5.83)		8.18 (2.15, 31.18)		
p-value [1]	0.78		0.002		
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.33, 0.44)		0.38 (0.19, 0.56)		
Adjusted Relative Risk (95% CI) [2]	1.46 (0.65, 3.29)		4.55 (1.45, 14.27)		
p-value [2]	0.36		0.009		
Interaction test for Treatment*Age Group [3]					0.074
Metabolism and nutrition disorders					
Any Event	11 (45.8%)	3 (33.3%)	12 (28.6%)	3 (10.0%)	
Unadjusted Relative Risk (95% CI)	1.38 (0.50, 3.82)		2.86 (0.88, 9.25)		
p-value [1]	0.54		0.080		
Unadjusted Odds Ratio (95% CI)	1.69 (0.34, 8.40)		3.60 (0.92, 14.14)		
p-value [1]	0.52		0.066		
Unadjusted Absolute Risk Difference (95% CI)	0.13 (-0.24, 0.49)		0.19 (0.01, 0.36)		
Adjusted Relative Risk (95% CI) [2]	1.38 (0.48, 3.98)		NE		
p-value [2]	0.55		NE		
Interaction test for Treatment*Age Group [3]					0.38

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE. [3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.1002: TEAEs of Grade 2 or less by SOC and PT by Age
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Investigations					
Any Event	8 (33.3%)	1 (11.1%)	9 (21.4%)	2 (6.7%)	
Unadjusted Relative Risk (95% CI)	3.00 (0.43, 20.72)		3.21 (0.75, 13.82)		
p-value [1]	0.27		0.12		
Unadjusted Odds Ratio (95% CI)	4.00 (0.42, 37.78)		3.82 (0.76, 19.16)		
p-value [1]	0.23		0.10		
Unadjusted Absolute Risk Difference (95% CI)	0.22 (-0.06, 0.50)		0.15 (-0.01, 0.30)		
Adjusted Relative Risk (95% CI) [2]	NE		3.34 (0.76, 14.66)		
p-value [2]	NE		0.11		
Interaction test for Treatment*Age Group [3]					0.96

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE. [3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.1004: TEAEs of Grade 2 or less by SOC and PT by Region
Randomized Treatment Phase
SAF-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Nervous system disorders					
Any Event	17 (58.6%)	2 (28.6%)	15 (40.5%)	5 (15.6%)	
Unadjusted Relative Risk (95% CI)	2.05 (0.61, 6.88)		2.59 (1.06, 6.35)		
p-value [1]	0.24		0.037		
Unadjusted Odds Ratio (95% CI)	3.54 (0.59, 21.40)		3.68 (1.16, 11.72)		
p-value [1]	0.17		0.027		
Unadjusted Absolute Risk Difference (95% CI)	0.30 (-0.08, 0.68)		0.25 (0.05, 0.45)		
Adjusted Relative Risk (95% CI) [2]	1.88 (0.64, 5.53)		2.76 (1.11, 6.84)		
p-value [2]	0.25		0.028		
Interaction test for Treatment*Region [3]					0.77
Metabolism and nutrition disorders					
Any Event	12 (41.4%)	3 (42.9%)	11 (29.7%)	3 (9.4%)	
Unadjusted Relative Risk (95% CI)	0.97 (0.37, 2.52)		3.17 (0.97, 10.38)		
p-value [1]	0.94		0.056		
Unadjusted Odds Ratio (95% CI)	0.94 (0.18, 5.00)		4.09 (1.03, 16.29)		
p-value [1]	0.94		0.046		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.42, 0.39)		0.20 (0.02, 0.38)		
Adjusted Relative Risk (95% CI) [2]	0.85 (0.33, 2.17)		3.54 (1.07, 11.72)		
p-value [2]	0.73		0.038		
Interaction test for Treatment*Region [3]					0.17

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE. [3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.1004: TEAEs of Grade 2 or less by SOC and PT by Region
Randomized Treatment Phase
SAF-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Investigations					
Any Event	11 (37.9%)	1 (14.3%)	6 (16.2%)	2 (6.3%)	
Unadjusted Relative Risk (95% CI)	2.66 (0.41, 17.29)		2.59 (0.56, 11.97)		
p-value [1]	0.31		0.22		
Unadjusted Odds Ratio (95% CI)	3.67 (0.39, 34.65)		2.90 (0.54, 15.53)		
p-value [1]	0.26		0.21		
Unadjusted Absolute Risk Difference (95% CI)	0.24 (-0.08, 0.55)		0.10 (-0.05, 0.25)		
Adjusted Relative Risk (95% CI) [2]	NE		NE		
p-value [2]	NE		NE		
Interaction test for Treatment*Region [3]					0.99

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE. [3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.1007: TEAEs of Grade 2 or less by SOC and PT by Baseline Hemoglobin Level
Randomized Treatment Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Nervous system disorders					
Any Event	14 (51.9%)	0	18 (46.2%)	7 (21.2%)	
Unadjusted Relative Risk (95% CI)	7.25 (0.49, 107.32)		2.18 (1.04, 4.56)		
p-value [1]	0.15		0.039		
Unadjusted Odds Ratio (95% CI)	13.96 (0.72, 272.29)		3.18 (1.12, 9.06)		
p-value [1]	0.082		0.030		
Unadjusted Absolute Risk Difference (95% CI)	0.45 (0.18, 0.71)		0.25 (0.04, 0.46)		
Adjusted Relative Risk (95% CI) [2]	NE		2.28 (1.09, 4.76)		
p-value [2]	NE		0.028		
Interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE
Metabolism and nutrition disorders					
Any Event	8 (29.6%)	1 (16.7%)	15 (38.5%)	5 (15.2%)	
Unadjusted Relative Risk (95% CI)	1.78 (0.27, 11.67)		2.54 (1.03, 6.24)		
p-value [1]	0.55		0.042		
Unadjusted Odds Ratio (95% CI)	2.11 (0.21, 21.01)		3.50 (1.11, 11.05)		
p-value [1]	0.53		0.033		
Unadjusted Absolute Risk Difference (95% CI)	0.13 (-0.21, 0.47)		0.23 (0.04, 0.43)		
Adjusted Relative Risk (95% CI) [2]	1.80 (0.26, 12.42)		2.68 (1.13, 6.38)		
p-value [2]	0.55		0.026		
Interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.76

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE. [3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-socpt-gle2-sub-gba.sas V.03.05 Output file: t-ae-socpt-gle2-gba-hgb.pdf 24AUG2023:16:59

Table 3.1007: TEAEs of Grade 2 or less by SOC and PT by Baseline Hemoglobin Level
Randomized Treatment Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Investigations					
Any Event	3 (11.1%)	0	14 (35.9%)	3 (9.1%)	
Unadjusted Relative Risk (95% CI)	1.75 (0.10, 30.11)		3.95 (1.24, 12.57)		
p-value [1]	0.70		0.020		
Unadjusted Odds Ratio (95% CI)	1.86 (0.08, 40.69)		5.60 (1.44, 21.71)		
p-value [1]	0.69		0.013		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.17, 0.28)		0.27 (0.09, 0.45)		
Adjusted Relative Risk (95% CI) [2]	NE		3.77 (1.16, 12.21)		
p-value [2]	NE		0.027		
Interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NE

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE. [3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.1006: TEAEs of Grade 2 or less by SOC and PT by Baseline DIPSS Two-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Nervous system disorders					
Any Event	23 (46.9%)	5 (16.1%)	9 (52.9%)	2 (25.0%)	
Unadjusted Relative Risk (95% CI)	2.91 (1.24, 6.85)		2.12 (0.59, 7.63)		
p-value [1]	0.014		0.25		
Unadjusted Odds Ratio (95% CI)	4.60 (1.52, 13.95)		3.38 (0.52, 21.73)		
p-value [1]	0.007		0.20		
Unadjusted Absolute Risk Difference (95% CI)	0.31 (0.12, 0.50)		0.28 (-0.10, 0.66)		
Adjusted Relative Risk (95% CI) [2]	3.27 (1.37, 7.77)		2.62 (0.73, 9.33)		
p-value [2]	0.007		0.14		
Interaction test for Treatment*Baseline DIPSS 2-Level Risk [3]					0.70
Metabolism and nutrition disorders					
Any Event	19 (38.8%)	4 (12.9%)	4 (23.5%)	2 (25.0%)	
Unadjusted Relative Risk (95% CI)	3.01 (1.13, 8.01)		0.94 (0.22, 4.11)		
p-value [1]	0.028		0.94		
Unadjusted Odds Ratio (95% CI)	4.28 (1.29, 14.15)		0.92 (0.13, 6.51)		
p-value [1]	0.017		0.94		
Unadjusted Absolute Risk Difference (95% CI)	0.26 (0.08, 0.44)		-0.01 (-0.38, 0.35)		
Adjusted Relative Risk (95% CI) [2]	3.46 (1.20, 10.02)		NE		
p-value [2]	0.022		NE		
Interaction test for Treatment*Baseline DIPSS 2-Level Risk [3]					0.30

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE. [3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.1006: TEAEs of Grade 2 or less by SOC and PT by Baseline DIPSS Two-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Investigations					
Any Event	12 (24.5%)	3 (9.7%)	5 (29.4%)	0	
Unadjusted Relative Risk (95% CI)	2.53 (0.78, 8.26)		5.50 (0.34, 88.86)		
p-value [1]	0.12		0.23		
Unadjusted Odds Ratio (95% CI)	3.03 (0.78, 11.76)		7.48 (0.36, 153.80)		
p-value [1]	0.11		0.19		
Unadjusted Absolute Risk Difference (95% CI)	0.15 (-0.01, 0.31)		0.25 (-0.01, 0.51)		
Adjusted Relative Risk (95% CI) [2]	2.00 (0.60, 6.63)		NE		
p-value [2]	0.26		NE		
Interaction test for Treatment*Baseline DIPSS 2-Level Risk [3]					NE

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE. [3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.1005: TEAEs of Grade 2 or less by SOC and PT by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Nervous system disorders				
Any Event	3 (60.0%)	2 (28.6%)	20 (45.5%)	3 (12.5%)
Unadjusted Relative Risk (95% CI)	2.10 (0.53, 8.29)		3.64 (1.20, 11.00)	
p-value [1]	0.29		0.022	
Unadjusted Odds Ratio (95% CI)	3.75 (0.33, 42.47)		5.83 (1.52, 22.44)	
p-value [1]	0.29		0.010	
Unadjusted Absolute Risk Difference (95% CI)	0.31 (-0.23, 0.86)		0.33 (0.13, 0.53)	
Adjusted Relative Risk (95% CI) [2]	NE		4.56 (1.48, 14.06)	
p-value [2]	NE		0.008	
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]				
Metabolism and nutrition disorders				
Any Event	3 (60.0%)	2 (28.6%)	16 (36.4%)	2 (8.3%)
Unadjusted Relative Risk (95% CI)	2.10 (0.53, 8.29)		4.36 (1.09, 17.40)	
p-value [1]	0.29		0.037	
Unadjusted Odds Ratio (95% CI)	3.75 (0.33, 42.47)		6.29 (1.30, 30.29)	
p-value [1]	0.29		0.022	
Unadjusted Absolute Risk Difference (95% CI)	0.31 (-0.23, 0.86)		0.28 (0.10, 0.46)	
Adjusted Relative Risk (95% CI) [2]	NE		6.51 (1.50, 28.25)	
p-value [2]	NE		0.012	
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE. [3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.1005: TEAEs of Grade 2 or less by SOC and PT by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=17)	BAT (N=8)	p-value
Nervous system disorders			
Any Event	9 (52.9%)	2 (25.0%)	
Unadjusted Relative Risk (95% CI)	2.12 (0.59, 7.63)		
p-value [1]	0.25		
Unadjusted Odds Ratio (95% CI)	3.38 (0.52, 21.73)		
p-value [1]	0.20		
Unadjusted Absolute Risk Difference (95% CI)	0.28 (-0.10, 0.66)		
Adjusted Relative Risk (95% CI) [2]	2.62 (0.73, 9.33)		
p-value [2]	0.14		
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]			0.76
Metabolism and nutrition disorders			
Any Event	4 (23.5%)	2 (25.0%)	
Unadjusted Relative Risk (95% CI)	0.94 (0.22, 4.11)		
p-value [1]	0.94		
Unadjusted Odds Ratio (95% CI)	0.92 (0.13, 6.51)		
p-value [1]	0.94		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.38, 0.35)		
Adjusted Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]			0.42

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE. [3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.1005: TEAEs of Grade 2 or less by SOC and PT by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Investigations				
Any Event	2 (40.0%)	1 (14.3%)	10 (22.7%)	2 (8.3%)
Unadjusted Relative Risk (95% CI)	2.80 (0.34, 23.06)		2.73 (0.65, 11.45)	
p-value [1]	0.34		0.17	
Unadjusted Odds Ratio (95% CI)	4.00 (0.25, 63.95)		3.24 (0.65, 16.19)	
p-value [1]	0.33		0.15	
Unadjusted Absolute Risk Difference (95% CI)	0.26 (-0.24, 0.76)		0.14 (-0.02, 0.31)	
Adjusted Relative Risk (95% CI) [2]	NE		2.33 (0.50, 10.77)	
p-value [2]	NE		0.28	
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE. [3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.1005: TEAEs of Grade 2 or less by SOC and PT by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=17)	BAT (N=8)	p-value
Investigations			
Any Event	5 (29.4%)	0	
Unadjusted Relative Risk (95% CI)	5.50 (0.34, 88.86)		
p-value [1]	0.23		
Unadjusted Odds Ratio (95% CI)	7.48 (0.36, 153.80)		
p-value [1]	0.19		
Unadjusted Absolute Risk Difference (95% CI)	0.25 (-0.01, 0.51)		
Adjusted Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]			NE

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE. [3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.1008: TEAEs of Grade 2 or less by SOC and PT by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
Nervous system disorders				
Any Event	23 (51.1%)	4 (17.4%)	5 (38.5%)	1 (12.5%)
Unadjusted Relative Risk (95% CI)	2.94 (1.15, 7.49)		3.08 (0.43, 21.80)	
p-value [1]	0.024		0.26	
Unadjusted Odds Ratio (95% CI)	4.97 (1.46, 16.93)		4.38 (0.41, 47.02)	
p-value [1]	0.010		0.22	
Unadjusted Absolute Risk Difference (95% CI)	0.34 (0.12, 0.55)		0.26 (-0.09, 0.61)	
Adjusted Relative Risk (95% CI) [2]	3.02 (1.19, 7.66)		NE	
p-value [2]	0.020		NE	
Interaction test for Treatment*Myelofibrosis Disease Type [3]				
Metabolism and nutrition disorders				
Any Event	16 (35.6%)	5 (21.7%)	5 (38.5%)	1 (12.5%)
Unadjusted Relative Risk (95% CI)	1.64 (0.69, 3.90)		3.08 (0.43, 21.80)	
p-value [1]	0.27		0.26	
Unadjusted Odds Ratio (95% CI)	1.99 (0.62, 6.36)		4.38 (0.41, 47.02)	
p-value [1]	0.25		0.22	
Unadjusted Absolute Risk Difference (95% CI)	0.14 (-0.08, 0.36)		0.26 (-0.09, 0.61)	
Adjusted Relative Risk (95% CI) [2]	1.72 (0.72, 4.12)		NE	
p-value [2]	0.22		NE	
Interaction test for Treatment*Myelofibrosis Disease Type [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE. [3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.1008: TEAEs of Grade 2 or less by SOC and PT by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=8)	BAT (N=8)	p-value
Nervous system disorders			
Any Event	4 (50.0%)	2 (25.0%)	
Unadjusted Relative Risk (95% CI)	2.00 (0.50, 8.00)		
p-value [1]	0.33		
Unadjusted Odds Ratio (95% CI)	3.00 (0.36, 24.92)		
p-value [1]	0.31		
Unadjusted Absolute Risk Difference (95% CI)	0.25 (-0.21, 0.71)		
Adjusted Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Interaction test for Treatment*Myelofibrosis Disease Type [3]			0.90
Metabolism and nutrition disorders			
Any Event	2 (25.0%)	0	
Unadjusted Relative Risk (95% CI)	5.00 (0.28, 90.19)		
p-value [1]	0.28		
Unadjusted Odds Ratio (95% CI)	6.54 (0.27, 160.98)		
p-value [1]	0.25		
Unadjusted Absolute Risk Difference (95% CI)	0.22 (-0.11, 0.55)		
Adjusted Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Interaction test for Treatment*Myelofibrosis Disease Type [3]			NE

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE. [3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.1008: TEAEs of Grade 2 or less by SOC and PT by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
Investigations				
Any Event	11 (24.4%)	3 (13.0%)	3 (23.1%)	0
Unadjusted Relative Risk (95% CI)	1.87 (0.58, 6.06)		4.50 (0.26, 77.21)	
p-value [1]	0.29		0.30	
Unadjusted Odds Ratio (95% CI)	2.16 (0.54, 8.67)		5.67 (0.26, 125.56)	
p-value [1]	0.28		0.27	
Unadjusted Absolute Risk Difference (95% CI)	0.11 (-0.07, 0.30)		0.19 (-0.08, 0.47)	
Adjusted Relative Risk (95% CI) [2]	1.71 (0.51, 5.69)		NE	
p-value [2]	0.38		NE	
Interaction test for Treatment*Myelofibrosis Disease Type [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE. [3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.1008: TEAEs of Grade 2 or less by SOC and PT by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=8)	BAT (N=8)	p-value
Investigations			
Any Event	3 (37.5%)	0	
Unadjusted Relative Risk (95% CI)	7.00 (0.42, 116.91)		
p-value [1]	0.18		
Unadjusted Odds Ratio (95% CI)	10.82 (0.46, 252.80)		
p-value [1]	0.14		
Unadjusted Absolute Risk Difference (95% CI)	0.33 (-0.02, 0.69)		
Adjusted Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Interaction test for Treatment*Myelofibrosis Disease Type [3]			NE

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE. [3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.1003: TEAEs of Grade 2 or less by SOC and PT by Gender
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Nervous system disorders					
Any Event	26 (50.0%)	1 (5.6%)	6 (42.9%)	6 (28.6%)	
Unadjusted Relative Risk (95% CI)	9.00 (1.31, 61.64)		1.50 (0.61, 3.72)		
p-value [1]	0.025		0.38		
Unadjusted Odds Ratio (95% CI)	17.00 (2.11, 137.28)		1.88 (0.45, 7.76)		
p-value [1]	0.008		0.39		
Unadjusted Absolute Risk Difference (95% CI)	0.44 (0.27, 0.62)		0.14 (-0.18, 0.47)		
Adjusted Relative Risk (95% CI) [2]	8.96 (1.31, 61.41)		NE		
p-value [2]	0.026		NE		
Interaction test for Treatment*Gender [3]					0.039
Metabolism and nutrition disorders					
Any Event	19 (36.5%)	4 (22.2%)	4 (28.6%)	2 (9.5%)	
Unadjusted Relative Risk (95% CI)	1.64 (0.65, 4.19)		3.00 (0.63, 14.23)		
p-value [1]	0.30		0.17		
Unadjusted Odds Ratio (95% CI)	2.02 (0.58, 7.01)		3.80 (0.59, 24.46)		
p-value [1]	0.27		0.16		
Unadjusted Absolute Risk Difference (95% CI)	0.14 (-0.09, 0.38)		0.19 (-0.08, 0.46)		
Adjusted Relative Risk (95% CI) [2]	1.68 (0.66, 4.26)		NE		
p-value [2]	0.27		NE		
Interaction test for Treatment*Gender [3]					0.51

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE. [3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.1003: TEAEs of Grade 2 or less by SOC and PT by Gender
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Investigations					
Any Event	16 (30.8%)	2 (11.1%)	1 (7.1%)	1 (4.8%)	
Unadjusted Relative Risk (95% CI)	2.77 (0.70, 10.88)		1.50 (0.10, 22.06)		
p-value [1]	0.14		0.77		
Unadjusted Odds Ratio (95% CI)	3.56 (0.73, 17.32)		1.54 (0.09, 26.82)		
p-value [1]	0.12		0.77		
Unadjusted Absolute Risk Difference (95% CI)	0.20 (0.00, 0.39)		0.02 (-0.14, 0.19)		
Adjusted Relative Risk (95% CI) [2]	2.86 (0.69, 11.85)		NE		
p-value [2]	0.15		NE		
Interaction test for Treatment*Gender [3]					0.70

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE. [3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.1010: TEAEs of Grade 2 or less by SOC and PT by Baseline Spleen Volume
Randomized Treatment Phase
SAF-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Nervous system disorders					
Any Event	14 (50.0%)	6 (25.0%)	18 (47.4%)	1 (6.7%)	
Unadjusted Relative Risk (95% CI)	2.00 (0.91, 4.39)		7.11 (1.04, 48.61)		
p-value [1]	0.084		0.046		
Unadjusted Odds Ratio (95% CI)	3.00 (0.92, 9.80)		12.60 (1.50, 105.64)		
p-value [1]	0.069		0.020		
Unadjusted Absolute Risk Difference (95% CI)	0.25 (0.00, 0.50)		0.41 (0.20, 0.61)		
Adjusted Relative Risk (95% CI) [2]	2.06 (0.94, 4.54)		8.39 (1.03, 68.22)		
p-value [2]	0.072		0.047		
Interaction test for Treatment*Baseline Spleen Volume Group [3]					0.13
Metabolism and nutrition disorders					
Any Event	10 (35.7%)	5 (20.8%)	13 (34.2%)	1 (6.7%)	
Unadjusted Relative Risk (95% CI)	1.71 (0.68, 4.32)		5.13 (0.73, 35.86)		
p-value [1]	0.25		0.099		
Unadjusted Odds Ratio (95% CI)	2.11 (0.60, 7.38)		7.28 (0.86, 61.67)		
p-value [1]	0.24		0.069		
Unadjusted Absolute Risk Difference (95% CI)	0.15 (-0.09, 0.39)		0.28 (0.08, 0.47)		
Adjusted Relative Risk (95% CI) [2]	1.92 (0.77, 4.82)		6.66 (1.21, 36.76)		
p-value [2]	0.16		0.030		
Interaction test for Treatment*Baseline Spleen Volume Group [3]					0.24

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE. [3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.1010: TEAEs of Grade 2 or less by SOC and PT by Baseline Spleen Volume
Randomized Treatment Phase
SAF-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Investigations					
Any Event	5 (17.9%)	3 (12.5%)	12 (31.6%)	0	
Unadjusted Relative Risk (95% CI)	1.43 (0.38, 5.37)		10.26 (0.65, 163.06)		
p-value [1]	0.60		0.099		
Unadjusted Odds Ratio (95% CI)	1.52 (0.32, 7.16)		14.62 (0.81, 264.53)		
p-value [1]	0.60		0.069		
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.14, 0.25)		0.29 (0.12, 0.46)		
Adjusted Relative Risk (95% CI) [2]	1.37 (0.40, 4.71)		NE		
p-value [2]	0.61		NE		
Interaction test for Treatment*Baseline Spleen Volume Group [3]					NE

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE. [3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.1009: TEAEs of Grade 2 or less by SOC and PT by Baseline TSS
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Nervous system disorders					
Any Event	20 (47.6%)	3 (15.0%)	12 (50.0%)	4 (21.1%)	
Unadjusted Relative Risk (95% CI)	3.17 (1.07, 9.45)		2.38 (0.91, 6.19)		
p-value [1]	0.038		0.077		
Unadjusted Odds Ratio (95% CI)	5.15 (1.31, 20.25)		3.75 (0.96, 14.65)		
p-value [1]	0.019		0.057		
Unadjusted Absolute Risk Difference (95% CI)	0.33 (0.11, 0.54)		0.29 (0.02, 0.56)		
Adjusted Relative Risk (95% CI) [2]	3.15 (1.06, 9.37)		2.36 (0.89, 6.26)		
p-value [2]	0.040		0.085		
Interaction test for Treatment*Baseline TSS Group [3]					0.69
Metabolism and nutrition disorders					
Any Event	14 (33.3%)	2 (10.0%)	9 (37.5%)	4 (21.1%)	
Unadjusted Relative Risk (95% CI)	3.33 (0.84, 13.28)		1.78 (0.65, 4.90)		
p-value [1]	0.088		0.26		
Unadjusted Odds Ratio (95% CI)	4.50 (0.91, 22.19)		2.25 (0.57, 8.93)		
p-value [1]	0.065		0.25		
Unadjusted Absolute Risk Difference (95% CI)	0.23 (0.04, 0.43)		0.16 (-0.10, 0.43)		
Adjusted Relative Risk (95% CI) [2]	3.35 (0.80, 13.99)		1.76 (0.62, 4.95)		
p-value [2]	0.098		0.29		
Interaction test for Treatment*Baseline TSS Group [3]					0.46

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, and baseline TD (yes, no) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.1009: TEAEs of Grade 2 or less by SOC and PT by Baseline TSS
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Investigations					
Any Event	12 (28.6%)	2 (10.0%)	5 (20.8%)	1 (5.3%)	
Unadjusted Relative Risk (95% CI)	2.86 (0.71, 11.58)		3.96 (0.50, 31.09)		
p-value [1]	0.14		0.19		
Unadjusted Odds Ratio (95% CI)	3.60 (0.72, 17.96)		4.74 (0.50, 44.57)		
p-value [1]	0.12		0.17		
Unadjusted Absolute Risk Difference (95% CI)	0.19 (0.00, 0.38)		0.16 (-0.04, 0.35)		
Adjusted Relative Risk (95% CI) [2]	2.57 (0.66, 10.02)		4.42 (0.49, 39.65)		
p-value [2]	0.17		0.18		
Interaction test for Treatment*Baseline TSS Group [3]					0.79

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03. Multiple AEs were counted only once per subject for each SOC and PT.
SOCs, and then PTs within a SOC were presented by descending order of the frequencies under "MMB" column.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, and baseline TD (yes, no) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.3502: Serious TEAEs by SOC and PT by Age
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 25JUN2019

Table 3.3504: Serious TEAEs by SOC and PT by Region
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 25JUN2019

Table 3.3507: Serious TEAEs by SOC and PT by Baseline Hemoglobin Level
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 25JUN2019

Table 3.3506: Serious TEAEs by SOC and PT by Baseline DIPSS Two-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.

Table 3.3505: Serious TEAEs by SOC and PT by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 25JUN2019

Table 3.3508: Serious TEAEs by SOC and PT by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 25JUN2019

Table 3.3503: Serious TEAEs by SOC and PT by Gender
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 25JUN2019

Table 3.3510: Serious TEAEs by SOC and PT by Baseline Spleen Volume
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 25JUN2019

Table 3.3509: Serious TEAEs by SOC and PT by Baseline TSS
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; PT = Preferred Term. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 25JUN2019

Table 3.3802: Any TE AESI by Age
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Number of subjects, n(%)	24 (100.0%)	7 (77.8%)	41 (97.6%)	27 (90.0%)	
Unadjusted Relative Risk (95% CI)	1.31 (0.91, 1.88)		1.08 (0.95, 1.23)		
p-value [1]	0.15		0.21		
Unadjusted Odds Ratio (95% CI)	16.33 (0.70, 379.12)		4.56 (0.45, 46.11)		
p-value [1]	0.082		0.20		
Unadjusted Absolute Risk Difference (95% CI)	0.23 (-0.04, 0.50)		0.08 (-0.04, 0.19)		
Adjusted Relative Risk (95% CI) [2]	1.24 (0.91, 1.69)		1.07 (0.92, 1.24)		
p-value [2]	0.16		0.40		
Interaction test for Treatment*Age Group [3]					0.35

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.3804: Any TE AESI by Region
Randomized Treatment Phase
SAF-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Number of subjects, n(%)	28 (96.6%)	5 (71.4%)	37 (100.0%)	29 (90.6%)	
Unadjusted Relative Risk (95% CI)	1.35 (0.84, 2.17)		1.10 (0.98, 1.25)		
p-value [1]	0.21		0.12		
Unadjusted Odds Ratio (95% CI)	11.20 (0.85, 148.14)		8.90 (0.44, 179.13)		
p-value [1]	0.067		0.15		
Unadjusted Absolute Risk Difference (95% CI)	0.25 (-0.09, 0.59)		0.09 (-0.02, 0.20)		
Adjusted Relative Risk (95% CI) [2]	1.34 (0.81, 2.22)		1.09 (0.99, 1.20)		
p-value [2]	0.25		0.083		
Interaction test for Treatment*Region [3]					0.39

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.3807: Any TE AESI by Baseline Hemoglobin Level
Randomized Treatment Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Number of subjects, n(%)	27 (100.0%)	4 (66.7%)	38 (97.4%)	30 (90.9%)	
Unadjusted Relative Risk (95% CI)	1.53 (0.88, 2.66)		1.07 (0.95, 1.21)		
p-value [1]	0.13		0.25		
Unadjusted Odds Ratio (95% CI)	30.56 (1.25, 746.47)		3.80 (0.38, 38.41)		
p-value [1]	0.036		0.26		
Unadjusted Absolute Risk Difference (95% CI)	0.34 (-0.02, 0.70)		0.07 (-0.04, 0.18)		
Adjusted Relative Risk (95% CI) [2]	1.50 (0.85, 2.64)		1.07 (0.94, 1.21)		
p-value [2]	0.16		0.29		
Interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.22

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-aesi-sub-gba.sas V.03.05 Output file: t-aesum-aesi-gba-hgb.pdf 24AUG2023:16:56

Table 3.3806: Any TE AESI by Baseline DIPSS Two-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Number of subjects, n(%)	49 (100.0%)	28 (90.3%)	16 (94.1%)	6 (75.0%)	
Unadjusted Relative Risk (95% CI)	1.11 (0.98, 1.26)		1.25 (0.83, 1.90)		
p-value [1]	0.096		0.29		
Unadjusted Odds Ratio (95% CI)	12.16 (0.61, 243.92)		5.33 (0.41, 70.20)		
p-value [1]	0.10		0.20		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.01, 0.21)		0.19 (-0.13, 0.51)		
Adjusted Relative Risk (95% CI) [2]	1.09 (0.99, 1.20)		1.23 (0.85, 1.78)		
p-value [2]	0.091		0.27		
Interaction test for Treatment*Baseline DIPSS 2-Level Risk [3]					0.56

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.3805: Any TE AESI by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Number of subjects, n(%)	5 (100.0%)	6 (85.7%)	44 (100.0%)	22 (91.7%)
Unadjusted Relative Risk (95% CI)	1.13 (0.75, 1.70)		1.10 (0.96, 1.26)	
p-value [1]	0.57		0.17	
Unadjusted Odds Ratio (95% CI)	2.54 (0.09, 75.77)		9.89 (0.46, 214.83)	
p-value [1]	0.59		0.14	
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.25, 0.45)		0.09 (-0.03, 0.21)	
Adjusted Relative Risk (95% CI) [2]	1.00 (1.00, 1.00)		1.05 (0.98, 1.14)	
p-value [2]	>0.99		0.17	
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.3805: Any TE AESI by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=17)	BAT (N=8)	p-value
Number of subjects, n(%)	16 (94.1%)	6 (75.0%)	
Unadjusted Relative Risk (95% CI)	1.25 (0.83, 1.90)		
p-value [1]	0.29		
Unadjusted Odds Ratio (95% CI)	5.33 (0.41, 70.20)		
p-value [1]	0.20		
Unadjusted Absolute Risk Difference (95% CI)	0.19 (-0.13, 0.51)		
Adjusted Relative Risk (95% CI) [2]	1.23 (0.85, 1.78)		
p-value [2]	0.27		
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]			0.76

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.3808: Any TE AESI by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
Number of subjects, n(%)	45 (100.0%)	21 (91.3%)	12 (92.3%)	6 (75.0%)
Unadjusted Relative Risk (95% CI)	1.10 (0.96, 1.27)		1.23 (0.80, 1.89)	
p-value [1]	0.16		0.34	
Unadjusted Odds Ratio (95% CI)	10.58 (0.49, 230.11)		4.00 (0.30, 53.47)	
p-value [1]	0.13		0.29	
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.03, 0.22)		0.17 (-0.16, 0.51)	
Adjusted Relative Risk (95% CI) [2]	1.10 (0.97, 1.25)		1.07 (0.68, 1.67)	
p-value [2]	0.15		0.78	
Interaction test for Treatment*Myelofibrosis Disease Type [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.3808: Any TE AESI by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=8)	BAT (N=8)	p-value
Number of subjects, n(%)	8 (100.0%)	7 (87.5%)	
Unadjusted Relative Risk (95% CI)	1.13 (0.81, 1.58)		
p-value [1]	0.46		
Unadjusted Odds Ratio (95% CI)	3.40 (0.12, 96.71)		
p-value [1]	0.47		
Unadjusted Absolute Risk Difference (95% CI)	0.11 (-0.17, 0.40)		
Adjusted Relative Risk (95% CI) [2]	1.00 (1.00, 1.00)		
p-value [2]	>0.99		
Interaction test for Treatment*Myelofibrosis Disease Type [3]			0.85

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.3803: Any TE AESI by Gender
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Number of subjects, n(%)	51 (98.1%)	15 (83.3%)	14 (100.0%)	19 (90.5%)	
Unadjusted Relative Risk (95% CI)	1.18 (0.95, 1.45)		1.09 (0.91, 1.30)		
p-value [1]	0.13		0.34		
Unadjusted Odds Ratio (95% CI)	10.20 (0.99, 105.39)		3.72 (0.17, 83.49)		
p-value [1]	0.051		0.41		
Unadjusted Absolute Risk Difference (95% CI)	0.15 (-0.03, 0.32)		0.08 (-0.08, 0.24)		
Adjusted Relative Risk (95% CI) [2]	1.17 (0.95, 1.45)		1.03 (0.97, 1.09)		
p-value [2]	0.15		0.40		
Interaction test for Treatment*Gender [3]					0.62

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.3810: Any TE AESI by Baseline Spleen Volume
Randomized Treatment Phase
SAF-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Number of subjects, n(%)	27 (96.4%)	21 (87.5%)	38 (100.0%)	13 (86.7%)	
Unadjusted Relative Risk (95% CI)	1.10 (0.93, 1.30)		1.17 (0.94, 1.45)		
p-value [1]	0.25		0.15		
Unadjusted Odds Ratio (95% CI)	3.86 (0.37, 39.80)		14.26 (0.64, 316.23)		
p-value [1]	0.26		0.093		
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.06, 0.24)		0.14 (-0.04, 0.32)		
Adjusted Relative Risk (95% CI) [2]	1.10 (0.94, 1.30)		1.13 (0.94, 1.35)		
p-value [2]	0.23		0.19		
Interaction test for Treatment*Baseline Spleen Volume Group [3]					0.73

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.3809: Any TE AESI by Baseline TSS
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Number of subjects, n(%)	42 (100.0%)	17 (85.0%)	23 (95.8%)	17 (89.5%)	
Unadjusted Relative Risk (95% CI)	1.19 (0.98, 1.44)		1.07 (0.90, 1.28)		
p-value [1]	0.085		0.44		
Unadjusted Odds Ratio (95% CI)	17.00 (0.83, 346.64)		2.71 (0.23, 32.34)		
p-value [1]	0.066		0.43		
Unadjusted Absolute Risk Difference (95% CI)	0.16 (-0.01, 0.32)		0.06 (-0.10, 0.22)		
Adjusted Relative Risk (95% CI) [2]	1.17 (0.98, 1.41)		1.06 (0.88, 1.27)		
p-value [2]	0.086		0.54		
Interaction test for Treatment*Baseline TSS Group [3]					0.47

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-aesi-sub-gba.sas V.03.05 Output file: t-aesum-aesi-gba-tss.pdf 24AUG2023:16:56

Table 3.4002: Any TE AESI of Grade 3 or more by Age
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Number of subjects, n(%)	14 (58.3%)	2 (22.2%)	16 (38.1%)	12 (40.0%)	
Unadjusted Relative Risk (95% CI)	2.63 (0.74, 9.33)		0.95 (0.53, 1.71)		
p-value [1]	0.14		0.87		
Unadjusted Odds Ratio (95% CI)	4.90 (0.84, 28.73)		0.92 (0.35, 2.41)		
p-value [1]	0.078		0.87		
Unadjusted Absolute Risk Difference (95% CI)	0.36 (0.03, 0.70)		-0.02 (-0.25, 0.21)		
Adjusted Relative Risk (95% CI) [2]	2.58 (0.72, 9.26)		0.87 (0.50, 1.51)		
p-value [2]	0.14		0.62		
Interaction test for Treatment*Age Group [3]					0.097

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.4004: Any TE AESI of Grade 3 or more by Region
Randomized Treatment Phase
SAF-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Number of subjects, n(%)	9 (31.0%)	1 (14.3%)	21 (56.8%)	13 (40.6%)	
Unadjusted Relative Risk (95% CI)	2.17 (0.33, 14.44)		1.40 (0.84, 2.31)		
p-value [1]	0.42		0.19		
Unadjusted Odds Ratio (95% CI)	2.70 (0.28, 25.84)		1.92 (0.73, 5.01)		
p-value [1]	0.39		0.18		
Unadjusted Absolute Risk Difference (95% CI)	0.17 (-0.14, 0.48)		0.16 (-0.07, 0.39)		
Adjusted Relative Risk (95% CI) [2]	NE		1.44 (0.87, 2.38)		
p-value [2]	NE		0.15		
Interaction test for Treatment*Region [3]					0.61

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.4007: Any TE AESI of Grade 3 or more by Baseline Hemoglobin Level
Randomized Treatment Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Number of subjects, n(%)	12 (44.4%)	2 (33.3%)	18 (46.2%)	12 (36.4%)	
Unadjusted Relative Risk (95% CI)	1.33 (0.40, 4.46)		1.27 (0.72, 2.23)		
p-value [1]	0.64		0.41		
Unadjusted Odds Ratio (95% CI)	1.60 (0.25, 10.27)		1.50 (0.58, 3.87)		
p-value [1]	0.62		0.40		
Unadjusted Absolute Risk Difference (95% CI)	0.11 (-0.31, 0.53)		0.10 (-0.13, 0.32)		
Adjusted Relative Risk (95% CI) [2]	1.41 (0.49, 4.03)		1.33 (0.76, 2.34)		
p-value [2]	0.52		0.32		
Interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.94

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.4006: Any TE AESI of Grade 3 or more by Baseline DIPSS Two-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Number of subjects, n(%)	21 (42.9%)	8 (25.8%)	9 (52.9%)	6 (75.0%)	
Unadjusted Relative Risk (95% CI)	1.66 (0.84, 3.27)		0.71 (0.39, 1.29)		
p-value [1]	0.14		0.26		
Unadjusted Odds Ratio (95% CI)	2.16 (0.81, 5.77)		0.38 (0.06, 2.41)		
p-value [1]	0.13		0.30		
Unadjusted Absolute Risk Difference (95% CI)	0.17 (-0.04, 0.38)		-0.22 (-0.60, 0.16)		
Adjusted Relative Risk (95% CI) [2]	1.77 (0.88, 3.55)		0.64 (0.35, 1.17)		
p-value [2]	0.11		0.14		
Interaction test for Treatment*Baseline DIPSS 2-Level Risk [3]					0.069

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.4005: Any TE AESI of Grade 3 or more by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Number of subjects, n(%)	2 (40.0%)	1 (14.3%)	19 (43.2%)	7 (29.2%)
Unadjusted Relative Risk (95% CI)	2.80 (0.34, 23.06)		1.48 (0.73, 3.01)	
p-value [1]	0.34		0.28	
Unadjusted Odds Ratio (95% CI)	4.00 (0.25, 63.95)		1.85 (0.64, 5.35)	
p-value [1]	0.33		0.26	
Unadjusted Absolute Risk Difference (95% CI)	0.26 (-0.24, 0.76)		0.14 (-0.09, 0.37)	
Adjusted Relative Risk (95% CI) [2]	NE		1.62 (0.77, 3.42)	
p-value [2]	NE		0.20	
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.4005: Any TE AESI of Grade 3 or more by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=17)	BAT (N=8)	p-value
Number of subjects, n(%)	9 (52.9%)	6 (75.0%)	
Unadjusted Relative Risk (95% CI)	0.71 (0.39, 1.29)		
p-value [1]	0.26		
Unadjusted Odds Ratio (95% CI)	0.38 (0.06, 2.41)		
p-value [1]	0.30		
Unadjusted Absolute Risk Difference (95% CI)	-0.22 (-0.60, 0.16)		
Adjusted Relative Risk (95% CI) [2]	0.64 (0.35, 1.17)		
p-value [2]	0.14		
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]			0.19

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.4008: Any TE AESI of Grade 3 or more by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
Number of subjects, n(%)	20 (44.4%)	9 (39.1%)	6 (46.2%)	2 (25.0%)
Unadjusted Relative Risk (95% CI)	1.14 (0.62, 2.08)		1.85 (0.49, 7.02)	
p-value [1]	0.68		0.37	
Unadjusted Odds Ratio (95% CI)	1.24 (0.45, 3.46)		2.57 (0.37, 17.83)	
p-value [1]	0.68		0.34	
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.19, 0.30)		0.21 (-0.19, 0.62)	
Adjusted Relative Risk (95% CI) [2]	1.15 (0.62, 2.12)		NE	
p-value [2]	0.66		NE	
Interaction test for Treatment*Myelofibrosis Disease Type [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.4008: Any TE AESI of Grade 3 or more by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=8)	BAT (N=8)	p-value
Number of subjects, n(%)	4 (50.0%)	3 (37.5%)	
Unadjusted Relative Risk (95% CI)	1.33 (0.43, 4.13)		
p-value [1]	0.62		
Unadjusted Odds Ratio (95% CI)	1.67 (0.23, 12.22)		
p-value [1]	0.62		
Unadjusted Absolute Risk Difference (95% CI)	0.13 (-0.36, 0.61)		
Adjusted Relative Risk (95% CI) [2]	1.47 (0.58, 3.72)		
p-value [2]	0.42		
Interaction test for Treatment*Myelofibrosis Disease Type [3]			0.78

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.4003: Any TE AESI of Grade 3 or more by Gender
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Number of subjects, n(%)	26 (50.0%)	7 (38.9%)	4 (28.6%)	7 (33.3%)	
Unadjusted Relative Risk (95% CI)	1.29 (0.68, 2.44)		0.86 (0.31, 2.39)		
p-value [1]	0.44		0.77		
Unadjusted Odds Ratio (95% CI)	1.57 (0.53, 4.69)		0.80 (0.18, 3.49)		
p-value [1]	0.42		0.77		
Unadjusted Absolute Risk Difference (95% CI)	0.11 (-0.15, 0.37)		-0.05 (-0.36, 0.26)		
Adjusted Relative Risk (95% CI) [2]	1.28 (0.68, 2.41)		0.87 (0.34, 2.23)		
p-value [2]	0.45		0.77		
Interaction test for Treatment*Gender [3]					0.50

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.4010: Any TE AESI of Grade 3 or more by Baseline Spleen Volume
Randomized Treatment Phase
SAF-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Number of subjects, n(%)	7 (25.0%)	7 (29.2%)	23 (60.5%)	7 (46.7%)	
Unadjusted Relative Risk (95% CI)	0.86 (0.35, 2.10)		1.30 (0.71, 2.36)		
p-value [1]	0.74		0.39		
Unadjusted Odds Ratio (95% CI)	0.81 (0.24, 2.76)		1.75 (0.53, 5.85)		
p-value [1]	0.74		0.36		
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.28, 0.20)		0.14 (-0.16, 0.44)		
Adjusted Relative Risk (95% CI) [2]	0.99 (0.42, 2.36)		1.27 (0.69, 2.35)		
p-value [2]	0.98		0.45		
Interaction test for Treatment*Baseline Spleen Volume Group [3]					0.45

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.4009: Any TE AESI of Grade 3 or more by Baseline TSS
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Number of subjects, n(%)	17 (40.5%)	6 (30.0%)	13 (54.2%)	8 (42.1%)	
Unadjusted Relative Risk (95% CI)	1.35 (0.63, 2.89)		1.29 (0.68, 2.45)		
p-value [1]	0.44		0.44		
Unadjusted Odds Ratio (95% CI)	1.59 (0.51, 4.95)		1.63 (0.48, 5.47)		
p-value [1]	0.43		0.43		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.14, 0.35)		0.12 (-0.18, 0.42)		
Adjusted Relative Risk (95% CI) [2]	1.42 (0.66, 3.07)		1.21 (0.64, 2.28)		
p-value [2]	0.38		0.55		
Interaction test for Treatment*Baseline TSS Group [3]					0.93

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, and baseline TD (yes, no) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.3902: Any TE AESI of Grade 2 or less by Age
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Number of subjects, n(%)	23 (95.8%)	7 (77.8%)	41 (97.6%)	27 (90.0%)	
Unadjusted Relative Risk (95% CI)	1.23 (0.86, 1.76)		1.08 (0.95, 1.23)		
p-value [1]	0.25		0.21		
Unadjusted Odds Ratio (95% CI)	6.57 (0.52, 83.76)		4.56 (0.45, 46.11)		
p-value [1]	0.15		0.20		
Unadjusted Absolute Risk Difference (95% CI)	0.18 (-0.10, 0.46)		0.08 (-0.04, 0.19)		
Adjusted Relative Risk (95% CI) [2]	1.21 (0.88, 1.67)		1.07 (0.92, 1.24)		
p-value [2]	0.23		0.40		
Interaction test for Treatment*Age Group [3]					0.50

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.3904: Any TE AESI of Grade 2 or less by Region
Randomized Treatment Phase
SAF-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Number of subjects, n(%)	28 (96.6%)	5 (71.4%)	36 (97.3%)	29 (90.6%)	
Unadjusted Relative Risk (95% CI)	1.35 (0.84, 2.17)		1.07 (0.95, 1.22)		
p-value [1]	0.21		0.26		
Unadjusted Odds Ratio (95% CI)	11.20 (0.85, 148.14)		3.72 (0.37, 37.72)		
p-value [1]	0.067		0.27		
Unadjusted Absolute Risk Difference (95% CI)	0.25 (-0.09, 0.59)		0.07 (-0.05, 0.18)		
Adjusted Relative Risk (95% CI) [2]	1.34 (0.81, 2.22)		1.07 (0.96, 1.19)		
p-value [2]	0.25		0.25		
Interaction test for Treatment*Region [3]					0.33

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-aesi-sub-gba.sas V.03.05 Output file: t-aesum-aesi-gle2-gba-geo.pdf 24AUG2023:16:56

Table 3.3907: Any TE AESI of Grade 2 or less by Baseline Hemoglobin Level
Randomized Treatment Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Number of subjects, n(%)	26 (96.3%)	4 (66.7%)	38 (97.4%)	30 (90.9%)	
Unadjusted Relative Risk (95% CI)	1.44 (0.82, 2.56)		1.07 (0.95, 1.21)		
p-value [1]	0.21		0.25		
Unadjusted Odds Ratio (95% CI)	13.00 (0.95, 178.77)		3.80 (0.38, 38.41)		
p-value [1]	0.055		0.26		
Unadjusted Absolute Risk Difference (95% CI)	0.30 (-0.09, 0.68)		0.07 (-0.04, 0.18)		
Adjusted Relative Risk (95% CI) [2]	1.45 (0.82, 2.57)		1.07 (0.94, 1.21)		
p-value [2]	0.20		0.29		
Interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.28

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.3906: Any TE AESI of Grade 2 or less by Baseline DIPSS Two-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Number of subjects, n(%)	48 (98.0%)	28 (90.3%)	16 (94.1%)	6 (75.0%)	
Unadjusted Relative Risk (95% CI)	1.08 (0.96, 1.23)		1.25 (0.83, 1.90)		
p-value [1]	0.19		0.29		
Unadjusted Odds Ratio (95% CI)	5.14 (0.51, 51.85)		5.33 (0.41, 70.20)		
p-value [1]	0.16		0.20		
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.03, 0.19)		0.19 (-0.13, 0.51)		
Adjusted Relative Risk (95% CI) [2]	1.07 (0.97, 1.18)		1.23 (0.85, 1.78)		
p-value [2]	0.19		0.27		
Interaction test for Treatment*Baseline DIPSS 2-Level Risk [3]					0.50

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.3905: Any TE AESI of Grade 2 or less by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Number of subjects, n(%)	5 (100.0%)	6 (85.7%)	43 (97.7%)	22 (91.7%)
Unadjusted Relative Risk (95% CI)	1.13 (0.75, 1.70)		1.07 (0.94, 1.21)	
p-value [1]	0.57		0.33	
Unadjusted Odds Ratio (95% CI)	2.54 (0.09, 75.77)		3.91 (0.34, 45.52)	
p-value [1]	0.59		0.28	
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.25, 0.45)		0.06 (-0.06, 0.18)	
Adjusted Relative Risk (95% CI) [2]	1.00 (1.00, 1.00)		1.04 (0.95, 1.13)	
p-value [2]	>0.99		0.40	
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.3905: Any TE AESI of Grade 2 or less by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=17)	BAT (N=8)	p-value
Number of subjects, n(%)	16 (94.1%)	6 (75.0%)	
Unadjusted Relative Risk (95% CI)	1.25 (0.83, 1.90)		
p-value [1]	0.29		
Unadjusted Odds Ratio (95% CI)	5.33 (0.41, 70.20)		
p-value [1]	0.20		
Unadjusted Absolute Risk Difference (95% CI)	0.19 (-0.13, 0.51)		
Adjusted Relative Risk (95% CI) [2]	1.23 (0.85, 1.78)		
p-value [2]	0.27		
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]			0.68

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.3908: Any TE AESI of Grade 2 or less by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
Number of subjects, n(%)	45 (100.0%)	21 (91.3%)	11 (84.6%)	6 (75.0%)
Unadjusted Relative Risk (95% CI)	1.10 (0.96, 1.27)		1.13 (0.71, 1.79)	
p-value [1]	0.16		0.61	
Unadjusted Odds Ratio (95% CI)	10.58 (0.49, 230.11)		1.83 (0.20, 16.51)	
p-value [1]	0.13		0.59	
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.03, 0.22)		0.10 (-0.26, 0.45)	
Adjusted Relative Risk (95% CI) [2]	1.10 (0.97, 1.25)		0.99 (0.62, 1.57)	
p-value [2]	0.15		0.95	
Interaction test for Treatment*Myelofibrosis Disease Type [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.3908: Any TE AESI of Grade 2 or less by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=8)	BAT (N=8)	p-value
Number of subjects, n(%)	8 (100.0%)	7 (87.5%)	
Unadjusted Relative Risk (95% CI)	1.13 (0.81, 1.58)		
p-value [1]	0.46		
Unadjusted Odds Ratio (95% CI)	3.40 (0.12, 96.71)		
p-value [1]	0.47		
Unadjusted Absolute Risk Difference (95% CI)	0.11 (-0.17, 0.40)		
Adjusted Relative Risk (95% CI) [2]	1.00 (1.00, 1.00)		
p-value [2]	>0.99		
Interaction test for Treatment*Myelofibrosis Disease Type [3]			0.96

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.3903: Any TE AESI of Grade 2 or less by Gender
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Number of subjects, n(%)	50 (96.2%)	15 (83.3%)	14 (100.0%)	19 (90.5%)	
Unadjusted Relative Risk (95% CI)	1.15 (0.93, 1.43)		1.09 (0.91, 1.30)		
p-value [1]	0.19		0.34		
Unadjusted Odds Ratio (95% CI)	5.00 (0.76, 32.77)		3.72 (0.17, 83.49)		
p-value [1]	0.093		0.41		
Unadjusted Absolute Risk Difference (95% CI)	0.13 (-0.05, 0.31)		0.08 (-0.08, 0.24)		
Adjusted Relative Risk (95% CI) [2]	1.15 (0.93, 1.43)		1.03 (0.97, 1.09)		
p-value [2]	0.21		0.40		
Interaction test for Treatment*Gender [3]					0.74

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.3910: Any TE AESI of Grade 2 or less by Baseline Spleen Volume
Randomized Treatment Phase
SAF-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Number of subjects, n(%)	27 (96.4%)	21 (87.5%)	37 (97.4%)	13 (86.7%)	
Unadjusted Relative Risk (95% CI)	1.10 (0.93, 1.30)		1.12 (0.91, 1.38)		
p-value [1]	0.25		0.27		
Unadjusted Odds Ratio (95% CI)	3.86 (0.37, 39.80)		5.69 (0.48, 68.13)		
p-value [1]	0.26		0.17		
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.06, 0.24)		0.11 (-0.07, 0.29)		
Adjusted Relative Risk (95% CI) [2]	1.10 (0.94, 1.30)		1.11 (0.92, 1.33)		
p-value [2]	0.23		0.27		
Interaction test for Treatment*Baseline Spleen Volume Group [3]					0.89

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.3909: Any TE AESI of Grade 2 or less by Baseline TSS
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Number of subjects, n(%)	41 (97.6%)	17 (85.0%)	23 (95.8%)	17 (89.5%)	
Unadjusted Relative Risk (95% CI)	1.15 (0.95, 1.39)		1.07 (0.90, 1.28)		
p-value [1]	0.15		0.44		
Unadjusted Odds Ratio (95% CI)	7.24 (0.70, 74.57)		2.71 (0.23, 32.34)		
p-value [1]	0.096		0.43		
Unadjusted Absolute Risk Difference (95% CI)	0.13 (-0.04, 0.29)		0.06 (-0.10, 0.22)		
Adjusted Relative Risk (95% CI) [2]	1.15 (0.95, 1.39)		1.06 (0.88, 1.27)		
p-value [2]	0.15		0.54		
Interaction test for Treatment*Baseline TSS Group [3]					0.60

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest. Adverse events were mapped according to MedDRA Version 22.0.
Severity grades were defined by CTCAE Version 4.03.
[1] p-values were obtained from a Z-test. [2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, and baseline TD (yes, no) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.4102: Any Serious TE AESI by Age
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Number of subjects, n(%)	8 (33.3%)	2 (22.2%)	13 (31.0%)	7 (23.3%)	
Unadjusted Relative Risk (95% CI)	1.50 (0.39, 5.77)		1.33 (0.60, 2.92)		
p-value [1]	0.56		0.48		
Unadjusted Odds Ratio (95% CI)	1.75 (0.29, 10.44)		1.47 (0.51, 4.29)		
p-value [1]	0.54		0.48		
Unadjusted Absolute Risk Difference (95% CI)	0.11 (-0.22, 0.44)		0.08 (-0.13, 0.28)		
Adjusted Relative Risk (95% CI) [2]	1.26 (0.32, 5.04)		NE		
p-value [2]	0.74		NE		
Interaction test for Treatment*Age Group [3]					0.88

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.4104: Any Serious TE AESI by Region
Randomized Treatment Phase
SAF-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Number of subjects, n(%)	5 (17.2%)	0	16 (43.2%)	9 (28.1%)	
Unadjusted Relative Risk (95% CI)	2.93 (0.18, 47.67)		1.54 (0.79, 2.99)		
p-value [1]	0.45		0.21		
Unadjusted Odds Ratio (95% CI)	3.37 (0.17, 68.21)		1.95 (0.71, 5.34)		
p-value [1]	0.43		0.20		
Unadjusted Absolute Risk Difference (95% CI)	0.12 (-0.10, 0.34)		0.15 (-0.07, 0.37)		
Adjusted Relative Risk (95% CI) [2]	NE		1.47 (0.75, 2.86)		
p-value [2]	NE		0.26		
Interaction test for Treatment*Region [3]					NE

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.4107: Any Serious TE AESI by Baseline Hemoglobin Level
Randomized Treatment Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Number of subjects, n(%)	8 (29.6%)	1 (16.7%)	13 (33.3%)	8 (24.2%)	
Unadjusted Relative Risk (95% CI)	1.78 (0.27, 11.67)		1.38 (0.65, 2.91)		
p-value [1]	0.55		0.40		
Unadjusted Odds Ratio (95% CI)	2.11 (0.21, 21.01)		1.56 (0.55, 4.41)		
p-value [1]	0.53		0.40		
Unadjusted Absolute Risk Difference (95% CI)	0.13 (-0.21, 0.47)		0.09 (-0.12, 0.30)		
Adjusted Relative Risk (95% CI) [2]	1.72 (0.27, 11.01)		1.36 (0.64, 2.89)		
p-value [2]	0.57		0.42		
Interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.79

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.4106: Any Serious TE AESI by Baseline DIPSS Two-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Number of subjects, n(%)	14 (28.6%)	7 (22.6%)	7 (41.2%)	2 (25.0%)	
Unadjusted Relative Risk (95% CI)	1.27 (0.58, 2.78)		1.65 (0.44, 6.21)		
p-value [1]	0.56		0.46		
Unadjusted Odds Ratio (95% CI)	1.37 (0.48, 3.90)		2.10 (0.32, 13.61)		
p-value [1]	0.55		0.44		
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.13, 0.25)		0.16 (-0.22, 0.54)		
Adjusted Relative Risk (95% CI) [2]	1.19 (0.52, 2.73)		NE		
p-value [2]	0.68		NE		
Interaction test for Treatment*Baseline DIPSS 2-Level Risk [3]					0.73

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.4105: Any Serious TE AESI by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Number of subjects, n(%)	2 (40.0%)	1 (14.3%)	12 (27.3%)	6 (25.0%)
Unadjusted Relative Risk (95% CI)	2.80 (0.34, 23.06)		1.09 (0.47, 2.54)	
p-value [1]	0.34		0.84	
Unadjusted Odds Ratio (95% CI)	4.00 (0.25, 63.95)		1.13 (0.36, 3.51)	
p-value [1]	0.33		0.84	
Unadjusted Absolute Risk Difference (95% CI)	0.26 (-0.24, 0.76)		0.02 (-0.19, 0.24)	
Adjusted Relative Risk (95% CI) [2]	NE		1.10 (0.42, 2.88)	
p-value [2]	NE		0.84	
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.4105: Any Serious TE AESI by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=17)	BAT (N=8)	p-value
Number of subjects, n(%)	7 (41.2%)	2 (25.0%)	
Unadjusted Relative Risk (95% CI)	1.65 (0.44, 6.21)		
p-value [1]	0.46		
Unadjusted Odds Ratio (95% CI)	2.10 (0.32, 13.61)		
p-value [1]	0.44		
Unadjusted Absolute Risk Difference (95% CI)	0.16 (-0.22, 0.54)		
Adjusted Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]			0.66

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.4108: Any Serious TE AESI by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
Number of subjects, n(%)	15 (33.3%)	7 (30.4%)	3 (23.1%)	1 (12.5%)
Unadjusted Relative Risk (95% CI)	1.10 (0.52, 2.30)		1.85 (0.23, 14.85)	
p-value [1]	0.81		0.56	
Unadjusted Odds Ratio (95% CI)	1.14 (0.39, 3.38)		2.10 (0.18, 24.60)	
p-value [1]	0.81		0.55	
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.20, 0.26)		0.11 (-0.22, 0.43)	
Adjusted Relative Risk (95% CI) [2]	1.02 (0.49, 2.12)		NE	
p-value [2]	0.96		NE	
Interaction test for Treatment*Myelofibrosis Disease Type [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.4108: Any Serious TE AESI by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=8)	BAT (N=8)	p-value
Number of subjects, n(%)	3 (37.5%)	1 (12.5%)	
Unadjusted Relative Risk (95% CI)	3.00 (0.39, 23.07)		
p-value [1]	0.29		
Unadjusted Odds Ratio (95% CI)	4.20 (0.33, 53.13)		
p-value [1]	0.27		
Unadjusted Absolute Risk Difference (95% CI)	0.25 (-0.16, 0.66)		
Adjusted Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Interaction test for Treatment*Myelofibrosis Disease Type [3]			0.57

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.4103: Any Serious TE AESI by Gender
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Number of subjects, n(%)	17 (32.7%)	6 (33.3%)	4 (28.6%)	3 (14.3%)	
Unadjusted Relative Risk (95% CI)	0.98 (0.46, 2.10)		2.00 (0.53, 7.60)		
p-value [1]	0.96		0.31		
Unadjusted Odds Ratio (95% CI)	0.97 (0.31, 3.03)		2.40 (0.45, 12.94)		
p-value [1]	0.96		0.31		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.26, 0.25)		0.14 (-0.14, 0.42)		
Adjusted Relative Risk (95% CI) [2]	0.96 (0.45, 2.03)		NE		
p-value [2]	0.91		NE		
Interaction test for Treatment*Gender [3]					0.37

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.4110: Any Serious TE AESI by Baseline Spleen Volume
Randomized Treatment Phase
SAF-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Number of subjects, n(%)	4 (14.3%)	6 (25.0%)	17 (44.7%)	3 (20.0%)	
Unadjusted Relative Risk (95% CI)	0.57 (0.18, 1.79)		2.24 (0.77, 6.53)		
p-value [1]	0.34		0.14		
Unadjusted Odds Ratio (95% CI)	0.50 (0.12, 2.04)		3.24 (0.78, 13.36)		
p-value [1]	0.33		0.10		
Unadjusted Absolute Risk Difference (95% CI)	-0.11 (-0.32, 0.11)		0.25 (-0.01, 0.50)		
Adjusted Relative Risk (95% CI) [2]	0.58 (0.19, 1.71)		1.93 (0.67, 5.60)		
p-value [2]	0.32		0.22		
Interaction test for Treatment*Baseline Spleen Volume Group [3]					0.077

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.4109: Any Serious TE AESI by Baseline TSS
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Number of subjects, n(%)	14 (33.3%)	6 (30.0%)	7 (29.2%)	3 (15.8%)	
Unadjusted Relative Risk (95% CI)	1.11 (0.50, 2.46)		1.85 (0.55, 6.20)		
p-value [1]	0.79		0.32		
Unadjusted Odds Ratio (95% CI)	1.17 (0.37, 3.69)		2.20 (0.48, 9.99)		
p-value [1]	0.79		0.31		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.21, 0.28)		0.13 (-0.11, 0.38)		
Adjusted Relative Risk (95% CI) [2]	1.15 (0.51, 2.58)		1.71 (0.51, 5.66)		
p-value [2]	0.73		0.38		
Interaction test for Treatment*Baseline TSS Group [3]					0.48

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TE AESI = Treatment-Emergent Adverse Event of Special Interest. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-aesi-sub-gba.sas V.03.05 Output file: t-aesum-aesi-ser-gba-tss.pdf 24AUG2023:16:57

Table 3.1402: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) by Age
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Number of subjects, n(%)	3 (12.5%)	0	4 (9.5%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Age Group [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.1404: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) by Region
Randomized Treatment Phase
SAF-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Number of subjects, n(%)	5 (17.2%)	0	2 (5.4%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Region [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.1407: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) by Baseline Hemoglobin Level
Randomized Treatment Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Number of subjects, n(%)	5 (18.5%)	0	2 (5.1%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.1406: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) by Baseline DIPSS Two-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Number of subjects, n(%)	4 (8.2%)	0	3 (17.6%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Baseline DIPSS 2-Level Risk [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.1405: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Number of subjects, n(%)	0	0	4 (9.1%)	0
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.1405: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=17)	BAT (N=8)	p-value
Number of subjects, n(%)	3 (17.6%)	0	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.1408: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
Number of subjects, n(%)	5 (11.1%)	0	1 (7.7%)	0
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Interaction test for Treatment*Myelofibrosis Disease Type [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.1408: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=8)	BAT (N=8)	p-value
Number of subjects, n(%)	1 (12.5%)	0	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Interaction test for Treatment*Myelofibrosis Disease Type [3]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.1403: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) by Gender
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Number of subjects, n(%)	5 (9.6%)	0	2 (14.3%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Gender [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.1410: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) by Baseline Spleen Volume
Randomized Treatment Phase
SAF-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Number of subjects, n(%)	4 (14.3%)	0	3 (7.9%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Baseline Spleen Volume Group [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.1409: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) by Baseline TSS
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Number of subjects, n(%)	4 (9.5%)	0	3 (12.5%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Baseline TSS Group [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-pn-sub-gba.sas V.03.05 Output file: t-aesum-pn-gba-tss.pdf 24AUG2023:16:51

Table 3.1602: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) of Grade 3 or more by Age
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03

Data Extracted: CRF data: 25JUN2019

Table 3.1604: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) of Grade 3 or more by Region
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03

Data Extracted: CRF data: 25JUN2019

Table 3.1607: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) of Grade 3 or more by Baseline Hemoglobin Level
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03

Data Extracted: CRF data: 25JUN2019

Table 3.1606: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) of Grade 3 or more by Baseline DIPSS Two-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03

Data Extracted: CRF data: 25JUN2019

Table 3.1605: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) of Grade 3 or more by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03

Data Extracted: CRF data: 25JUN2019

Table 3.1608: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) of Grade 3 or more by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03

Data Extracted: CRF data: 25JUN2019

Table 3.1603: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) of Grade 3 or more by Gender
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03

Data Extracted: CRF data: 25JUN2019

Table 3.1610: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) of Grade 3 or more by Baseline Spleen Volume
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03

Data Extracted: CRF data: 25JUN2019

Table 3.1609: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) of Grade 3 or more by Baseline TSS
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03

Data Extracted: CRF data: 25JUN2019

Table 3.1502: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) of Grade 2 or less by Age
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Number of subjects, n(%)	3 (12.5%)	0	4 (9.5%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Age Group [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-pn-sub-gba.sas V.03.05 Output file: t-aesum-pn-gle2-gba-age.pdf 24AUG2023:16:51

Table 3.1504: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) of Grade 2 or less by Region
Randomized Treatment Phase
SAF-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Number of subjects, n(%)	5 (17.2%)	0	2 (5.4%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Region [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-pn-sub-gba.sas V.03.05 Output file: t-aesum-pn-gle2-gba-geo.pdf 24AUG2023:16:51

Table 3.1507: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) of Grade 2 or less by Baseline Hemoglobin Level
Randomized Treatment Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Number of subjects, n(%)	5 (18.5%)	0	2 (5.1%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-pn-sub-gba.sas V.03.05 Output file: t-aesum-pn-gle2-gba-hgb.pdf 24AUG2023:16:51

Table 3.1506: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) of Grade 2 or less by Baseline DIPSS Two-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Number of subjects, n(%)	4 (8.2%)	0	3 (17.6%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Baseline DIPSS 2-Level Risk [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.1505: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) of Grade 2 or less by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Number of subjects, n(%)	0	0	4 (9.1%)	0
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-pn-sub-gba.sas V.03.05 Output file: t-aesum-pn-gle2-gba-ipss3.pdf 24AUG2023:16:51

Table 3.1505: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) of Grade 2 or less by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=17)	BAT (N=8)	p-value
Number of subjects, n(%)	3 (17.6%)	0	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.1508: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) of Grade 2 or less by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
Number of subjects, n(%)	5 (11.1%)	0	1 (7.7%)	0
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Interaction test for Treatment*Myelofibrosis Disease Type [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.1508: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) of Grade 2 or less by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=8)	BAT (N=8)	p-value
Number of subjects, n(%)	1 (12.5%)	0	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Interaction test for Treatment*Myelofibrosis Disease Type [3]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.1503: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) of Grade 2 or less by Gender
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Number of subjects, n(%)	5 (9.6%)	0	2 (14.3%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Gender [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-pn-sub-gba.sas V.03.05 Output file: t-aesum-pn-gle2-gba-sex.pdf 24AUG2023:16:51

Table 3.1510: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) of Grade 2 or less by Baseline Spleen Volume
Randomized Treatment Phase
SAF-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Number of subjects, n(%)	4 (14.3%)	0	3 (7.9%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Baseline Spleen Volume Group [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-pn-sub-gba.sas V.03.05 Output file: t-aesum-pn-gle2-gba-svb.pdf 24AUG2023:16:51

Table 3.1509: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) of Grade 2 or less by Baseline TSS
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Number of subjects, n(%)	4 (9.5%)	0	3 (12.5%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Baseline TSS Group [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.1702: Serious TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) by Age
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Table 3.1704: Serious TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) by Region
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Table 3.1707: Serious TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) by Baseline Hemoglobin Level
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 25JUN2019

Table 3.1706: Serious TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) by Baseline DIPSS Two-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 25JUN2019

Table 3.1705: Serious TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 25JUN2019

Table 3.1708: Serious TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 25JUN2019

Table 3.1703: Serious TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) by Gender
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Table 3.1710: Serious TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) by Baseline Spleen Volume
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 25JUN2019

Table 3.1709: Serious TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) by Baseline TSS
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Table 3.1802: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) Leading to Discontinuation of Study Drug by Age
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Number of subjects, n(%)	1 (4.2%)	0	0	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Age Group [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.1804: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) Leading to Discontinuation of Study Drug by Region
Randomized Treatment Phase
SAF-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Number of subjects, n(%)	0	0	1 (2.7%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Region [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.1807: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) Leading to Discontinuation of Study Drug by Baseline Hemoglobin Level
Randomized Treatment Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Number of subjects, n(%)	0	0	1 (2.6%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-pn-sub-gba.sas V.03.05 Output file: t-aesum-pn-dct-gba-hgb.pdf 24AUG2023:16:51

Table 3.1806: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) Leading to Discontinuation of Study Drug by Baseline DIPSS Two-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Number of subjects, n(%)	1 (2.0%)	0	0	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Baseline DIPSS 2-Level Risk [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.1805: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) Leading to Discontinuation of Study Drug by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Number of subjects, n(%)	0	0	1 (2.3%)	0
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-pn-sub-gba.sas V.03.05 Output file: t-aesum-pn-dct-gba-ipss3.pdf 24AUG2023:16:51

Table 3.1805: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) Leading to Discontinuation of Study Drug by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=17)	BAT (N=8)	p-value
Number of subjects, n(%)	0	0	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.1808: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) Leading to Discontinuation of Study Drug by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
Number of subjects, n(%)	0	0	0	0
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Interaction test for Treatment*Myelofibrosis Disease Type [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-pn-sub-gba.sas V.03.05 Output file: t-aesum-pn-dct-gba-mf.pdf 24AUG2023:16:51

Table 3.1808: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) Leading to Discontinuation of Study Drug by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=8)	BAT (N=8)	p-value
Number of subjects, n(%)	1 (12.5%)	0	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Interaction test for Treatment*Myelofibrosis Disease Type [3]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.1803: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) Leading to Discontinuation of Study Drug by Gender
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Number of subjects, n(%)	1 (1.9%)	0	0	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Gender [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.1810: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) Leading to Discontinuation of Study Drug by Baseline Spleen Volume
Randomized Treatment Phase
SAF-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Number of subjects, n(%)	1 (3.6%)	0	0	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Baseline Spleen Volume Group [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.1809: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) Leading to Discontinuation of Study Drug by Baseline TSS
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Number of subjects, n(%)	0	0	1 (4.2%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Baseline TSS Group [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.2002: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) Leading to Discontinuation of Study Drug of Grade 3 or more by Age

Randomized Treatment Phase

SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.

TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03

Data Extracted: CRF data: 25JUN2019

Table 3.2004: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) Leading to Discontinuation of Study Drug of Grade 3 or more by Region

Randomized Treatment Phase

SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.

TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03

Data Extracted: CRF data: 25JUN2019

Table 3.2007: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) Leading to Discontinuation of Study Drug of Grade 3 or more
by Baseline Hemoglobin Level
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03

Data Extracted: CRF data: 25JUN2019

Table 3.2006: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) Leading to Discontinuation of Study Drug of Grade 3 or more
by Baseline DIPSS Two-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03

Data Extracted: CRF data: 25JUN2019

Table 3.2005: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) Leading to Discontinuation of Study Drug of Grade 3 or more
by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03

Data Extracted: CRF data: 25JUN2019

Table 3.2008: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) Leading to Discontinuation of Study Drug of Grade 3 or more
by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03

Data Extracted: CRF data: 25JUN2019

Table 3.2003: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) Leading to Discontinuation of Study Drug of Grade 3 or more by Gender

Randomized Treatment Phase

SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.

TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03

Data Extracted: CRF data: 25JUN2019

Table 3.2010: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) Leading to Discontinuation of Study Drug of Grade 3 or more
by Baseline Spleen Volume
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03

Data Extracted: CRF data: 25JUN2019

Table 3.2009: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) Leading to Discontinuation of Study Drug of Grade 3 or more by Baseline TSS

Randomized Treatment Phase

SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.

TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03

Table 3.1902: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) Leading to Discontinuation of Study Drug of Grade 2 or less by Age
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Number of subjects, n(%)	1 (4.2%)	0	0	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Age Group [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.1904: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) Leading to Discontinuation of Study Drug of Grade 2 or less by Region

Randomized Treatment Phase

SAF-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Number of subjects, n(%)	0	0	1 (2.7%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Region [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-pn-sub-gba.sas V.03.05 Output file: t-aesum-pn-dctle2-gba-geo.pdf 24AUG2023:16:51

Table 3.1907: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) Leading to Discontinuation of Study Drug of Grade 2 or less by Baseline Hemoglobin Level
Randomized Treatment Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Number of subjects, n(%)	0	0	1 (2.6%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-pn-sub-gba.sas V.03.05 Output file: t-aesum-pn-dctle2-gba-hgb.pdf 24AUG2023:16:52

Table 3.1906: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) Leading to Discontinuation of Study Drug of Grade 2 or less by Baseline DIPSS Two-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Number of subjects, n(%)	1 (2.0%)	0	0	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Baseline DIPSS 2-Level Risk [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.1905: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) Leading to Discontinuation of Study Drug of Grade 2 or less
by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Number of subjects, n(%)	0	0	1 (2.3%)	0
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.1905: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) Leading to Discontinuation of Study Drug of Grade 2 or less
by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=17)	BAT (N=8)	p-value
Number of subjects, n(%)	0	0	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.1908: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) Leading to Discontinuation of Study Drug of Grade 2 or less
by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
Number of subjects, n(%)	0	0	0	0
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Interaction test for Treatment*Myelofibrosis Disease Type [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-pn-sub-gba.sas V.03.05 Output file: t-aesum-pn-dctle2-gba-mf.pdf 24AUG2023:16:52

Table 3.1908: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) Leading to Discontinuation of Study Drug of Grade 2 or less
by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=8)	BAT (N=8)	p-value
Number of subjects, n(%)	1 (12.5%)	0	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Interaction test for Treatment*Myelofibrosis Disease Type [3]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.1903: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) Leading to Discontinuation of Study Drug of Grade 2 or less by Gender

Randomized Treatment Phase

SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Number of subjects, n(%)	1 (1.9%)	0	0	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Gender [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-pn-sub-gba.sas V.03.05 Output file: t-aesum-pn-dctle2-gba-sex.pdf 24AUG2023:16:51

Table 3.1910: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) Leading to Discontinuation of Study Drug of Grade 2 or less by Baseline Spleen Volume
Randomized Treatment Phase
SAF-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Number of subjects, n(%)	1 (3.6%)	0	0	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Baseline Spleen Volume Group [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-pn-sub-gba.sas V.03.05 Output file: t-aesum-pn-dctle2-gba-svb.pdf 24AUG2023:16:52

Table 3.1909: TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) Leading to Discontinuation of Study Drug of Grade 2 or less by Baseline TSS
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Number of subjects, n(%)	0	0	1 (4.2%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Baseline TSS Group [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-pn-sub-gba.sas V.03.05 Output file: t-aesum-pn-dctle2-gba-tss.pdf 24AUG2023:16:52

Table 3.2102: Serious TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) Leading to Discontinuation of Study Drug by Age

Randomized Treatment Phase

SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 25JUN2019

Table 3.2104: Serious TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) Leading to Discontinuation of Study Drug by Region

Randomized Treatment Phase

SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 25JUN2019

Table 3.2107: Serious TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) Leading to Discontinuation of Study Drug by Baseline Hemoglobin Level

Randomized Treatment Phase

SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 25JUN2019

Table 3.2106: Serious TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) Leading to Discontinuation of Study Drug by Baseline DIPSS Two-level Risk

Randomized Treatment Phase

SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 25JUN2019

Table 3.2105: Serious TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) Leading to Discontinuation of Study Drug
by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 25JUN2019

Table 3.2108: Serious TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) Leading to Discontinuation of Study Drug by Baseline MF Disease Status

Randomized Treatment Phase

SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 25JUN2019

Table 3.2103: Serious TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) Leading to Discontinuation of Study Drug by Gender

Randomized Treatment Phase

SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Table 3.2110: Serious TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) Leading to Discontinuation of Study Drug by Baseline Spleen Volume

Randomized Treatment Phase

SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 25JUN2019

Table 3.2109: Serious TEAEs of Peripheral Neuropathy SMQ (Narrow Terms Only) Leading to Discontinuation of Study Drug by Baseline TSS
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Table 3.2202: TEAEs of Non-Hematological MST by Age
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Number of subjects, n(%)	24 (100.0%)	7 (77.8%)	41 (97.6%)	27 (90.0%)	
Unadjusted Relative Risk (95% CI)	1.31 (0.91, 1.88)		1.08 (0.95, 1.23)		
p-value [1]	0.15		0.21		
Unadjusted Odds Ratio (95% CI)	16.33 (0.70, 379.12)		4.56 (0.45, 46.11)		
p-value [1]	0.082		0.20		
Unadjusted Absolute Risk Difference (95% CI)	0.23 (-0.04, 0.50)		0.08 (-0.04, 0.19)		
Adjusted Relative Risk (95% CI) [2]	1.24 (0.91, 1.69)		1.07 (0.92, 1.24)		
p-value [2]	0.16		0.40		
Interaction test for Treatment*Age Group [3]					0.35

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-gba-age.pdf 24AUG2023:16:53

Table 3.2204: TEAEs of Non-Hematological MST by Region
Randomized Treatment Phase
SAF-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Number of subjects, n(%)	28 (96.6%)	5 (71.4%)	37 (100.0%)	29 (90.6%)	
Unadjusted Relative Risk (95% CI)	1.35 (0.84, 2.17)		1.10 (0.98, 1.25)		
p-value [1]	0.21		0.12		
Unadjusted Odds Ratio (95% CI)	11.20 (0.85, 148.14)		8.90 (0.44, 179.13)		
p-value [1]	0.067		0.15		
Unadjusted Absolute Risk Difference (95% CI)	0.25 (-0.09, 0.59)		0.09 (-0.02, 0.20)		
Adjusted Relative Risk (95% CI) [2]	1.34 (0.81, 2.22)		1.09 (0.99, 1.20)		
p-value [2]	0.25		0.083		
Interaction test for Treatment*Region [3]					0.39

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-gba-geo.pdf 24AUG2023:16:53

Table 3.2207: TEAEs of Non-Hematological MST by Baseline Hemoglobin Level
Randomized Treatment Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Number of subjects, n(%)	27 (100.0%)	4 (66.7%)	38 (97.4%)	30 (90.9%)	
Unadjusted Relative Risk (95% CI)	1.53 (0.88, 2.66)		1.07 (0.95, 1.21)		
p-value [1]	0.13		0.25		
Unadjusted Odds Ratio (95% CI)	30.56 (1.25, 746.47)		3.80 (0.38, 38.41)		
p-value [1]	0.036		0.26		
Unadjusted Absolute Risk Difference (95% CI)	0.34 (-0.02, 0.70)		0.07 (-0.04, 0.18)		
Adjusted Relative Risk (95% CI) [2]	1.50 (0.85, 2.64)		1.07 (0.94, 1.21)		
p-value [2]	0.16		0.29		
Interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.22

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.2206: TEAEs of Non-Hematological MST by Baseline DIPSS Two-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Number of subjects, n(%)	49 (100.0%)	28 (90.3%)	16 (94.1%)	6 (75.0%)	
Unadjusted Relative Risk (95% CI)	1.11 (0.98, 1.26)		1.25 (0.83, 1.90)		
p-value [1]	0.096		0.29		
Unadjusted Odds Ratio (95% CI)	12.16 (0.61, 243.92)		5.33 (0.41, 70.20)		
p-value [1]	0.10		0.20		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.01, 0.21)		0.19 (-0.13, 0.51)		
Adjusted Relative Risk (95% CI) [2]	1.09 (0.99, 1.20)		1.23 (0.85, 1.78)		
p-value [2]	0.091		0.27		
Interaction test for Treatment*Baseline DIPSS 2-Level Risk [3]					0.56

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.2205: TEAEs of Non-Hematological MST by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Number of subjects, n(%)	5 (100.0%)	6 (85.7%)	44 (100.0%)	22 (91.7%)
Unadjusted Relative Risk (95% CI)	1.13 (0.75, 1.70)		1.10 (0.96, 1.26)	
p-value [1]	0.57		0.17	
Unadjusted Odds Ratio (95% CI)	2.54 (0.09, 75.77)		9.89 (0.46, 214.83)	
p-value [1]	0.59		0.14	
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.25, 0.45)		0.09 (-0.03, 0.21)	
Adjusted Relative Risk (95% CI) [2]	1.00 (1.00, 1.00)		1.05 (0.98, 1.14)	
p-value [2]	>0.99		0.17	
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.2205: TEAEs of Non-Hematological MST by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=17)	BAT (N=8)	p-value
Number of subjects, n(%)	16 (94.1%)	6 (75.0%)	
Unadjusted Relative Risk (95% CI)	1.25 (0.83, 1.90)		
p-value [1]	0.29		
Unadjusted Odds Ratio (95% CI)	5.33 (0.41, 70.20)		
p-value [1]	0.20		
Unadjusted Absolute Risk Difference (95% CI)	0.19 (-0.13, 0.51)		
Adjusted Relative Risk (95% CI) [2]	1.23 (0.85, 1.78)		
p-value [2]	0.27		
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]			0.76

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.2208: TEAEs of Non-Hematological MST by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
Number of subjects, n(%)	45 (100.0%)	21 (91.3%)	12 (92.3%)	6 (75.0%)
Unadjusted Relative Risk (95% CI)	1.10 (0.96, 1.27)		1.23 (0.80, 1.89)	
p-value [1]	0.16		0.34	
Unadjusted Odds Ratio (95% CI)	10.58 (0.49, 230.11)		4.00 (0.30, 53.47)	
p-value [1]	0.13		0.29	
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.03, 0.22)		0.17 (-0.16, 0.51)	
Adjusted Relative Risk (95% CI) [2]	1.10 (0.97, 1.25)		1.07 (0.68, 1.67)	
p-value [2]	0.15		0.78	
Interaction test for Treatment*Myelofibrosis Disease Type [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.2208: TEAEs of Non-Hematological MST by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=8)	BAT (N=8)	p-value
Number of subjects, n(%)	8 (100.0%)	7 (87.5%)	
Unadjusted Relative Risk (95% CI)	1.13 (0.81, 1.58)		
p-value [1]	0.46		
Unadjusted Odds Ratio (95% CI)	3.40 (0.12, 96.71)		
p-value [1]	0.47		
Unadjusted Absolute Risk Difference (95% CI)	0.11 (-0.17, 0.40)		
Adjusted Relative Risk (95% CI) [2]	1.00 (1.00, 1.00)		
p-value [2]	>0.99		
Interaction test for Treatment*Myelofibrosis Disease Type [3]			0.85

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.2203: TEAEs of Non-Hematological MST by Gender
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Number of subjects, n(%)	51 (98.1%)	15 (83.3%)	14 (100.0%)	19 (90.5%)	
Unadjusted Relative Risk (95% CI)	1.18 (0.95, 1.45)		1.09 (0.91, 1.30)		
p-value [1]	0.13		0.34		
Unadjusted Odds Ratio (95% CI)	10.20 (0.99, 105.39)		3.72 (0.17, 83.49)		
p-value [1]	0.051		0.41		
Unadjusted Absolute Risk Difference (95% CI)	0.15 (-0.03, 0.32)		0.08 (-0.08, 0.24)		
Adjusted Relative Risk (95% CI) [2]	1.17 (0.95, 1.45)		1.03 (0.97, 1.09)		
p-value [2]	0.15		0.40		
Interaction test for Treatment*Gender [3]					0.62

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-gba-sex.pdf 24AUG2023:16:53

Table 3.2210: TEAEs of Non-Hematological MST by Baseline Spleen Volume
Randomized Treatment Phase
SAF-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Number of subjects, n(%)	27 (96.4%)	21 (87.5%)	38 (100.0%)	13 (86.7%)	
Unadjusted Relative Risk (95% CI)	1.10 (0.93, 1.30)		1.17 (0.94, 1.45)		
p-value [1]	0.25		0.15		
Unadjusted Odds Ratio (95% CI)	3.86 (0.37, 39.80)		14.26 (0.64, 316.23)		
p-value [1]	0.26		0.093		
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.06, 0.24)		0.14 (-0.04, 0.32)		
Adjusted Relative Risk (95% CI) [2]	1.10 (0.94, 1.30)		1.13 (0.94, 1.35)		
p-value [2]	0.23		0.19		
Interaction test for Treatment*Baseline Spleen Volume Group [3]					0.73

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-gba-svb.pdf 24AUG2023:16:53

Table 3.2209: TEAEs of Non-Hematological MST by Baseline TSS
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Number of subjects, n(%)	42 (100.0%)	17 (85.0%)	23 (95.8%)	17 (89.5%)	
Unadjusted Relative Risk (95% CI)	1.19 (0.98, 1.44)		1.07 (0.90, 1.28)		
p-value [1]	0.085		0.44		
Unadjusted Odds Ratio (95% CI)	17.00 (0.83, 346.64)		2.71 (0.23, 32.34)		
p-value [1]	0.066		0.43		
Unadjusted Absolute Risk Difference (95% CI)	0.16 (-0.01, 0.32)		0.06 (-0.10, 0.22)		
Adjusted Relative Risk (95% CI) [2]	1.17 (0.98, 1.41)		1.06 (0.88, 1.27)		
p-value [2]	0.086		0.54		
Interaction test for Treatment*Baseline TSS Group [3]					0.47

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.2402: TEAEs of Non-Hematological MST of Grade 3 or more by Age
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Number of subjects, n(%)	14 (58.3%)	2 (22.2%)	16 (38.1%)	12 (40.0%)	
Unadjusted Relative Risk (95% CI)	2.63 (0.74, 9.33)		0.95 (0.53, 1.71)		
p-value [1]	0.14		0.87		
Unadjusted Odds Ratio (95% CI)	4.90 (0.84, 28.73)		0.92 (0.35, 2.41)		
p-value [1]	0.078		0.87		
Unadjusted Absolute Risk Difference (95% CI)	0.36 (0.03, 0.70)		-0.02 (-0.25, 0.21)		
Adjusted Relative Risk (95% CI) [2]	2.58 (0.72, 9.26)		0.87 (0.50, 1.51)		
p-value [2]	0.14		0.62		
Interaction test for Treatment*Age Group [3]					0.097

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-gge3-gba-age.pdf 24AUG2023:16:53

Table 3.2404: TEAEs of Non-Hematological MST of Grade 3 or more by Region
Randomized Treatment Phase
SAF-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Number of subjects, n(%)	9 (31.0%)	1 (14.3%)	21 (56.8%)	13 (40.6%)	
Unadjusted Relative Risk (95% CI)	2.17 (0.33, 14.44)		1.40 (0.84, 2.31)		
p-value [1]	0.42		0.19		
Unadjusted Odds Ratio (95% CI)	2.70 (0.28, 25.84)		1.92 (0.73, 5.01)		
p-value [1]	0.39		0.18		
Unadjusted Absolute Risk Difference (95% CI)	0.17 (-0.14, 0.48)		0.16 (-0.07, 0.39)		
Adjusted Relative Risk (95% CI) [2]	NE		1.44 (0.87, 2.38)		
p-value [2]	NE		0.15		
Interaction test for Treatment*Region [3]					0.61

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-gge3-gba-geo.pdf 24AUG2023:16:53

Table 3.2407: TEAEs of Non-Hematological MST of Grade 3 or more by Baseline Hemoglobin Level
Randomized Treatment Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Number of subjects, n(%)	12 (44.4%)	2 (33.3%)	18 (46.2%)	12 (36.4%)	
Unadjusted Relative Risk (95% CI)	1.33 (0.40, 4.46)		1.27 (0.72, 2.23)		
p-value [1]	0.64		0.41		
Unadjusted Odds Ratio (95% CI)	1.60 (0.25, 10.27)		1.50 (0.58, 3.87)		
p-value [1]	0.62		0.40		
Unadjusted Absolute Risk Difference (95% CI)	0.11 (-0.31, 0.53)		0.10 (-0.13, 0.32)		
Adjusted Relative Risk (95% CI) [2]	1.41 (0.49, 4.03)		1.33 (0.76, 2.34)		
p-value [2]	0.52		0.32		
Interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.94

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-gge3-gba-hgb.pdf 24AUG2023:16:53

Table 3.2406: TEAEs of Non-Hematological MST of Grade 3 or more by Baseline DIPSS Two-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Number of subjects, n(%)	21 (42.9%)	8 (25.8%)	9 (52.9%)	6 (75.0%)	
Unadjusted Relative Risk (95% CI)	1.66 (0.84, 3.27)		0.71 (0.39, 1.29)		
p-value [1]	0.14		0.26		
Unadjusted Odds Ratio (95% CI)	2.16 (0.81, 5.77)		0.38 (0.06, 2.41)		
p-value [1]	0.13		0.30		
Unadjusted Absolute Risk Difference (95% CI)	0.17 (-0.04, 0.38)		-0.22 (-0.60, 0.16)		
Adjusted Relative Risk (95% CI) [2]	1.77 (0.88, 3.55)		0.64 (0.35, 1.17)		
p-value [2]	0.11		0.14		
Interaction test for Treatment*Baseline DIPSS 2-Level Risk [3]					0.069

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.2405: TEAEs of Non-Hematological MST of Grade 3 or more by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Number of subjects, n(%)	2 (40.0%)	1 (14.3%)	19 (43.2%)	7 (29.2%)
Unadjusted Relative Risk (95% CI)	2.80 (0.34, 23.06)		1.48 (0.73, 3.01)	
p-value [1]	0.34		0.28	
Unadjusted Odds Ratio (95% CI)	4.00 (0.25, 63.95)		1.85 (0.64, 5.35)	
p-value [1]	0.33		0.26	
Unadjusted Absolute Risk Difference (95% CI)	0.26 (-0.24, 0.76)		0.14 (-0.09, 0.37)	
Adjusted Relative Risk (95% CI) [2]	NE		1.62 (0.77, 3.42)	
p-value [2]	NE		0.20	
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.2405: TEAEs of Non-Hematological MST of Grade 3 or more by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=17)	BAT (N=8)	p-value
Number of subjects, n(%)	9 (52.9%)	6 (75.0%)	
Unadjusted Relative Risk (95% CI)	0.71 (0.39, 1.29)		
p-value [1]	0.26		
Unadjusted Odds Ratio (95% CI)	0.38 (0.06, 2.41)		
p-value [1]	0.30		
Unadjusted Absolute Risk Difference (95% CI)	-0.22 (-0.60, 0.16)		
Adjusted Relative Risk (95% CI) [2]	0.64 (0.35, 1.17)		
p-value [2]	0.14		
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]			0.19

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.2408: TEAEs of Non-Hematological MST of Grade 3 or more by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
Number of subjects, n(%)	20 (44.4%)	9 (39.1%)	6 (46.2%)	2 (25.0%)
Unadjusted Relative Risk (95% CI)	1.14 (0.62, 2.08)		1.85 (0.49, 7.02)	
p-value [1]	0.68		0.37	
Unadjusted Odds Ratio (95% CI)	1.24 (0.45, 3.46)		2.57 (0.37, 17.83)	
p-value [1]	0.68		0.34	
Unadjusted Absolute Risk Difference (95% CI)	0.05 (-0.19, 0.30)		0.21 (-0.19, 0.62)	
Adjusted Relative Risk (95% CI) [2]	1.15 (0.62, 2.12)		NE	
p-value [2]	0.66		NE	
Interaction test for Treatment*Myelofibrosis Disease Type [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-gge3-gba-mf.pdf 24AUG2023:16:53

Table 3.2408: TEAEs of Non-Hematological MST of Grade 3 or more by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=8)	BAT (N=8)	p-value
Number of subjects, n(%)	4 (50.0%)	3 (37.5%)	
Unadjusted Relative Risk (95% CI)	1.33 (0.43, 4.13)		
p-value [1]	0.62		
Unadjusted Odds Ratio (95% CI)	1.67 (0.23, 12.22)		
p-value [1]	0.62		
Unadjusted Absolute Risk Difference (95% CI)	0.13 (-0.36, 0.61)		
Adjusted Relative Risk (95% CI) [2]	1.47 (0.58, 3.72)		
p-value [2]	0.42		
Interaction test for Treatment*Myelofibrosis Disease Type [3]			0.78

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.2403: TEAEs of Non-Hematological MST of Grade 3 or more by Gender
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Number of subjects, n(%)	26 (50.0%)	7 (38.9%)	4 (28.6%)	7 (33.3%)	
Unadjusted Relative Risk (95% CI)	1.29 (0.68, 2.44)		0.86 (0.31, 2.39)		
p-value [1]	0.44		0.77		
Unadjusted Odds Ratio (95% CI)	1.57 (0.53, 4.69)		0.80 (0.18, 3.49)		
p-value [1]	0.42		0.77		
Unadjusted Absolute Risk Difference (95% CI)	0.11 (-0.15, 0.37)		-0.05 (-0.36, 0.26)		
Adjusted Relative Risk (95% CI) [2]	1.28 (0.68, 2.41)		0.87 (0.34, 2.23)		
p-value [2]	0.45		0.77		
Interaction test for Treatment*Gender [3]					0.50

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
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Table 3.2410: TEAEs of Non-Hematological MST of Grade 3 or more by Baseline Spleen Volume
Randomized Treatment Phase
SAF-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Number of subjects, n(%)	7 (25.0%)	7 (29.2%)	23 (60.5%)	7 (46.7%)	
Unadjusted Relative Risk (95% CI)	0.86 (0.35, 2.10)		1.30 (0.71, 2.36)		
p-value [1]	0.74		0.39		
Unadjusted Odds Ratio (95% CI)	0.81 (0.24, 2.76)		1.75 (0.53, 5.85)		
p-value [1]	0.74		0.36		
Unadjusted Absolute Risk Difference (95% CI)	-0.04 (-0.28, 0.20)		0.14 (-0.16, 0.44)		
Adjusted Relative Risk (95% CI) [2]	0.99 (0.42, 2.36)		1.27 (0.69, 2.35)		
p-value [2]	0.98		0.45		
Interaction test for Treatment*Baseline Spleen Volume Group [3]					0.45

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-gge3-gba-svb.pdf 24AUG2023:16:53

Table 3.2409: TEAEs of Non-Hematological MST of Grade 3 or more by Baseline TSS
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Number of subjects, n(%)	17 (40.5%)	6 (30.0%)	13 (54.2%)	8 (42.1%)	
Unadjusted Relative Risk (95% CI)	1.35 (0.63, 2.89)		1.29 (0.68, 2.45)		
p-value [1]	0.44		0.44		
Unadjusted Odds Ratio (95% CI)	1.59 (0.51, 4.95)		1.63 (0.48, 5.47)		
p-value [1]	0.43		0.43		
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.14, 0.35)		0.12 (-0.18, 0.42)		
Adjusted Relative Risk (95% CI) [2]	1.42 (0.66, 3.07)		1.21 (0.64, 2.28)		
p-value [2]	0.38		0.55		
Interaction test for Treatment*Baseline TSS Group [3]					0.93

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-gge3-gba-tss.pdf 24AUG2023:16:53

Table 3.2302: TEAEs of Non-Hematological MST of Grade 2 or less by Age
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Number of subjects, n(%)	23 (95.8%)	7 (77.8%)	41 (97.6%)	27 (90.0%)	
Unadjusted Relative Risk (95% CI)	1.23 (0.86, 1.76)		1.08 (0.95, 1.23)		
p-value [1]	0.25		0.21		
Unadjusted Odds Ratio (95% CI)	6.57 (0.52, 83.76)		4.56 (0.45, 46.11)		
p-value [1]	0.15		0.20		
Unadjusted Absolute Risk Difference (95% CI)	0.18 (-0.10, 0.46)		0.08 (-0.04, 0.19)		
Adjusted Relative Risk (95% CI) [2]	1.21 (0.88, 1.67)		1.07 (0.92, 1.24)		
p-value [2]	0.23		0.40		
Interaction test for Treatment*Age Group [3]					0.50

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-gle2-gba-age.pdf 24AUG2023:16:53

Table 3.2304: TEAEs of Non-Hematological MST of Grade 2 or less by Region
Randomized Treatment Phase
SAF-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Number of subjects, n(%)	28 (96.6%)	5 (71.4%)	36 (97.3%)	29 (90.6%)	
Unadjusted Relative Risk (95% CI)	1.35 (0.84, 2.17)		1.07 (0.95, 1.22)		
p-value [1]	0.21		0.26		
Unadjusted Odds Ratio (95% CI)	11.20 (0.85, 148.14)		3.72 (0.37, 37.72)		
p-value [1]	0.067		0.27		
Unadjusted Absolute Risk Difference (95% CI)	0.25 (-0.09, 0.59)		0.07 (-0.05, 0.18)		
Adjusted Relative Risk (95% CI) [2]	1.34 (0.81, 2.22)		1.07 (0.96, 1.19)		
p-value [2]	0.25		0.25		
Interaction test for Treatment*Region [3]					0.33

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-gle2-gba-geo.pdf 24AUG2023:16:53

Table 3.2307: TEAEs of Non-Hematological MST of Grade 2 or less by Baseline Hemoglobin Level
Randomized Treatment Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Number of subjects, n(%)	26 (96.3%)	4 (66.7%)	38 (97.4%)	30 (90.9%)	
Unadjusted Relative Risk (95% CI)	1.44 (0.82, 2.56)		1.07 (0.95, 1.21)		
p-value [1]	0.21		0.25		
Unadjusted Odds Ratio (95% CI)	13.00 (0.95, 178.77)		3.80 (0.38, 38.41)		
p-value [1]	0.055		0.26		
Unadjusted Absolute Risk Difference (95% CI)	0.30 (-0.09, 0.68)		0.07 (-0.04, 0.18)		
Adjusted Relative Risk (95% CI) [2]	1.45 (0.82, 2.57)		1.07 (0.94, 1.21)		
p-value [2]	0.20		0.29		
Interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.28

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-gle2-gba-hgb.pdf 24AUG2023:16:53

Table 3.2306: TEAEs of Non-Hematological MST of Grade 2 or less by Baseline DIPSS Two-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Number of subjects, n(%)	48 (98.0%)	28 (90.3%)	16 (94.1%)	6 (75.0%)	
Unadjusted Relative Risk (95% CI)	1.08 (0.96, 1.23)		1.25 (0.83, 1.90)		
p-value [1]	0.19		0.29		
Unadjusted Odds Ratio (95% CI)	5.14 (0.51, 51.85)		5.33 (0.41, 70.20)		
p-value [1]	0.16		0.20		
Unadjusted Absolute Risk Difference (95% CI)	0.08 (-0.03, 0.19)		0.19 (-0.13, 0.51)		
Adjusted Relative Risk (95% CI) [2]	1.07 (0.97, 1.18)		1.23 (0.85, 1.78)		
p-value [2]	0.19		0.27		
Interaction test for Treatment*Baseline DIPSS 2-Level Risk [3]					0.50

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.2305: TEAEs of Non-Hematological MST of Grade 2 or less by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Number of subjects, n(%)	5 (100.0%)	6 (85.7%)	43 (97.7%)	22 (91.7%)
Unadjusted Relative Risk (95% CI)	1.13 (0.75, 1.70)		1.07 (0.94, 1.21)	
p-value [1]	0.57		0.33	
Unadjusted Odds Ratio (95% CI)	2.54 (0.09, 75.77)		3.91 (0.34, 45.52)	
p-value [1]	0.59		0.28	
Unadjusted Absolute Risk Difference (95% CI)	0.10 (-0.25, 0.45)		0.06 (-0.06, 0.18)	
Adjusted Relative Risk (95% CI) [2]	1.00 (1.00, 1.00)		1.04 (0.95, 1.13)	
p-value [2]	>0.99		0.40	
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.2305: TEAEs of Non-Hematological MST of Grade 2 or less by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=17)	BAT (N=8)	p-value
Number of subjects, n(%)	16 (94.1%)	6 (75.0%)	
Unadjusted Relative Risk (95% CI)	1.25 (0.83, 1.90)		
p-value [1]	0.29		
Unadjusted Odds Ratio (95% CI)	5.33 (0.41, 70.20)		
p-value [1]	0.20		
Unadjusted Absolute Risk Difference (95% CI)	0.19 (-0.13, 0.51)		
Adjusted Relative Risk (95% CI) [2]	1.23 (0.85, 1.78)		
p-value [2]	0.27		
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]			0.68

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.2308: TEAEs of Non-Hematological MST of Grade 2 or less by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
Number of subjects, n(%)	45 (100.0%)	21 (91.3%)	11 (84.6%)	6 (75.0%)
Unadjusted Relative Risk (95% CI)	1.10 (0.96, 1.27)		1.13 (0.71, 1.79)	
p-value [1]	0.16		0.61	
Unadjusted Odds Ratio (95% CI)	10.58 (0.49, 230.11)		1.83 (0.20, 16.51)	
p-value [1]	0.13		0.59	
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.03, 0.22)		0.10 (-0.26, 0.45)	
Adjusted Relative Risk (95% CI) [2]	1.10 (0.97, 1.25)		0.99 (0.62, 1.57)	
p-value [2]	0.15		0.95	
Interaction test for Treatment*Myelofibrosis Disease Type [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.2308: TEAEs of Non-Hematological MST of Grade 2 or less by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=8)	BAT (N=8)	p-value
Number of subjects, n(%)	8 (100.0%)	7 (87.5%)	
Unadjusted Relative Risk (95% CI)	1.13 (0.81, 1.58)		
p-value [1]	0.46		
Unadjusted Odds Ratio (95% CI)	3.40 (0.12, 96.71)		
p-value [1]	0.47		
Unadjusted Absolute Risk Difference (95% CI)	0.11 (-0.17, 0.40)		
Adjusted Relative Risk (95% CI) [2]	1.00 (1.00, 1.00)		
p-value [2]	>0.99		
Interaction test for Treatment*Myelofibrosis Disease Type [3]			0.96

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.2303: TEAEs of Non-Hematological MST of Grade 2 or less by Gender
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Number of subjects, n(%)	50 (96.2%)	15 (83.3%)	14 (100.0%)	19 (90.5%)	
Unadjusted Relative Risk (95% CI)	1.15 (0.93, 1.43)		1.09 (0.91, 1.30)		
p-value [1]	0.19		0.34		
Unadjusted Odds Ratio (95% CI)	5.00 (0.76, 32.77)		3.72 (0.17, 83.49)		
p-value [1]	0.093		0.41		
Unadjusted Absolute Risk Difference (95% CI)	0.13 (-0.05, 0.31)		0.08 (-0.08, 0.24)		
Adjusted Relative Risk (95% CI) [2]	1.15 (0.93, 1.43)		1.03 (0.97, 1.09)		
p-value [2]	0.21		0.40		
Interaction test for Treatment*Gender [3]					0.74

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-gle2-gba-sex.pdf 24AUG2023:16:53

Table 3.2310: TEAEs of Non-Hematological MST of Grade 2 or less by Baseline Spleen Volume
Randomized Treatment Phase
SAF-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Number of subjects, n(%)	27 (96.4%)	21 (87.5%)	37 (97.4%)	13 (86.7%)	
Unadjusted Relative Risk (95% CI)	1.10 (0.93, 1.30)		1.12 (0.91, 1.38)		
p-value [1]	0.25		0.27		
Unadjusted Odds Ratio (95% CI)	3.86 (0.37, 39.80)		5.69 (0.48, 68.13)		
p-value [1]	0.26		0.17		
Unadjusted Absolute Risk Difference (95% CI)	0.09 (-0.06, 0.24)		0.11 (-0.07, 0.29)		
Adjusted Relative Risk (95% CI) [2]	1.10 (0.94, 1.30)		1.11 (0.92, 1.33)		
p-value [2]	0.23		0.27		
Interaction test for Treatment*Baseline Spleen Volume Group [3]					0.89

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-gle2-gba-svb.pdf 24AUG2023:16:53

Table 3.2309: TEAEs of Non-Hematological MST of Grade 2 or less by Baseline TSS
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Number of subjects, n(%)	41 (97.6%)	17 (85.0%)	23 (95.8%)	17 (89.5%)	
Unadjusted Relative Risk (95% CI)	1.15 (0.95, 1.39)		1.07 (0.90, 1.28)		
p-value [1]	0.15		0.44		
Unadjusted Odds Ratio (95% CI)	7.24 (0.70, 74.57)		2.71 (0.23, 32.34)		
p-value [1]	0.096		0.43		
Unadjusted Absolute Risk Difference (95% CI)	0.13 (-0.04, 0.29)		0.06 (-0.10, 0.22)		
Adjusted Relative Risk (95% CI) [2]	1.15 (0.95, 1.39)		1.06 (0.88, 1.27)		
p-value [2]	0.15		0.54		
Interaction test for Treatment*Baseline TSS Group [3]					0.60

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-gle2-gba-tss.pdf 24AUG2023:16:53

Table 3.2502: Serious TEAEs of Non-Hematological MST by Age
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Number of subjects, n(%)	8 (33.3%)	2 (22.2%)	13 (31.0%)	7 (23.3%)	
Unadjusted Relative Risk (95% CI)	1.50 (0.39, 5.77)		1.33 (0.60, 2.92)		
p-value [1]	0.56		0.48		
Unadjusted Odds Ratio (95% CI)	1.75 (0.29, 10.44)		1.47 (0.51, 4.29)		
p-value [1]	0.54		0.48		
Unadjusted Absolute Risk Difference (95% CI)	0.11 (-0.22, 0.44)		0.08 (-0.13, 0.28)		
Adjusted Relative Risk (95% CI) [2]	1.26 (0.32, 5.04)		NE		
p-value [2]	0.74		NE		
Interaction test for Treatment*Age Group [3]					0.88

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.2504: Serious TEAEs of Non-Hematological MST by Region
Randomized Treatment Phase
SAF-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Number of subjects, n(%)	5 (17.2%)	0	16 (43.2%)	9 (28.1%)	
Unadjusted Relative Risk (95% CI)	2.93 (0.18, 47.67)		1.54 (0.79, 2.99)		
p-value [1]	0.45		0.21		
Unadjusted Odds Ratio (95% CI)	3.37 (0.17, 68.21)		1.95 (0.71, 5.34)		
p-value [1]	0.43		0.20		
Unadjusted Absolute Risk Difference (95% CI)	0.12 (-0.10, 0.34)		0.15 (-0.07, 0.37)		
Adjusted Relative Risk (95% CI) [2]	NE		1.47 (0.75, 2.86)		
p-value [2]	NE		0.26		
Interaction test for Treatment*Region [3]					NE

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.2507: Serious TEAEs of Non-Hematological MST by Baseline Hemoglobin Level
Randomized Treatment Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Number of subjects, n(%)	8 (29.6%)	1 (16.7%)	13 (33.3%)	8 (24.2%)	
Unadjusted Relative Risk (95% CI)	1.78 (0.27, 11.67)		1.38 (0.65, 2.91)		
p-value [1]	0.55		0.40		
Unadjusted Odds Ratio (95% CI)	2.11 (0.21, 21.01)		1.56 (0.55, 4.41)		
p-value [1]	0.53		0.40		
Unadjusted Absolute Risk Difference (95% CI)	0.13 (-0.21, 0.47)		0.09 (-0.12, 0.30)		
Adjusted Relative Risk (95% CI) [2]	1.72 (0.27, 11.01)		1.36 (0.64, 2.89)		
p-value [2]	0.57		0.42		
Interaction test for Treatment*Baseline Hemoglobin Level Group [3]					0.79

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.2506: Serious TEAEs of Non-Hematological MST by Baseline DIPSS Two-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Number of subjects, n(%)	14 (28.6%)	7 (22.6%)	7 (41.2%)	2 (25.0%)	
Unadjusted Relative Risk (95% CI)	1.27 (0.58, 2.78)		1.65 (0.44, 6.21)		
p-value [1]	0.56		0.46		
Unadjusted Odds Ratio (95% CI)	1.37 (0.48, 3.90)		2.10 (0.32, 13.61)		
p-value [1]	0.55		0.44		
Unadjusted Absolute Risk Difference (95% CI)	0.06 (-0.13, 0.25)		0.16 (-0.22, 0.54)		
Adjusted Relative Risk (95% CI) [2]	1.19 (0.52, 2.73)		NE		
p-value [2]	0.68		NE		
Interaction test for Treatment*Baseline DIPSS 2-Level Risk [3]					0.73

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.2505: Serious TEAEs of Non-Hematological MST by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Number of subjects, n(%)	2 (40.0%)	1 (14.3%)	12 (27.3%)	6 (25.0%)
Unadjusted Relative Risk (95% CI)	2.80 (0.34, 23.06)		1.09 (0.47, 2.54)	
p-value [1]	0.34		0.84	
Unadjusted Odds Ratio (95% CI)	4.00 (0.25, 63.95)		1.13 (0.36, 3.51)	
p-value [1]	0.33		0.84	
Unadjusted Absolute Risk Difference (95% CI)	0.26 (-0.24, 0.76)		0.02 (-0.19, 0.24)	
Adjusted Relative Risk (95% CI) [2]	NE		1.10 (0.42, 2.88)	
p-value [2]	NE		0.84	
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-ser-gba-ipss3.pdf 24AUG2023:16:53

Table 3.2505: Serious TEAEs of Non-Hematological MST by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=17)	BAT (N=8)	p-value
Number of subjects, n(%)	7 (41.2%)	2 (25.0%)	
Unadjusted Relative Risk (95% CI)	1.65 (0.44, 6.21)		
p-value [1]	0.46		
Unadjusted Odds Ratio (95% CI)	2.10 (0.32, 13.61)		
p-value [1]	0.44		
Unadjusted Absolute Risk Difference (95% CI)	0.16 (-0.22, 0.54)		
Adjusted Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]			0.66

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.2508: Serious TEAEs of Non-Hematological MST by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
Number of subjects, n(%)	15 (33.3%)	7 (30.4%)	3 (23.1%)	1 (12.5%)
Unadjusted Relative Risk (95% CI)	1.10 (0.52, 2.30)		1.85 (0.23, 14.85)	
p-value [1]	0.81		0.56	
Unadjusted Odds Ratio (95% CI)	1.14 (0.39, 3.38)		2.10 (0.18, 24.60)	
p-value [1]	0.81		0.55	
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.20, 0.26)		0.11 (-0.22, 0.43)	
Adjusted Relative Risk (95% CI) [2]	1.02 (0.49, 2.12)		NE	
p-value [2]	0.96		NE	
Interaction test for Treatment*Myelofibrosis Disease Type [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.2508: Serious TEAEs of Non-Hematological MST by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=8)	BAT (N=8)	p-value
Number of subjects, n(%)	3 (37.5%)	1 (12.5%)	
Unadjusted Relative Risk (95% CI)	3.00 (0.39, 23.07)		
p-value [1]	0.29		
Unadjusted Odds Ratio (95% CI)	4.20 (0.33, 53.13)		
p-value [1]	0.27		
Unadjusted Absolute Risk Difference (95% CI)	0.25 (-0.16, 0.66)		
Adjusted Relative Risk (95% CI) [2]	NE		
p-value [2]	NE		
Interaction test for Treatment*Myelofibrosis Disease Type [3]			0.57

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019

Table 3.2503: Serious TEAEs of Non-Hematological MST by Gender
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Number of subjects, n(%)	17 (32.7%)	6 (33.3%)	4 (28.6%)	3 (14.3%)	
Unadjusted Relative Risk (95% CI)	0.98 (0.46, 2.10)		2.00 (0.53, 7.60)		
p-value [1]	0.96		0.31		
Unadjusted Odds Ratio (95% CI)	0.97 (0.31, 3.03)		2.40 (0.45, 12.94)		
p-value [1]	0.96		0.31		
Unadjusted Absolute Risk Difference (95% CI)	-0.01 (-0.26, 0.25)		0.14 (-0.14, 0.42)		
Adjusted Relative Risk (95% CI) [2]	0.96 (0.45, 2.03)		NE		
p-value [2]	0.91		NE		
Interaction test for Treatment*Gender [3]					0.37

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates. Modified Poisson regression model did not converge for some categories so these values are presented as NE.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.
Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-nh-sub-gba.sas V.03.05 Output file: t-aesum-nh-ser-gba-sex.pdf 24AUG2023:16:53

Table 3.2510: Serious TEAEs of Non-Hematological MST by Baseline Spleen Volume
Randomized Treatment Phase
SAF-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Number of subjects, n(%)	4 (14.3%)	6 (25.0%)	17 (44.7%)	3 (20.0%)	
Unadjusted Relative Risk (95% CI)	0.57 (0.18, 1.79)		2.24 (0.77, 6.53)		
p-value [1]	0.34		0.14		
Unadjusted Odds Ratio (95% CI)	0.50 (0.12, 2.04)		3.24 (0.78, 13.36)		
p-value [1]	0.33		0.10		
Unadjusted Absolute Risk Difference (95% CI)	-0.11 (-0.32, 0.11)		0.25 (-0.01, 0.50)		
Adjusted Relative Risk (95% CI) [2]	0.58 (0.19, 1.71)		1.93 (0.67, 5.60)		
p-value [2]	0.32		0.22		
Interaction test for Treatment*Baseline Spleen Volume Group [3]					0.077

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.2509: Serious TEAEs of Non-Hematological MST by Baseline TSS
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Number of subjects, n(%)	14 (33.3%)	6 (30.0%)	7 (29.2%)	3 (15.8%)	
Unadjusted Relative Risk (95% CI)	1.11 (0.50, 2.46)		1.85 (0.55, 6.20)		
p-value [1]	0.79		0.32		
Unadjusted Odds Ratio (95% CI)	1.17 (0.37, 3.69)		2.20 (0.48, 9.99)		
p-value [1]	0.79		0.31		
Unadjusted Absolute Risk Difference (95% CI)	0.03 (-0.21, 0.28)		0.13 (-0.11, 0.38)		
Adjusted Relative Risk (95% CI) [2]	1.15 (0.51, 2.58)		1.71 (0.51, 5.66)		
p-value [2]	0.73		0.38		
Interaction test for Treatment*Baseline TSS Group [3]					0.48

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.2602: TEAEs of Cataract MST by Age
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Number of subjects, n(%)	1 (4.2%)	0	2 (4.8%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Age Group [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.2604: TEAEs of Cataract MST by Region
Randomized Treatment Phase
SAF-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Number of subjects, n(%)	0	0	3 (8.1%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Region [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.2607: TEAEs of Cataract MST by Baseline Hemoglobin Level
Randomized Treatment Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Number of subjects, n(%)	1 (3.7%)	0	2 (5.1%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.2606: TEAEs of Cataract MST by Baseline DIPSS Two-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Number of subjects, n(%)	3 (6.1%)	0	0	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Baseline DIPSS 2-Level Risk [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.2605: TEAEs of Cataract MST by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Number of subjects, n(%)	0	0	3 (6.8%)	0
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.2605: TEAEs of Cataract MST by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=17)	BAT (N=8)	p-value
Number of subjects, n(%)	0	0	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.2608: TEAEs of Cataract MST by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
Number of subjects, n(%)	3 (6.7%)	0	0	0
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Interaction test for Treatment*Myelofibrosis Disease Type [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-cat-sub-gba.sas V.03.05 Output file: t-aesum-cat-gba-mf.pdf 24AUG2023:16:51

Table 3.2608: TEAEs of Cataract MST by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=8)	BAT (N=8)	p-value
Number of subjects, n(%)	0	0	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Interaction test for Treatment*Myelofibrosis Disease Type [3]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.2603: TEAEs of Cataract MST by Gender
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Number of subjects, n(%)	3 (5.8%)	0	0	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Gender [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.2610: TEAEs of Cataract MST by Baseline Spleen Volume
Randomized Treatment Phase
SAF-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Number of subjects, n(%)	1 (3.6%)	0	2 (5.3%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Baseline Spleen Volume Group [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-cat-sub-gba.sas V.03.05 Output file: t-aesum-cat-gba-svb.pdf 24AUG2023:16:51

Table 3.2609: TEAEs of Cataract MST by Baseline TSS
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Number of subjects, n(%)	2 (4.8%)	0	1 (4.2%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Baseline TSS Group [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.2802: TEAEs of Cataract MST of Grade 3 or more by Age
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03

Data Extracted: CRF data: 25JUN2019

Table 3.2804: TEAEs of Cataract MST of Grade 3 or more by Region
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03

Data Extracted: CRF data: 25JUN2019

Table 3.2807: TEAEs of Cataract MST of Grade 3 or more by Baseline Hemoglobin Level
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03

Data Extracted: CRF data: 25JUN2019

Table 3.2806: TEAEs of Cataract MST of Grade 3 or more by Baseline DIPSS Two-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03

Data Extracted: CRF data: 25JUN2019

Table 3.2805: TEAEs of Cataract MST of Grade 3 or more by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03

Data Extracted: CRF data: 25JUN2019

Table 3.2808: TEAEs of Cataract MST of Grade 3 or more by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03

Data Extracted: CRF data: 25JUN2019

Table 3.2803: TEAEs of Cataract MST of Grade 3 or more by Gender
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03

Data Extracted: CRF data: 25JUN2019

Table 3.2810: TEAEs of Cataract MST of Grade 3 or more by Baseline Spleen Volume
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03

Data Extracted: CRF data: 25JUN2019

Table 3.2809: TEAEs of Cataract MST of Grade 3 or more by Baseline TSS
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03

Data Extracted: CRF data: 25JUN2019

Table 3.2702: TEAEs of Cataract MST of Grade 2 or less by Age
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Number of subjects, n(%)	1 (4.2%)	0	2 (4.8%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Age Group [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.2704: TEAEs of Cataract MST of Grade 2 or less by Region
Randomized Treatment Phase
SAF-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Number of subjects, n(%)	0	0	3 (8.1%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Region [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-cat-sub-gba.sas V.03.05 Output file: t-aesum-cat-gle2-gba-geo.pdf 24AUG2023:16:51

Table 3.2707: TEAEs of Cataract MST of Grade 2 or less by Baseline Hemoglobin Level
Randomized Treatment Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Number of subjects, n(%)	1 (3.7%)	0	2 (5.1%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-cat-sub-gba.sas V.03.05 Output file: t-aesum-cat-gle2-gba-hgb.pdf 24AUG2023:16:52

Table 3.2706: TEAEs of Cataract MST of Grade 2 or less by Baseline DIPSS Two-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Number of subjects, n(%)	3 (6.1%)	0	0	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Baseline DIPSS 2-Level Risk [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.2705: TEAEs of Cataract MST of Grade 2 or less by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Number of subjects, n(%)	0	0	3 (6.8%)	0
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.2705: TEAEs of Cataract MST of Grade 2 or less by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=17)	BAT (N=8)	p-value
Number of subjects, n(%)	0	0	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.2708: TEAEs of Cataract MST of Grade 2 or less by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
Number of subjects, n(%)	3 (6.7%)	0	0	0
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Interaction test for Treatment*Myelofibrosis Disease Type [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.2708: TEAEs of Cataract MST of Grade 2 or less by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=8)	BAT (N=8)	p-value
Number of subjects, n(%)	0	0	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Interaction test for Treatment*Myelofibrosis Disease Type [3]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.2703: TEAEs of Cataract MST of Grade 2 or less by Gender
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Number of subjects, n(%)	3 (5.8%)	0	0	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Gender [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-cat-sub-gba.sas V.03.05 Output file: t-aesum-cat-gle2-gba-sex.pdf 24AUG2023:16:51

Table 3.2710: TEAEs of Cataract MST of Grade 2 or less by Baseline Spleen Volume
Randomized Treatment Phase
SAF-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Number of subjects, n(%)	1 (3.6%)	0	2 (5.3%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Baseline Spleen Volume Group [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.2709: TEAEs of Cataract MST of Grade 2 or less by Baseline TSS
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Number of subjects, n(%)	2 (4.8%)	0	1 (4.2%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Baseline TSS Group [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-cat-sub-gba.sas V.03.05 Output file: t-aesum-cat-gle2-gba-tss.pdf 24AUG2023:16:52

Table 3.2902: Serious TEAEs of Cataract MST by Age
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 25JUN2019

Table 3.2904: Serious TEAEs of Cataract MST by Region
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 25JUN2019

Table 3.2907: Serious TEAEs of Cataract MST by Baseline Hemoglobin Level
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 25JUN2019

Table 3.2906: Serious TEAEs of Cataract MST by Baseline DIPSS Two-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 25JUN2019

Table 3.2905: Serious TEAEs of Cataract MST by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 25JUN2019

Table 3.2908: Serious TEAEs of Cataract MST by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 25JUN2019

Table 3.2903: Serious TEAEs of Cataract MST by Gender
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 25JUN2019

Table 3.2910: Serious TEAEs of Cataract MST by Baseline Spleen Volume
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 25JUN2019

Table 3.2909: Serious TEAEs of Cataract MST by Baseline TSS
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 25JUN2019

Table 3.3002: TEAEs of First Dose Effect by Age
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Number of subjects, n(%)	1 (4.2%)	0	0	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Age Group [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.3004: TEAEs of First Dose Effect by Region
Randomized Treatment Phase
SAF-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Number of subjects, n(%)	1 (3.4%)	0	0	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Region [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.3007: TEAEs of First Dose Effect by Baseline Hemoglobin Level
Randomized Treatment Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Number of subjects, n(%)	0	0	1 (2.6%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.3006: TEAEs of First Dose Effect by Baseline DIPSS Two-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Number of subjects, n(%)	1 (2.0%)	0	0	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Baseline DIPSS 2-Level Risk [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.3005: TEAEs of First Dose Effect by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Number of subjects, n(%)	0	0	1 (2.3%)	0
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.3005: TEAEs of First Dose Effect by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=17)	BAT (N=8)	p-value
Number of subjects, n(%)	0	0	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.3008: TEAEs of First Dose Effect by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
Number of subjects, n(%)	0	0	1 (7.7%)	0
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Interaction test for Treatment*Myelofibrosis Disease Type [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.3008: TEAEs of First Dose Effect by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=8)	BAT (N=8)	p-value
Number of subjects, n(%)	0	0	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Interaction test for Treatment*Myelofibrosis Disease Type [3]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.3003: TEAEs of First Dose Effect by Gender
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Number of subjects, n(%)	1 (1.9%)	0	0	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Gender [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.3010: TEAEs of First Dose Effect by Baseline Spleen Volume
Randomized Treatment Phase
SAF-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Number of subjects, n(%)	1 (3.6%)	0	0	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Baseline Spleen Volume Group [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.3009: TEAEs of First Dose Effect by Baseline TSS
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Number of subjects, n(%)	1 (2.4%)	0	0	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Baseline TSS Group [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.3202: TEAEs of First Dose Effect of Grade 3 or more by Age
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03

Data Extracted: CRF data: 25JUN2019

Table 3.3204: TEAEs of First Dose Effect of Grade 3 or more by Region
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03

Data Extracted: CRF data: 25JUN2019

Table 3.3207: TEAEs of First Dose Effect of Grade 3 or more by Baseline Hemoglobin Level
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03

Data Extracted: CRF data: 25JUN2019

Table 3.3206: TEAEs of First Dose Effect of Grade 3 or more by Baseline DIPSS Two-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03

Data Extracted: CRF data: 25JUN2019

Table 3.3205: TEAEs of First Dose Effect of Grade 3 or more by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03

Data Extracted: CRF data: 25JUN2019

Table 3.3208: TEAEs of First Dose Effect of Grade 3 or more by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03

Data Extracted: CRF data: 25JUN2019

Table 3.3203: TEAEs of First Dose Effect of Grade 3 or more by Gender
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03

Data Extracted: CRF data: 25JUN2019

Table 3.3210: TEAEs of First Dose Effect of Grade 3 or more by Baseline Spleen Volume
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03

Data Extracted: CRF data: 25JUN2019

Table 3.3209: TEAEs of First Dose Effect of Grade 3 or more by Baseline TSS
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03

Data Extracted: CRF data: 25JUN2019

Table 3.3102: TEAEs of First Dose Effect of Grade 2 or less by Age
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<65 Years		>=65 Years		
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)	p-value
Number of subjects, n(%)	1 (4.2%)	0	0	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Age Group [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-fds-sub-gba.sas V.03.05 Output file: t-aesum-fds-gle2-gba-age.pdf 24AUG2023:16:53

Table 3.3104: TEAEs of First Dose Effect of Grade 2 or less by Region
Randomized Treatment Phase
SAF-Anemic Analysis Set

	North America		Europe		
	MMB (N=29)	BAT (N=7)	MMB (N=37)	BAT (N=32)	p-value
Number of subjects, n(%)	1 (3.4%)	0	0	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Region [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.3107: TEAEs of First Dose Effect of Grade 2 or less by Baseline Hemoglobin Level
Randomized Treatment Phase
SAF-Anemic Analysis Set

	HGB <8 g/dL		HGB >=8 g/dL		
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)	p-value
Number of subjects, n(%)	0	0	1 (2.6%)	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Baseline Hemoglobin Level Group [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-fds-sub-gba.sas V.03.05 Output file: t-aesum-fds-gle2-gba-hgb.pdf 24AUG2023:16:53

Table 3.3106: TEAEs of First Dose Effect of Grade 2 or less by Baseline DIPSS Two-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk		High Risk		
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)	p-value
Number of subjects, n(%)	1 (2.0%)	0	0	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Baseline DIPSS 2-Level Risk [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.3105: TEAEs of First Dose Effect of Grade 2 or less by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Intermediate Risk-1		Intermediate Risk-2	
	MMB (N=5)	BAT (N=7)	MMB (N=44)	BAT (N=24)
Number of subjects, n(%)	0	0	1 (2.3%)	0
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.3105: TEAEs of First Dose Effect of Grade 2 or less by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

	High Risk		
	MMB (N=17)	BAT (N=8)	p-value
Number of subjects, n(%)	0	0	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Interaction test for Treatment*Baseline DIPSS 3-Level Risk [3]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.3108: TEAEs of First Dose Effect of Grade 2 or less by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
Number of subjects, n(%)	0	0	1 (7.7%)	0
Unadjusted Relative Risk (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Odds Ratio (95% CI)	NA		NA	
p-value [1]	NA		NA	
Unadjusted Absolute Risk Difference (95% CI)	NA		NA	
Adjusted Relative Risk (95% CI) [2]	NA		NA	
p-value [2]	NA		NA	
Interaction test for Treatment*Myelofibrosis Disease Type [3]				

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.3108: TEAEs of First Dose Effect of Grade 2 or less by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Post-PV Myelofibrosis		
	MMB (N=8)	BAT (N=8)	p-value
Number of subjects, n(%)	0	0	
Unadjusted Relative Risk (95% CI)	NA		
p-value [1]	NA		
Unadjusted Odds Ratio (95% CI)	NA		
p-value [1]	NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		
Adjusted Relative Risk (95% CI) [2]	NA		
p-value [2]	NA		
Interaction test for Treatment*Myelofibrosis Disease Type [3]			NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019

Table 3.3103: TEAEs of First Dose Effect of Grade 2 or less by Gender
Randomized Treatment Phase
SAF-Anemic Analysis Set

	Male		Female		
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)	p-value
Number of subjects, n(%)	1 (1.9%)	0	0	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Gender [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-fds-sub-gba.sas V.03.05 Output file: t-aesum-fds-gle2-gba-sex.pdf 24AUG2023:16:53

Table 3.3110: TEAEs of First Dose Effect of Grade 2 or less by Baseline Spleen Volume
Randomized Treatment Phase
SAF-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3		
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)	p-value
Number of subjects, n(%)	1 (3.6%)	0	0	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Baseline Spleen Volume Group [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no), and Baseline TSS (<18, >=18) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-fds-sub-gba.sas V.03.05 Output file: t-aesum-fds-gle2-gba-svb.pdf 24AUG2023:16:53

Table 3.3109: TEAEs of First Dose Effect of Grade 2 or less by Baseline TSS
Randomized Treatment Phase
SAF-Anemic Analysis Set

	<18		>=18		
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)	p-value
Number of subjects, n(%)	1 (2.4%)	0	0	0	
Unadjusted Relative Risk (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Odds Ratio (95% CI)	NA		NA		
p-value [1]	NA		NA		
Unadjusted Absolute Risk Difference (95% CI)	NA		NA		
Adjusted Relative Risk (95% CI) [2]	NA		NA		
p-value [2]	NA		NA		
Interaction test for Treatment*Baseline TSS Group [3]					NA

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0. Severity grades were defined by CTCAE Version 4.03
[1] p-values were obtained from a Z-test.
[2] Adjusted Relative Risk and corresponding p-value were obtained from a modified Poisson regression model, including treatment, baseline TD (yes, no) as covariates.
[3] The Interaction test p-value was obtained for the treatment by subgroup interaction term from a modified Poisson regression, including treatment, subgroup and treatment by subgroup interaction as covariates.

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-aesum-fds-sub-gba.sas V.03.05 Output file: t-aesum-fds-gle2-gba-tss.pdf 24AUG2023:16:53

Table 3.3302: Serious TEAEs of First Dose Effect by Age
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 25JUN2019

Table 3.3304: Serious TEAEs of First Dose Effect by Region
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 25JUN2019

Table 3.3307: Serious TEAEs of First Dose Effect by Baseline Hemoglobin Level
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 25JUN2019

Table 3.3306: Serious TEAEs of First Dose Effect by Baseline DIPSS Two-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 25JUN2019

Table 3.3305: Serious TEAEs of First Dose Effect by Baseline DIPSS Three-level Risk
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 25JUN2019

Table 3.3308: Serious TEAEs of First Dose Effect by Baseline MF Disease Status
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 25JUN2019

Table 3.3303: Serious TEAEs of First Dose Effect by Gender
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 25JUN2019

Table 3.3310: Serious TEAEs of First Dose Effect by Baseline Spleen Volume
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 25JUN2019

Table 3.3309: Serious TEAEs of First Dose Effect by Baseline TSS
Randomized Treatment Phase
SAF-Anemic Analysis Set

No data to report

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
TEAE=Treatment-Emergent Adverse Event. Adverse events were mapped according to MedDRA Version 22.0.

Data Extracted: CRF data: 25JUN2019

Table 2.0117: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years	
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)
All Stratum Combined				
Splenic Response Rate at Week 24				
Responder, n(%)	6 (25.0%)	13 (36.1%)	21 (33.9%)	18 (31.0%)
95% Exact CI	0.0977, 0.4671	0.2082, 0.5378	0.2233, 0.4701	0.1954, 0.4454
Noninferior Proportion Difference - Stratified CMH (95% CI)	-0.01 (-0.24, 0.23)		0.13 (-0.01, 0.28)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	0.03 (-0.17, 0.24)		0.15 (0.01, 0.29)	
Superior Proportion Difference - Stratified CMH (95% CI)	-0.16 (-0.43, 0.11)		0.01 (-0.17, 0.19)	
Superior Proportion Difference - Unstratified CMH (95% CI)	-0.11 (-0.35, 0.13)		0.03 (-0.14, 0.20)	
Superior Proportion Difference - Unstratified Exact (95% CI)	-0.11 (-0.36, 0.15)		0.03 (-0.15, 0.20)	
Non-Responder, n(%)	18 (75.0%)	23 (63.9%)	41 (66.1%)	40 (69.0%)
Baseline Spleen Volume not available	0	0	0	0
Spleen Volume at Week 24 not available	4 (16.7%)	3 (8.3%)	12 (19.4%)	5 (8.6%)
>0% Spleen Volume increase at Week 24	5 (20.8%)	4 (11.1%)	5 (8.1%)	4 (6.9%)
<35% Spleen Volume reduction at Week 24	14 (58.3%)	20 (55.6%)	29 (46.8%)	35 (60.3%)
Last participation date < Day 141 in DB phase	2 (8.3%)	2 (5.6%)	10 (16.1%)	2 (3.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-srr24.sas V.03.05 Output file: t-subgrp-srr24-age.pdf 29AUG2023: 9:03

Table 2.0117: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years	
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)
Splenic Response Rate at Week 12				
Responder, n(%)	7 (29.2%)	11 (30.6%)	18 (29.0%)	16 (27.6%)
95% Exact CI	0.1262, 0.5109	0.1635, 0.4811	0.1820, 0.4195	0.1666, 0.4090
Noninferior Proportion Difference - Stratified CMH (95% CI)	0.08 (-0.16, 0.32)		0.13 (-0.01, 0.27)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	0.11 (-0.10, 0.32)		0.12 (-0.01, 0.26)	
Superior Proportion Difference - Stratified CMH (95% CI)	-0.05 (-0.31, 0.22)		0.02 (-0.15, 0.19)	
Superior Proportion Difference - Unstratified CMH (95% CI)	-0.01 (-0.26, 0.23)		0.01 (-0.15, 0.18)	
Superior Proportion Difference - Unstratified Exact (95% CI)	-0.01 (-0.27, 0.25)		0.01 (-0.17, 0.19)	
Non-Responder, n(%)	17 (70.8%)	25 (69.4%)	44 (71.0%)	42 (72.4%)
Baseline Spleen Volume not available	0	0	0	0
Spleen Volume at Week 12 not available	1 (4.2%)	2 (5.6%)	10 (16.1%)	3 (5.2%)
>0% Spleen Volume increase at Week 12	3 (12.5%)	4 (11.1%)	3 (4.8%)	6 (10.3%)
<35% Spleen Volume reduction at Week 12	16 (66.7%)	23 (63.9%)	34 (54.8%)	39 (67.2%)
Last participation date < Day 57 in DB phase	1 (4.2%)	0	7 (11.3%)	0
Splenic Response Rate at Any Timepoint in DB Phase				
Responder, n(%)	8 (33.3%)	13 (36.1%)	23 (37.1%)	23 (39.7%)
95% Exact CI	0.1563, 0.5532	0.2082, 0.5378	0.2516, 0.5031	0.2705, 0.5336

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-srr24.sas V.03.05 Output file: t-subgrp-srr24-age.pdf 29AUG2023: 9:03

Table 2.0124: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by IPSS
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk	
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)
All Stratum Combined				
Splenic Response Rate at Week 24				
Responder, n(%)	8 (28.6%)	9 (37.5%)	19 (32.8%)	22 (31.4%)
95% Exact CI	0.1322, 0.4867	0.1880, 0.5941	0.2101, 0.4634	0.2085, 0.4363
Noninferior Proportion Difference - Stratified CMH (95% CI)	0.09 (-0.15, 0.33)		0.14 (-0.00, 0.28)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	0.06 (-0.15, 0.27)		0.14 (0.00, 0.28)	
Superior Proportion Difference - Stratified CMH (95% CI)	-0.07 (-0.37, 0.23)		0.02 (-0.15, 0.19)	
Superior Proportion Difference - Unstratified CMH (95% CI)	-0.09 (-0.35, 0.17)		0.01 (-0.15, 0.18)	
Superior Proportion Difference - Unstratified Exact (95% CI)	-0.09 (-0.35, 0.18)		0.01 (-0.16, 0.19)	
Non-Responder, n(%)	20 (71.4%)	15 (62.5%)	39 (67.2%)	48 (68.6%)
Baseline Spleen Volume not available	0	0	0	0
Spleen Volume at Week 24 not available	5 (17.9%)	2 (8.3%)	11 (19.0%)	6 (8.6%)
>0% Spleen Volume increase at Week 24	4 (14.3%)	3 (12.5%)	6 (10.3%)	5 (7.1%)
<35% Spleen Volume reduction at Week 24	15 (53.6%)	13 (54.2%)	28 (48.3%)	42 (60.0%)
Last participation date < Day 141 in DB phase	3 (10.7%)	2 (8.3%)	9 (15.5%)	2 (2.9%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel
IPSS = International Prognostic Scoring System

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-srr24.sas V.03.05 Output file: t-subgrp-srr24-dipss.pdf 29AUG2023: 9:04

Table 2.0124: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by IPSS
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk	
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)
Splenic Response Rate at Week 12				
Responder, n(%)	7 (25.0%)	7 (29.2%)	18 (31.0%)	20 (28.6%)
95% Exact CI	0.1069, 0.4487	0.1262, 0.5109	0.1954, 0.4454	0.1840, 0.4062
Noninferior Proportion Difference - Stratified CMH (95% CI)	0.08 (-0.15, 0.31)		0.15 (0.01, 0.29)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	0.08 (-0.12, 0.27)		0.14 (0.00, 0.28)	
Superior Proportion Difference - Stratified CMH (95% CI)	-0.04 (-0.33, 0.24)		0.04 (-0.12, 0.20)	
Superior Proportion Difference - Unstratified CMH (95% CI)	-0.04 (-0.29, 0.21)		0.02 (-0.14, 0.19)	
Superior Proportion Difference - Unstratified Exact (95% CI)	-0.04 (-0.31, 0.23)		0.02 (-0.15, 0.20)	
Non-Responder, n(%)	21 (75.0%)	17 (70.8%)	40 (69.0%)	50 (71.4%)
Baseline Spleen Volume not available	0	0	0	0
Spleen Volume at Week 12 not available	3 (10.7%)	1 (4.2%)	8 (13.8%)	4 (5.7%)
>0% Spleen Volume increase at Week 12	0	4 (16.7%)	6 (10.3%)	6 (8.6%)
<35% Spleen Volume reduction at Week 12	18 (64.3%)	16 (66.7%)	32 (55.2%)	46 (65.7%)
Last participation date < Day 57 in DB phase	3 (10.7%)	0	5 (8.6%)	0
Splenic Response Rate at Any Timepoint in DB Phase				
Responder, n(%)	9 (32.1%)	9 (37.5%)	22 (37.9%)	27 (38.6%)
95% Exact CI	0.1588, 0.5235	0.1880, 0.5941	0.2551, 0.5163	0.2717, 0.5097

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel
IPSS = International Prognostic Scoring System

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-srr24.sas V.03.05 Output file: t-subgrp-srr24-dipss.pdf 29AUG2023: 9:04

Table 2.0128: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by Geographic Area
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Europe		Eastern Europe		Asia	
	MMB (N=53)	RUX (N=51)	MMB (N=25)	RUX (N=36)	MMB (N=8)	RUX (N=7)
All Stratum Combined						
Splenic Response Rate at Week 24						
Responder, n(%)	17 (32.1%)	16 (31.4%)	8 (32.0%)	11 (30.6%)	2 (25.0%)	4 (57.1%)
95% Exact CI	0.1992, 0.4632	0.1911, 0.4589	0.1495, 0.5350	0.1635, 0.4811	0.0319, 0.6509	0.1841, 0.9010
Noninferior Proportion Difference - Stratified CMH (95% CI)	0.16 (0.01, 0.32)		0.13 (-0.09, 0.35)		-0.03 (-0.55, 0.48)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	0.13 (-0.02, 0.28)		0.14 (-0.07, 0.35)		-0.09 (-0.50, 0.32)	
Superior Proportion Difference - Stratified CMH (95% CI)	0.05 (-0.13, 0.24)		0.00 (-0.26, 0.27)		-0.24 (-0.83, 0.35)	
Superior Proportion Difference - Unstratified CMH (95% CI)	0.01 (-0.17, 0.19)		0.01 (-0.23, 0.26)		-0.32 (-0.84, 0.20)	
Superior Proportion Difference - Unstratified Exact (95% CI)	0.01 (-0.18, 0.20)		0.01 (-0.24, 0.27)		-0.32 (-0.74, 0.22)	
Non-Responder, n(%)	36 (67.9%)	35 (68.6%)	17 (68.0%)	25 (69.4%)	6 (75.0%)	3 (42.9%)
Baseline Spleen Volume not available	0	0	0	0	0	0
Spleen Volume at Week 24 not available	9 (17.0%)	4 (7.8%)	5 (20.0%)	4 (11.1%)	2 (25.0%)	0
>0% Spleen Volume increase at Week 24	5 (9.4%)	6 (11.8%)	4 (16.0%)	1 (2.8%)	1 (12.5%)	1 (14.3%)
<35% Spleen Volume reduction at Week 24	27 (50.9%)	31 (60.8%)	12 (48.0%)	21 (58.3%)	4 (50.0%)	3 (42.9%)
Last participation date < Day 141 in DB phase	8 (15.1%)	4 (7.8%)	3 (12.0%)	0	1 (12.5%)	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-srr24.sas V.03.05 Output file: t-subgrp-srr24-geo.pdf 29AUG2023: 9:05

Table 2.0128: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by Geographic Area
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Europe		Eastern Europe		Asia	
	MMB (N=53)	RUX (N=51)	MMB (N=25)	RUX (N=36)	MMB (N=8)	RUX (N=7)
Splenic Response Rate at Week 12						
Responder, n(%)	15 (28.3%)	10 (19.6%)	7 (28.0%)	11 (30.6%)	3 (37.5%)	6 (85.7%)
95% Exact CI	0.1679, 0.4235	0.0982, 0.3312	0.1207, 0.4939	0.1635, 0.4811	0.0852, 0.7551	0.4213, 0.9964
Noninferior Proportion Difference - Stratified CMH (95% CI)	0.20 (0.04, 0.35)		0.06 (-0.17, 0.28)		-0.11 (-0.60, 0.38)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	0.17 (0.03, 0.31)		0.10 (-0.11, 0.30)		-0.14 (-0.55, 0.27)	
Superior Proportion Difference - Stratified CMH (95% CI)	0.13 (-0.05, 0.31)		-0.09 (-0.36, 0.18)		-0.41 (-0.94, 0.11)	
Superior Proportion Difference - Unstratified CMH (95% CI)	0.09 (-0.08, 0.25)		-0.03 (-0.26, 0.21)		-0.48 (-0.96, -0.00)	
Superior Proportion Difference - Unstratified Exact (95% CI)	0.09 (-0.11, 0.27)		-0.03 (-0.28, 0.23)		-0.48 (-0.84, 0.04)	
Non-Responder, n(%)	38 (71.7%)	41 (80.4%)	18 (72.0%)	25 (69.4%)	5 (62.5%)	1 (14.3%)
Baseline Spleen Volume not available	0	0	0	0	0	0
Spleen Volume at Week 12 not available	7 (13.2%)	4 (7.8%)	3 (12.0%)	1 (2.8%)	1 (12.5%)	0
>0% Spleen Volume increase at Week 12	3 (5.7%)	5 (9.8%)	3 (12.0%)	4 (11.1%)	0	1 (14.3%)
<35% Spleen Volume reduction at Week 12	31 (58.5%)	37 (72.5%)	15 (60.0%)	24 (66.7%)	4 (50.0%)	1 (14.3%)
Last participation date < Day 57 in DB phase	4 (7.5%)	0	3 (12.0%)	0	1 (12.5%)	0
Splenic Response Rate at Any Timepoint in DB Phase						
Responder, n(%)	19 (35.8%)	16 (31.4%)	9 (36.0%)	14 (38.9%)	3 (37.5%)	6 (85.7%)
95% Exact CI	0.2314, 0.5020	0.1911, 0.4589	0.1797, 0.5748	0.2314, 0.5654	0.0852, 0.7551	0.4213, 0.9964

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-srr24.sas V.03.05 Output file: t-subgrp-srr24-geo.pdf 29AUG2023: 9:05

Table 2.0123: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by HGB at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	<8 g/dL		>=8 g/dL	
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)
All Stratum Combined				
Splenic Response Rate at Week 24				
Responder, n(%)	6 (21.4%)	7 (33.3%)	21 (36.2%)	24 (32.9%)
95% Exact CI	0.0830, 0.4095	0.1459, 0.5697	0.2399, 0.4988	0.2233, 0.4487
Noninferior Proportion Difference - Stratified CMH (95% CI)	0.02 (-0.17, 0.21)		0.18 (0.03, 0.32)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	0.01 (-0.19, 0.21)		0.16 (0.02, 0.31)	
Superior Proportion Difference - Stratified CMH (95% CI)	-0.11 (-0.35, 0.13)		0.05 (-0.12, 0.22)	
Superior Proportion Difference - Unstratified CMH (95% CI)	-0.12 (-0.38, 0.14)		0.03 (-0.13, 0.20)	
Superior Proportion Difference - Unstratified Exact (95% CI)	-0.12 (-0.39, 0.17)		0.03 (-0.14, 0.20)	
Non-Responder, n(%)	22 (78.6%)	14 (66.7%)	37 (63.8%)	49 (67.1%)
Baseline Spleen Volume not available	0	0	0	0
Spleen Volume at Week 24 not available	5 (17.9%)	3 (14.3%)	11 (19.0%)	5 (6.8%)
>0% Spleen Volume increase at Week 24	4 (14.3%)	3 (14.3%)	6 (10.3%)	5 (6.8%)
<35% Spleen Volume reduction at Week 24	17 (60.7%)	11 (52.4%)	26 (44.8%)	44 (60.3%)
Last participation date < Day 141 in DB phase	5 (17.9%)	2 (9.5%)	7 (12.1%)	2 (2.7%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-srr24.sas V.03.05 Output file: t-subgrp-srr24-hgb.pdf 29AUG2023: 9:04

Table 2.0123: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by HGB at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	<8 g/dL		>=8 g/dL	
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)
Splenic Response Rate at Week 12				
Responder, n(%)	7 (25.0%)	6 (28.6%)	18 (31.0%)	21 (28.8%)
95% Exact CI	0.1069, 0.4487	0.1128, 0.5218	0.1954, 0.4454	0.1877, 0.4055
Noninferior Proportion Difference - Stratified CMH (95% CI)	0.08 (-0.11, 0.28)		0.15 (0.01, 0.29)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	0.08 (-0.13, 0.28)		0.14 (0.00, 0.27)	
Superior Proportion Difference - Stratified CMH (95% CI)	-0.03 (-0.26, 0.20)		0.04 (-0.12, 0.21)	
Superior Proportion Difference - Unstratified CMH (95% CI)	-0.04 (-0.30, 0.22)		0.02 (-0.14, 0.18)	
Superior Proportion Difference - Unstratified Exact (95% CI)	-0.04 (-0.32, 0.25)		0.02 (-0.15, 0.19)	
Non-Responder, n(%)	21 (75.0%)	15 (71.4%)	40 (69.0%)	52 (71.2%)
Baseline Spleen Volume not available	0	0	0	0
Spleen Volume at Week 12 not available	5 (17.9%)	2 (9.5%)	6 (10.3%)	3 (4.1%)
>0% Spleen Volume increase at Week 12	3 (10.7%)	3 (14.3%)	3 (5.2%)	7 (9.6%)
<35% Spleen Volume reduction at Week 12	16 (57.1%)	13 (61.9%)	34 (58.6%)	49 (67.1%)
Last participation date < Day 57 in DB phase	4 (14.3%)	0	4 (6.9%)	0
Splenic Response Rate at Any Timepoint in DB Phase				
Responder, n(%)	8 (28.6%)	8 (38.1%)	23 (39.7%)	28 (38.4%)
95% Exact CI	0.1322, 0.4867	0.1811, 0.6156	0.2705, 0.5336	0.2721, 0.5048

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-srr24.sas V.03.05 Output file: t-subgrp-srr24-hgb.pdf 29AUG2023: 9:04

Table 2.0125: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by JAK2V617F Mutation
Double-Blind Phase
ITT-Anemic Analysis Set

	Positive		Negative	
	MMB (N=39)	RUX (N=56)	MMB (N=36)	RUX (N=29)
All Stratum Combined				
Splenic Response Rate at Week 24				
Responder, n(%)	15 (38.5%)	20 (35.7%)	10 (27.8%)	8 (27.6%)
95% Exact CI	0.2336, 0.5538	0.2336, 0.4964	0.1420, 0.4519	0.1273, 0.4724
Noninferior Proportion Difference - Stratified CMH (95% CI)	0.20 (0.02, 0.37)		0.12 (-0.07, 0.31)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	0.17 (-0.00, 0.34)		0.11 (-0.07, 0.29)	
Superior Proportion Difference - Stratified CMH (95% CI)	0.06 (-0.15, 0.26)		0.01 (-0.23, 0.24)	
Superior Proportion Difference - Unstratified CMH (95% CI)	0.03 (-0.17, 0.23)		0.00 (-0.22, 0.23)	
Superior Proportion Difference - Unstratified Exact (95% CI)	0.03 (-0.18, 0.23)		0.00 (-0.24, 0.24)	
Non-Responder, n(%)	24 (61.5%)	36 (64.3%)	26 (72.2%)	21 (72.4%)
Baseline Spleen Volume not available	0	0	0	0
Spleen Volume at Week 24 not available	7 (17.9%)	6 (10.7%)	6 (16.7%)	2 (6.9%)
>0% Spleen Volume increase at Week 24	7 (17.9%)	3 (5.4%)	1 (2.8%)	5 (17.2%)
<35% Spleen Volume reduction at Week 24	17 (43.6%)	30 (53.6%)	20 (55.6%)	19 (65.5%)
Last participation date < Day 141 in DB phase	6 (15.4%)	3 (5.4%)	4 (11.1%)	1 (3.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-srr24.sas V.03.05 Output file: t-subgrp-srr24-jak.pdf 29AUG2023: 9:04

Table 2.0125: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by JAK2V617F Mutation
Double-Blind Phase
ITT-Anemic Analysis Set

	Positive		Negative	
	MMB (N=39)	RUX (N=56)	MMB (N=36)	RUX (N=29)
Splenic Response Rate at Week 12				
Responder, n(%)	13 (33.3%)	16 (28.6%)	10 (27.8%)	7 (24.1%)
95% Exact CI	0.1909, 0.5022	0.1730, 0.4221	0.1420, 0.4519	0.1030, 0.4354
Noninferior Proportion Difference - Stratified CMH (95% CI)	0.18 (0.00, 0.37)		0.15 (-0.04, 0.34)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	0.16 (-0.00, 0.33)		0.13 (-0.04, 0.31)	
Superior Proportion Difference - Stratified CMH (95% CI)	0.09 (-0.12, 0.29)		0.05 (-0.19, 0.28)	
Superior Proportion Difference - Unstratified CMH (95% CI)	0.05 (-0.14, 0.24)		0.04 (-0.18, 0.26)	
Superior Proportion Difference - Unstratified Exact (95% CI)	0.05 (-0.16, 0.25)		0.04 (-0.21, 0.27)	
Non-Responder, n(%)	26 (66.7%)	40 (71.4%)	26 (72.2%)	22 (75.9%)
Baseline Spleen Volume not available	0	0	0	0
Spleen Volume at Week 12 not available	5 (12.8%)	3 (5.4%)	4 (11.1%)	2 (6.9%)
>0% Spleen Volume increase at Week 12	3 (7.7%)	5 (8.9%)	1 (2.8%)	5 (17.2%)
<35% Spleen Volume reduction at Week 12	21 (53.8%)	37 (66.1%)	22 (61.1%)	20 (69.0%)
Last participation date < Day 57 in DB phase	3 (7.7%)	0	3 (8.3%)	0
Splenic Response Rate at Any Timepoint in DB Phase				
Responder, n(%)	17 (43.6%)	22 (39.3%)	11 (30.6%)	8 (27.6%)
95% Exact CI	0.2781, 0.6038	0.2650, 0.5325	0.1635, 0.4811	0.1273, 0.4724

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-srr24.sas V.03.05 Output file: t-subgrp-srr24-jak.pdf 29AUG2023: 9:04

Table 2.0127: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by Disease Type
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis		Post-PV Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)	MMB (N=11)	RUX (N=12)
All Stratum Combined						
Splenic Response Rate at Week 24						
Responder, n(%)	21 (35.6%)	17 (31.5%)	2 (12.5%)	9 (32.1%)	4 (36.4%)	5 (41.7%)
95% Exact CI	0.2355, 0.4913	0.1952, 0.4555	0.0155, 0.3835	0.1588, 0.5235	0.1093, 0.6921	0.1517, 0.7233
Noninferior Proportion Difference - Stratified CMH (95% CI)	0.16 (0.02, 0.30)		-0.04 (-0.29, 0.22)		0.01 (-0.30, 0.31)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	0.17 (0.02, 0.31)		-0.07 (-0.28, 0.14)		0.11 (-0.23, 0.46)	
Superior Proportion Difference - Stratified CMH (95% CI)	0.03 (-0.15, 0.20)		-0.16 (-0.46, 0.13)		-0.23 (-0.67, 0.21)	
Superior Proportion Difference - Unstratified CMH (95% CI)	0.04 (-0.13, 0.22)		-0.20 (-0.45, 0.06)		-0.05 (-0.47, 0.37)	
Superior Proportion Difference - Unstratified Exact (95% CI)	0.04 (-0.14, 0.22)		-0.20 (-0.48, 0.12)		-0.05 (-0.46, 0.35)	
Non-Responder, n(%)	38 (64.4%)	37 (68.5%)	14 (87.5%)	19 (67.9%)	7 (63.6%)	7 (58.3%)
Baseline Spleen Volume not available	0	0	0	0	0	0
Spleen Volume at Week 24 not available	9 (15.3%)	5 (9.3%)	4 (25.0%)	2 (7.1%)	3 (27.3%)	1 (8.3%)
>0% Spleen Volume increase at Week 24	7 (11.9%)	4 (7.4%)	1 (6.3%)	3 (10.7%)	2 (18.2%)	1 (8.3%)
<35% Spleen Volume reduction at Week 24	29 (49.2%)	32 (59.3%)	10 (62.5%)	17 (60.7%)	4 (36.4%)	6 (50.0%)
Last participation date < Day 141 in DB phase	7 (11.9%)	2 (3.7%)	2 (12.5%)	2 (7.1%)	3 (27.3%)	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-srr24.sas V.03.05 Output file: t-subgrp-srr24-mf.pdf 29AUG2023: 9:05

Table 2.0127: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by Disease Type
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis		Post-PV Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)	MMB (N=11)	RUX (N=12)
Splenic Response Rate at Week 12						
Responder, n(%)	19 (32.2%)	13 (24.1%)	2 (12.5%)	10 (35.7%)	4 (36.4%)	4 (33.3%)
95% Exact CI	0.2062, 0.4564	0.1349, 0.3764	0.0155, 0.3835	0.1864, 0.5593	0.1093, 0.6921	0.0992, 0.6511
Noninferior Proportion Difference - Stratified CMH (95% CI)	0.17 (0.03, 0.31)		-0.05 (-0.31, 0.21)		0.18 (-0.13, 0.49)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	0.18 (0.04, 0.32)		-0.09 (-0.30, 0.12)		0.16 (-0.18, 0.51)	
Superior Proportion Difference - Stratified CMH (95% CI)	0.07 (-0.10, 0.24)		-0.19 (-0.48, 0.11)		0.06 (-0.38, 0.50)	
Superior Proportion Difference - Unstratified CMH (95% CI)	0.08 (-0.09, 0.25)		-0.23 (-0.49, 0.02)		0.03 (-0.38, 0.44)	
Superior Proportion Difference - Unstratified Exact (95% CI)	0.08 (-0.10, 0.26)		-0.23 (-0.51, 0.08)		0.03 (-0.39, 0.42)	
Non-Responder, n(%)	40 (67.8%)	41 (75.9%)	14 (87.5%)	18 (64.3%)	7 (63.6%)	8 (66.7%)
Baseline Spleen Volume not available	0	0	0	0	0	0
Spleen Volume at Week 12 not available	7 (11.9%)	2 (3.7%)	1 (6.3%)	3 (10.7%)	3 (27.3%)	0
>0% Spleen Volume increase at Week 12	4 (6.8%)	7 (13.0%)	1 (6.3%)	2 (7.1%)	1 (9.1%)	1 (8.3%)
<35% Spleen Volume reduction at Week 12	33 (55.9%)	39 (72.2%)	13 (81.3%)	15 (53.6%)	4 (36.4%)	8 (66.7%)
Last participation date < Day 57 in DB phase	5 (8.5%)	0	1 (6.3%)	0	2 (18.2%)	0
Splenic Response Rate at Any Timepoint in DB Phase						
Responder, n(%)	25 (42.4%)	18 (33.3%)	2 (12.5%)	12 (42.9%)	4 (36.4%)	6 (50.0%)
95% Exact CI	0.2961, 0.5593	0.2109, 0.4747	0.0155, 0.3835	0.2446, 0.6282	0.1093, 0.6921	0.2109, 0.7891

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-srr24.sas V.03.05 Output file: t-subgrp-srr24-mf.pdf 29AUG2023: 9:05

Table 2.0126: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by Platelet Count at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	<100X10E9/L		>=100X10E9/L and <=200X10E9/L		>200X10E9/L	
	MMB (N=13)	RUX (N=13)	MMB (N=36)	RUX (N=34)	MMB (N=37)	RUX (N=47)
All Stratum Combined						
Splenic Response Rate at Week 24						
Responder, n(%)	6 (46.2%)	0	13 (36.1%)	8 (23.5%)	8 (21.6%)	23 (48.9%)
95% Exact CI	0.1922, 0.7487	0.0000, 0.2471	0.2082, 0.5378	0.1075, 0.4117	0.0983, 0.3821	0.3408, 0.6394
Noninferior Proportion Difference - Stratified CMH (95% CI)	0.46 (0.14, 0.77)		0.22 (0.04, 0.41)		-0.06 (-0.23, 0.11)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	0.46 (0.17, 0.75)		0.22 (0.04, 0.40)		-0.08 (-0.24, 0.08)	
Superior Proportion Difference - Stratified CMH (95% CI)	0.46 (0.12, 0.79)		0.13 (-0.09, 0.35)		-0.26 (-0.46, -0.05)	
Superior Proportion Difference - Unstratified CMH (95% CI)	0.46 (0.16, 0.76)		0.13 (-0.09, 0.34)		-0.27 (-0.47, -0.07)	
Superior Proportion Difference - Unstratified Exact (95% CI)	0.46 (0.04, 0.77)		0.13 (-0.11, 0.35)		-0.27 (-0.47, -0.06)	
Non-Responder, n(%)	7 (53.8%)	13 (100.0%)	23 (63.9%)	26 (76.5%)	29 (78.4%)	24 (51.1%)
Baseline Spleen Volume not available	0	0	0	0	0	0
Spleen Volume at Week 24 not available	1 (7.7%)	4 (30.8%)	6 (16.7%)	3 (8.8%)	9 (24.3%)	1 (2.1%)
>0% Spleen Volume increase at Week 24	2 (15.4%)	2 (15.4%)	4 (11.1%)	3 (8.8%)	4 (10.8%)	3 (6.4%)
<35% Spleen Volume reduction at Week 24	6 (46.2%)	9 (69.2%)	17 (47.2%)	23 (67.6%)	20 (54.1%)	23 (48.9%)
Last participation date < Day 141 in DB phase	1 (7.7%)	2 (15.4%)	6 (16.7%)	2 (5.9%)	5 (13.5%)	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Stratification factor is transfusion dependence (Yes vs. No) at baseline.
CMH = Cochran-Mantel-Haenszel

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-srr24.sas V.03.05 Output file: t-subgrp-srr24-plate.pdf 29AUG2023: 9:05

Table 2.0126: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by Platelet Count at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	<100X10E9/L		>=100X10E9/L and <=200X10E9/L		>200X10E9/L	
	MMB (N=13)	RUX (N=13)	MMB (N=36)	RUX (N=34)	MMB (N=37)	RUX (N=47)
Splenic Response Rate at Week 12						
Responder, n(%)	4 (30.8%)	0	12 (33.3%)	5 (14.7%)	9 (24.3%)	22 (46.8%)
95% Exact CI	0.0909, 0.6143	0.0000, 0.2471	0.1856, 0.5097	0.0495, 0.3106	0.1177, 0.4120	0.3211, 0.6192
Noninferior Proportion Difference - Stratified CMH (95% CI)	0.31 (0.01, 0.61)		0.25 (0.08, 0.42)		-0.02 (-0.19, 0.15)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	0.31 (0.04, 0.58)		0.25 (0.07, 0.42)		-0.04 (-0.20, 0.13)	
Superior Proportion Difference - Stratified CMH (95% CI)	0.31 (-0.01, 0.63)		0.19 (-0.00, 0.39)		-0.21 (-0.42, 0.00)	
Superior Proportion Difference - Unstratified CMH (95% CI)	0.31 (0.02, 0.59)		0.19 (-0.01, 0.39)		-0.22 (-0.43, -0.02)	
Superior Proportion Difference - Unstratified Exact (95% CI)	0.31 (-0.11, 0.66)		0.19 (-0.05, 0.41)		-0.22 (-0.42, -0.01)	
Non-Responder, n(%)	9 (69.2%)	13 (100.0%)	24 (66.7%)	29 (85.3%)	28 (75.7%)	25 (53.2%)
Baseline Spleen Volume not available	0	0	0	0	0	0
Spleen Volume at Week 12 not available	1 (7.7%)	1 (7.7%)	6 (16.7%)	3 (8.8%)	4 (10.8%)	1 (2.1%)
>0% Spleen Volume increase at Week 12	1 (7.7%)	3 (23.1%)	2 (5.6%)	4 (11.8%)	3 (8.1%)	3 (6.4%)
<35% Spleen Volume reduction at Week 12	8 (61.5%)	12 (92.3%)	18 (50.0%)	26 (76.5%)	24 (64.9%)	24 (51.1%)
Last participation date < Day 57 in DB phase	1 (7.7%)	0	4 (11.1%)	0	3 (8.1%)	0
Splenic Response Rate at Any Timepoint in DB Phase						
Responder, n(%)	6 (46.2%)	0	15 (41.7%)	9 (26.5%)	10 (27.0%)	27 (57.4%)
95% Exact CI	0.1922, 0.7487	0.0000, 0.2471	0.2551, 0.5924	0.1288, 0.4436	0.1379, 0.4412	0.4218, 0.7174

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Stratification factor is transfusion dependence (Yes vs. No) at baseline.
CMH = Cochran-Mantel-Haenszel

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-srr24.sas V.03.05 Output file: t-subgrp-srr24-plate.pdf 29AUG2023: 9:05

Table 2.0119: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by Race
Double-Blind Phase
ITT-Anemic Analysis Set

	White		All Other Races	
	MMB (N=69)	RUX (N=76)	MMB (N=11)	RUX (N=8)
All Stratum Combined				
Splenic Response Rate at Week 24				
Responder, n(%)	22 (31.9%)	25 (32.9%)	3 (27.3%)	4 (50.0%)
95% Exact CI	0.2117, 0.4421	0.2254, 0.4463	0.0602, 0.6097	0.1570, 0.8430
Noninferior Proportion Difference - Stratified CMH (95% CI)	0.13 (-0.00, 0.26)		-0.08 (-0.53, 0.37)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	0.12 (-0.01, 0.25)		-0.03 (-0.39, 0.33)	
Superior Proportion Difference - Stratified CMH (95% CI)	0.00 (-0.16, 0.16)		-0.29 (-0.82, 0.25)	
Superior Proportion Difference - Unstratified CMH (95% CI)	-0.01 (-0.16, 0.14)		-0.23 (-0.69, 0.24)	
Superior Proportion Difference - Unstratified Exact (95% CI)	-0.01 (-0.17, 0.15)		-0.23 (-0.63, 0.24)	
Non-Responder, n(%)	47 (68.1%)	51 (67.1%)	8 (72.7%)	4 (50.0%)
Baseline Spleen Volume not available	0	0	0	0
Spleen Volume at Week 24 not available	13 (18.8%)	7 (9.2%)	2 (18.2%)	0
>0% Spleen Volume increase at Week 24	8 (11.6%)	5 (6.6%)	1 (9.1%)	1 (12.5%)
<35% Spleen Volume reduction at Week 24	34 (49.3%)	44 (57.9%)	6 (54.5%)	4 (50.0%)
Last participation date < Day 141 in DB phase	11 (15.9%)	3 (3.9%)	1 (9.1%)	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-srr24.sas V.03.05 Output file: t-subgrp-srr24-race.pdf 29AUG2023: 9:03

Table 2.0119: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by Race
Double-Blind Phase
ITT-Anemic Analysis Set

	White		All Other Races	
	MMB (N=69)	RUX (N=76)	MMB (N=11)	RUX (N=8)
Splenic Response Rate at Week 12				
Responder, n(%)	20 (29.0%)	20 (26.3%)	4 (36.4%)	6 (75.0%)
95% Exact CI	0.1869, 0.4116	0.1687, 0.3768	0.1093, 0.6921	0.3491, 0.9681
Noninferior Proportion Difference - Stratified CMH (95% CI)	0.15 (0.02, 0.28)		-0.18 (-0.59, 0.24)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	0.13 (0.01, 0.26)		-0.09 (-0.45, 0.27)	
Superior Proportion Difference - Stratified CMH (95% CI)	0.06 (-0.09, 0.21)		-0.49 (-0.95, -0.02)	
Superior Proportion Difference - Unstratified CMH (95% CI)	0.03 (-0.12, 0.17)		-0.39 (-0.83, 0.06)	
Superior Proportion Difference - Unstratified Exact (95% CI)	0.03 (-0.14, 0.19)		-0.39 (-0.76, 0.09)	
Non-Responder, n(%)	49 (71.0%)	56 (73.7%)	7 (63.6%)	2 (25.0%)
Baseline Spleen Volume not available	0	0	0	0
Spleen Volume at Week 12 not available	9 (13.0%)	4 (5.3%)	1 (9.1%)	0
>0% Spleen Volume increase at Week 12	5 (7.2%)	8 (10.5%)	0	1 (12.5%)
<35% Spleen Volume reduction at Week 12	40 (58.0%)	52 (68.4%)	6 (54.5%)	2 (25.0%)
Last participation date < Day 57 in DB phase	7 (10.1%)	0	1 (9.1%)	0
Splenic Response Rate at Any Timepoint in DB Phase				
Responder, n(%)	25 (36.2%)	28 (36.8%)	4 (36.4%)	6 (75.0%)
95% Exact CI	0.2499, 0.4869	0.2606, 0.4869	0.1093, 0.6921	0.3491, 0.9681

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-srr24.sas V.03.05 Output file: t-subgrp-srr24-race.pdf 29AUG2023: 9:03

Table 2.0118: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female	
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)
All Stratum Combined				
Splenic Response Rate at Week 24				
Responder, n(%)	14 (28.0%)	14 (25.0%)	13 (36.1%)	17 (44.7%)
95% Exact CI	0.1623, 0.4249	0.1439, 0.3837	0.2082, 0.5378	0.2862, 0.6170
Noninferior Proportion Difference - Stratified CMH (95% CI)	0.15 (-0.00, 0.30)		0.09 (-0.10, 0.28)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	0.13 (-0.01, 0.27)		0.09 (-0.09, 0.28)	
Superior Proportion Difference - Stratified CMH (95% CI)	0.06 (-0.12, 0.24)		-0.09 (-0.32, 0.15)	
Superior Proportion Difference - Unstratified CMH (95% CI)	0.03 (-0.14, 0.20)		-0.09 (-0.31, 0.14)	
Superior Proportion Difference - Unstratified Exact (95% CI)	0.03 (-0.16, 0.22)		-0.09 (-0.31, 0.14)	
Non-Responder, n(%)	36 (72.0%)	42 (75.0%)	23 (63.9%)	21 (55.3%)
Baseline Spleen Volume not available	0	0	0	0
Spleen Volume at Week 24 not available	7 (14.0%)	6 (10.7%)	9 (25.0%)	2 (5.3%)
>0% Spleen Volume increase at Week 24	6 (12.0%)	6 (10.7%)	4 (11.1%)	2 (5.3%)
<35% Spleen Volume reduction at Week 24	29 (58.0%)	36 (64.3%)	14 (38.9%)	19 (50.0%)
Last participation date < Day 141 in DB phase	4 (8.0%)	4 (7.1%)	8 (22.2%)	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-srr24.sas V.03.05 Output file: t-subgrp-srr24-sex.pdf 29AUG2023: 9:03

Table 2.0118: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female	
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)
Splenic Response Rate at Week 12				
Responder, n(%)	12 (24.0%)	11 (19.6%)	13 (36.1%)	16 (42.1%)
95% Exact CI	0.1306, 0.3817	0.1023, 0.3243	0.2082, 0.5378	0.2631, 0.5918
Noninferior Proportion Difference - Stratified CMH (95% CI)	0.14 (-0.00, 0.29)		0.11 (-0.07, 0.30)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	0.12 (-0.01, 0.26)		0.11 (-0.08, 0.29)	
Superior Proportion Difference - Stratified CMH (95% CI)	0.08 (-0.09, 0.24)		-0.05 (-0.27, 0.18)	
Superior Proportion Difference - Unstratified CMH (95% CI)	0.04 (-0.12, 0.20)		-0.06 (-0.29, 0.17)	
Superior Proportion Difference - Unstratified Exact (95% CI)	0.04 (-0.15, 0.23)		-0.06 (-0.29, 0.17)	
Non-Responder, n(%)	38 (76.0%)	45 (80.4%)	23 (63.9%)	22 (57.9%)
Baseline Spleen Volume not available	0	0	0	0
Spleen Volume at Week 12 not available	4 (8.0%)	3 (5.4%)	7 (19.4%)	2 (5.3%)
>0% Spleen Volume increase at Week 12	6 (12.0%)	7 (12.5%)	0	3 (7.9%)
<35% Spleen Volume reduction at Week 12	34 (68.0%)	42 (75.0%)	16 (44.4%)	20 (52.6%)
Last participation date < Day 57 in DB phase	1 (2.0%)	0	7 (19.4%)	0
Splenic Response Rate at Any Timepoint in DB Phase				
Responder, n(%)	17 (34.0%)	17 (30.4%)	14 (38.9%)	19 (50.0%)
95% Exact CI	0.2121, 0.4877	0.1878, 0.4410	0.2314, 0.5654	0.3338, 0.6662

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-srr24.sas V.03.05 Output file: t-subgrp-srr24-sex.pdf 29AUG2023: 9:03

Table 2.0121: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by Spleen Volume at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3	
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)
All Stratum Combined				
Splenic Response Rate at Week 24				
Responder, n(%)	20 (42.6%)	17 (39.5%)	7 (17.9%)	14 (27.5%)
95% Exact CI	0.2826, 0.5782	0.2498, 0.5559	0.0754, 0.3353	0.1589, 0.4174
Noninferior Proportion Difference - Stratified CMH (95% CI)	0.17 (-0.00, 0.35)		0.01 (-0.16, 0.19)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	0.19 (0.02, 0.36)		0.01 (-0.13, 0.16)	
Superior Proportion Difference - Stratified CMH (95% CI)	0.02 (-0.19, 0.24)		-0.10 (-0.32, 0.11)	
Superior Proportion Difference - Unstratified CMH (95% CI)	0.03 (-0.18, 0.24)		-0.10 (-0.27, 0.08)	
Superior Proportion Difference - Unstratified Exact (95% CI)	0.03 (-0.17, 0.24)		-0.10 (-0.30, 0.11)	
Non-Responder, n(%)	27 (57.4%)	26 (60.5%)	32 (82.1%)	37 (72.5%)
Baseline Spleen Volume not available	0	0	0	0
Spleen Volume at Week 24 not available	7 (14.9%)	4 (9.3%)	9 (23.1%)	4 (7.8%)
>0% Spleen Volume increase at Week 24	5 (10.6%)	1 (2.3%)	5 (12.8%)	7 (13.7%)
<35% Spleen Volume reduction at Week 24	20 (42.6%)	22 (51.2%)	23 (59.0%)	33 (64.7%)
Last participation date < Day 141 in DB phase	7 (14.9%)	1 (2.3%)	5 (12.8%)	3 (5.9%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-srr24.sas V.03.05 Output file: t-subgrp-srr24-svb.pdf 29AUG2023: 9:04

Table 2.0121: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by Spleen Volume at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3	
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)
Splenic Response Rate at Week 12				
Responder, n(%)	16 (34.0%)	18 (41.9%)	9 (23.1%)	9 (17.6%)
95% Exact CI	0.2086, 0.4931	0.2701, 0.5787	0.1113, 0.3933	0.0840, 0.3087
Noninferior Proportion Difference - Stratified CMH (95% CI)	0.10 (-0.07, 0.27)		0.12 (-0.06, 0.30)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	0.09 (-0.07, 0.25)		0.12 (-0.02, 0.27)	
Superior Proportion Difference - Stratified CMH (95% CI)	-0.05 (-0.26, 0.15)		0.04 (-0.17, 0.24)	
Superior Proportion Difference - Unstratified CMH (95% CI)	-0.08 (-0.28, 0.12)		0.05 (-0.12, 0.23)	
Superior Proportion Difference - Unstratified Exact (95% CI)	-0.08 (-0.28, 0.13)		0.05 (-0.16, 0.26)	
Non-Responder, n(%)	31 (66.0%)	25 (58.1%)	30 (76.9%)	42 (82.4%)
Baseline Spleen Volume not available	0	0	0	0
Spleen Volume at Week 12 not available	7 (14.9%)	2 (4.7%)	4 (10.3%)	3 (5.9%)
>0% Spleen Volume increase at Week 12	2 (4.3%)	3 (7.0%)	4 (10.3%)	7 (13.7%)
<35% Spleen Volume reduction at Week 12	24 (51.1%)	23 (53.5%)	26 (66.7%)	39 (76.5%)
Last participation date < Day 57 in DB phase	6 (12.8%)	0	2 (5.1%)	0
Splenic Response Rate at Any Timepoint in DB Phase				
Responder, n(%)	21 (44.7%)	21 (48.8%)	10 (25.6%)	15 (29.4%)
95% Exact CI	0.3017, 0.5988	0.3331, 0.6454	0.1304, 0.4213	0.1749, 0.4383

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-srr24.sas V.03.05 Output file: t-subgrp-srr24-svb.pdf 29AUG2023: 9:04

Table 2.0120: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by Transfusion Dependence at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	Yes		No	
	MMB (N=49)	RUX (N=43)	MMB (N=37)	RUX (N=51)
All Stratum Combined				
Splenic Response Rate at Week 24				
Responder, n(%)	12 (24.5%)	12 (27.9%)	15 (40.5%)	19 (37.3%)
95% Exact CI	0.1334, 0.3887	0.1533, 0.4367	0.2475, 0.5790	0.2413, 0.5192
Noninferior Proportion Difference - Stratified CMH (95% CI)	0.08 (-0.07, 0.22)		0.18 (0.00, 0.37)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	0.08 (-0.07, 0.22)		0.18 (0.00, 0.36)	
Superior Proportion Difference - Stratified CMH (95% CI)	-0.03 (-0.21, 0.14)		0.04 (-0.17, 0.25)	
Superior Proportion Difference - Unstratified CMH (95% CI)	-0.03 (-0.22, 0.15)		0.03 (-0.18, 0.24)	
Superior Proportion Difference - Unstratified Exact (95% CI)	-0.03 (-0.24, 0.17)		0.03 (-0.18, 0.24)	
Non-Responder, n(%)	37 (75.5%)	31 (72.1%)	22 (59.5%)	32 (62.7%)
Baseline Spleen Volume not available	0	0	0	0
Spleen Volume at Week 24 not available	10 (20.4%)	6 (14.0%)	6 (16.2%)	2 (3.9%)
>0% Spleen Volume increase at Week 24	7 (14.3%)	5 (11.6%)	3 (8.1%)	3 (5.9%)
<35% Spleen Volume reduction at Week 24	27 (55.1%)	25 (58.1%)	16 (43.2%)	30 (58.8%)
Last participation date < Day 141 in DB phase	8 (16.3%)	4 (9.3%)	4 (10.8%)	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Stratification factor is platelet count (<100X10^9/L, =100X10^9/L and = 200X10^9/L, or > 200X10^9/L) at baseline.
CMH = Cochran-Mantel-Haenszel

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-srr24.sas V.03.05 Output file: t-subgrp-srr24-tf.pdf 29AUG2023: 9:03

Table 2.0120: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by Transfusion Dependence at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	Yes		No	
	MMB (N=49)	RUX (N=43)	MMB (N=37)	RUX (N=51)
Splenic Response Rate at Week 12				
Responder, n(%)	11 (22.4%)	7 (16.3%)	14 (37.8%)	20 (39.2%)
95% Exact CI	0.1177, 0.3662	0.0681, 0.3070	0.2246, 0.5524	0.2584, 0.5389
Noninferior Proportion Difference - Stratified CMH (95% CI)	0.13 (-0.01, 0.26)		0.15 (-0.04, 0.33)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	0.13 (-0.01, 0.26)		0.14 (-0.04, 0.32)	
Superior Proportion Difference - Stratified CMH (95% CI)	0.06 (-0.10, 0.22)		-0.01 (-0.22, 0.21)	
Superior Proportion Difference - Unstratified CMH (95% CI)	0.06 (-0.10, 0.23)		-0.01 (-0.22, 0.19)	
Superior Proportion Difference - Unstratified Exact (95% CI)	0.06 (-0.14, 0.26)		-0.01 (-0.22, 0.20)	
Non-Responder, n(%)	38 (77.6%)	36 (83.7%)	23 (62.2%)	31 (60.8%)
Baseline Spleen Volume not available	0	0	0	0
Spleen Volume at Week 12 not available	8 (16.3%)	4 (9.3%)	3 (8.1%)	1 (2.0%)
>0% Spleen Volume increase at Week 12	4 (8.2%)	6 (14.0%)	2 (5.4%)	4 (7.8%)
<35% Spleen Volume reduction at Week 12	30 (61.2%)	32 (74.4%)	20 (54.1%)	30 (58.8%)
Last participation date < Day 57 in DB phase	5 (10.2%)	0	3 (8.1%)	0
Splenic Response Rate at Any Timepoint in DB Phase				
Responder, n(%)	14 (28.6%)	13 (30.2%)	17 (45.9%)	23 (45.1%)
95% Exact CI	0.1658, 0.4326	0.1718, 0.4613	0.2949, 0.6308	0.3113, 0.5966

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Stratification factor is platelet count (<100X10^9/L, =100X10^9/L and = 200X10^9/L, or > 200X10^9/L) at baseline.
CMH = Cochran-Mantel-Haenszel

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-srr24.sas V.03.05 Output file: t-subgrp-srr24-tf.pdf 29AUG2023: 9:03

Table 2.0122: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by TSS at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	< Q1 7.8		>= Q1 7.8 and < Median 16.8	
	MMB (N=24)	RUX (N=20)	MMB (N=16)	RUX (N=29)
All Stratum Combined				
Splenic Response Rate at Week 24				
Responder, n(%)	9 (37.5%)	6 (30.0%)	6 (37.5%)	8 (27.6%)
95% Exact CI	0.1880, 0.5941	0.1189, 0.5428	0.1520, 0.6457	0.1273, 0.4724
Noninferior Proportion Difference - Stratified CMH (95% CI)	0.23 (-0.02, 0.47)		0.26 (-0.03, 0.54)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	0.20 (-0.04, 0.43)		0.21 (-0.06, 0.48)	
Superior Proportion Difference - Stratified CMH (95% CI)	0.11 (-0.18, 0.40)		0.15 (-0.18, 0.47)	
Superior Proportion Difference - Unstratified CMH (95% CI)	0.08 (-0.21, 0.36)		0.10 (-0.20, 0.40)	
Superior Proportion Difference - Unstratified Exact (95% CI)	0.08 (-0.22, 0.36)		0.10 (-0.21, 0.40)	
Non-Responder, n(%)	15 (62.5%)	14 (70.0%)	10 (62.5%)	21 (72.4%)
Baseline Spleen Volume not available	0	0	0	0
Spleen Volume at Week 24 not available	2 (8.3%)	0	2 (12.5%)	4 (13.8%)
>0% Spleen Volume increase at Week 24	2 (8.3%)	1 (5.0%)	2 (12.5%)	2 (6.9%)
<35% Spleen Volume reduction at Week 24	13 (54.2%)	14 (70.0%)	8 (50.0%)	17 (58.6%)
Last participation date < Day 141 in DB phase	1 (4.2%)	0	2 (12.5%)	2 (6.9%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel
TSS = Total Symptom Score

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-srr24.sas V.03.05 Output file: t-subgrp-srr24-tss.pdf 29AUG2023: 9:04

Table 2.0122: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by TSS at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

(Continued)	>= Median 16.8 and < Q3 25.7		>= Q3 25.7	
	MMB (N=21)	RUX (N=23)	MMB (N=24)	RUX (N=21)
All Stratum Combined				
Splenic Response Rate at Week 24				
Responder, n(%)	6 (28.6%)	10 (43.5%)	5 (20.8%)	7 (33.3%)
95% Exact CI	0.1128, 0.5218	0.2319, 0.6551	0.0713, 0.4215	0.1459, 0.5697
Noninferior Proportion Difference - Stratified CMH (95% CI)	0.10 (-0.19, 0.39)		-0.06 (-0.28, 0.15)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	0.02 (-0.21, 0.26)		0.01 (-0.20, 0.22)	
Superior Proportion Difference - Stratified CMH (95% CI)	-0.06 (-0.41, 0.28)		-0.20 (-0.47, 0.06)	
Superior Proportion Difference - Unstratified CMH (95% CI)	-0.15 (-0.44, 0.14)		-0.13 (-0.39, 0.14)	
Superior Proportion Difference - Unstratified Exact (95% CI)	-0.15 (-0.43, 0.14)		-0.13 (-0.41, 0.17)	
Non-Responder, n(%)	15 (71.4%)	13 (56.5%)	19 (79.2%)	14 (66.7%)
Baseline Spleen Volume not available	0	0	0	0
Spleen Volume at Week 24 not available	3 (14.3%)	1 (4.3%)	9 (37.5%)	3 (14.3%)
>0% Spleen Volume increase at Week 24	1 (4.8%)	2 (8.7%)	5 (20.8%)	3 (14.3%)
<35% Spleen Volume reduction at Week 24	12 (57.1%)	12 (52.2%)	10 (41.7%)	11 (52.4%)
Last participation date < Day 141 in DB phase	4 (19.0%)	0	5 (20.8%)	2 (9.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel
TSS = Total Symptom Score

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-srr24.sas V.03.05 Output file: t-subgrp-srr24-tss.pdf 29AUG2023: 9:04

Table 2.0122: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by TSS at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	< Q1 7.8		>= Q1 7.8 and < Median 16.8	
	MMB (N=24)	RUX (N=20)	MMB (N=16)	RUX (N=29)
Splenic Response Rate at Week 12				
Responder, n(%)	8 (33.3%)	6 (30.0%)	4 (25.0%)	7 (24.1%)
95% Exact CI	0.1563, 0.5532	0.1189, 0.5428	0.0727, 0.5238	0.1030, 0.4354
Noninferior Proportion Difference - Stratified CMH (95% CI)	0.18 (-0.06, 0.43)		0.13 (-0.14, 0.40)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	0.15 (-0.08, 0.38)		0.11 (-0.14, 0.35)	
Superior Proportion Difference - Stratified CMH (95% CI)	0.07 (-0.22, 0.36)		0.04 (-0.27, 0.34)	
Superior Proportion Difference - Unstratified CMH (95% CI)	0.03 (-0.25, 0.32)		0.01 (-0.27, 0.28)	
Superior Proportion Difference - Unstratified Exact (95% CI)	0.03 (-0.26, 0.33)		0.01 (-0.29, 0.31)	
Non-Responder, n(%)	16 (66.7%)	14 (70.0%)	12 (75.0%)	22 (75.9%)
Baseline Spleen Volume not available	0	0	0	0
Spleen Volume at Week 12 not available	2 (8.3%)	0	2 (12.5%)	3 (10.3%)
>0% Spleen Volume increase at Week 12	1 (4.2%)	1 (5.0%)	2 (12.5%)	2 (6.9%)
<35% Spleen Volume reduction at Week 12	14 (58.3%)	14 (70.0%)	10 (62.5%)	19 (65.5%)
Last participation date < Day 57 in DB phase	1 (4.2%)	0	2 (12.5%)	0
Splenic Response Rate at Any Timepoint in DB Phase				
Responder, n(%)	10 (41.7%)	7 (35.0%)	7 (43.8%)	11 (37.9%)
95% Exact CI	0.2211, 0.6336	0.1539, 0.5922	0.1975, 0.7012	0.2069, 0.5774

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel
TSS = Total Symptom Score

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-srr24.sas V.03.05 Output file: t-subgrp-srr24-tss.pdf 29AUG2023: 9:04

Table 2.0122: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by TSS at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

(Continued)	>= Median 16.8 and < Q3 25.7		>= Q3 25.7	
	MMB (N=21)	RUX (N=23)	MMB (N=24)	RUX (N=21)
Splenic Response Rate at Week 12				
Responder, n(%)	8 (38.1%)	8 (34.8%)	4 (16.7%)	6 (28.6%)
95% Exact CI	0.1811, 0.6156	0.1638, 0.5727	0.0474, 0.3738	0.1128, 0.5218
Noninferior Proportion Difference - Stratified CMH (95% CI)	0.27 (-0.01, 0.56)		-0.10 (-0.30, 0.10)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	0.17 (-0.07, 0.42)		-0.00 (-0.20, 0.19)	
Superior Proportion Difference - Stratified CMH (95% CI)	0.17 (-0.15, 0.49)		-0.23 (-0.48, 0.03)	
Superior Proportion Difference - Unstratified CMH (95% CI)	0.03 (-0.26, 0.33)		-0.12 (-0.37, 0.14)	
Superior Proportion Difference - Unstratified Exact (95% CI)	0.03 (-0.27, 0.32)		-0.12 (-0.40, 0.18)	
Non-Responder, n(%)	13 (61.9%)	15 (65.2%)	20 (83.3%)	15 (71.4%)
Baseline Spleen Volume not available	0	0	0	0
Spleen Volume at Week 12 not available	1 (4.8%)	1 (4.3%)	6 (25.0%)	1 (4.8%)
>0% Spleen Volume increase at Week 12	1 (4.8%)	3 (13.0%)	2 (8.3%)	4 (19.0%)
<35% Spleen Volume reduction at Week 12	12 (57.1%)	14 (60.9%)	14 (58.3%)	14 (66.7%)
Last participation date < Day 57 in DB phase	1 (4.8%)	0	4 (16.7%)	0
Splenic Response Rate at Any Timepoint in DB Phase				
Responder, n(%)	8 (38.1%)	10 (43.5%)	5 (20.8%)	8 (38.1%)
95% Exact CI	0.1811, 0.6156	0.2319, 0.6551	0.0713, 0.4215	0.1811, 0.6156

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel
TSS = Total Symptom Score

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-srr24.sas V.03.05 Output file: t-subgrp-srr24-tss.pdf 29AUG2023: 9:04

Table 2.0717: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years	
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)
Total Symptom Score Status				
Missing TSS at baseline (excluded from rate calculation)	0	0	1 (1.6%)	1 (1.7%)
TSS = 0 at baseline	0	0	2 (3.2%)	0
TSS > 0 at baseline	24 (100.0%)	36 (100.0%)	59 (95.2%)	57 (98.3%)
Response Rate of Total Symptom Score at Week 24				
Subjects Evaluable at Week 24, n	24	36	60	57
TSS = 0 at baseline and TSS >0 or missing at Week 24	0	0	1 (1.7%)	0
Responder, n(%)	8 (33.3%)	13 (36.1%)	13 (21.7%)	20 (35.1%)
95% Exact CI	0.1563, 0.5532	0.2082, 0.5378	0.1207, 0.3420	0.2291, 0.4887
Noninferior Proportion Difference - Stratified CMH (95% CI)	0.02 (-0.25, 0.28)		-0.03 (-0.17, 0.12)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	0.09 (-0.13, 0.31)		-0.02 (-0.15, 0.12)	
Superior Proportion Difference - Stratified CMH (95% CI)	-0.11 (-0.40, 0.19)		-0.14 (-0.32, 0.03)	
Superior Proportion Difference - Unstratified CMH (95% CI)	-0.03 (-0.28, 0.22)		-0.13 (-0.30, 0.03)	
Superior Proportion Difference - Unstratified Exact (95% CI)	-0.03 (-0.29, 0.23)		-0.13 (-0.31, 0.05)	
Non-Responder, n(%)	16 (66.7%)	23 (63.9%)	47 (78.3%)	37 (64.9%)
Last participation date < Day 162 in DB phase	4 (16.7%)	3 (8.3%)	12 (20.0%)	5 (8.8%)
Last participation date >= Day 162 and TSS at Week 24 not available	1 (4.2%)	2 (5.6%)	2 (3.3%)	4 (7.0%)
>0% increase from baseline at Week 24	4 (16.7%)	4 (11.1%)	13 (21.7%)	9 (15.8%)
<50% reduction from baseline at Week 24	11 (45.8%)	18 (50.0%)	32 (53.3%)	28 (49.1%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-age.pdf 29AUG2023: 9:02

Table 2.0717: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years	
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)
Response Rate of Total Symptom Score at Week 12				
Subjects Evaluable at Week 12, n	24	36	60	57
TSS = 0 at baseline and TSS >0 or missing at Week 12	0	0	1 (1.7%)	0
Responder, n(%)	9 (37.5%)	10 (27.8%)	11 (18.3%)	18 (31.6%)
95% Exact CI	0.1880, 0.5941	0.1420, 0.4519	0.0952, 0.3044	0.1991, 0.4524
Noninferior Proportion Difference - Stratified CMH (95% CI)	0.15 (-0.11, 0.41)		-0.05 (-0.18, 0.09)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	0.19 (-0.03, 0.41)		-0.03 (-0.16, 0.10)	
Superior Proportion Difference - Stratified CMH (95% CI)	0.06 (-0.22, 0.35)		-0.15 (-0.32, 0.02)	
Superior Proportion Difference - Unstratified CMH (95% CI)	0.10 (-0.15, 0.35)		-0.13 (-0.29, 0.03)	
Superior Proportion Difference - Unstratified Exact (95% CI)	0.10 (-0.17, 0.35)		-0.13 (-0.31, 0.05)	
Non-Responder, n(%)	15 (62.5%)	26 (72.2%)	49 (81.7%)	39 (68.4%)
Last participation date < Day 78 in DB phase	1 (4.2%)	0	9 (15.0%)	0
Last participation date >= Day 78 and TSS at Week 12 not available	0	1 (2.8%)	2 (3.3%)	2 (3.5%)
>0% increase from baseline at Week 12	4 (16.7%)	4 (11.1%)	17 (28.3%)	14 (24.6%)
<50% reduction from baseline at Week 12	14 (58.3%)	25 (69.4%)	37 (61.7%)	37 (64.9%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-age.pdf 29AUG2023: 9:02

Table 2.0724: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by IPSS
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk	
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)
Total Symptom Score Status				
Missing TSS at baseline (excluded from rate calculation)	0	0	1 (1.7%)	1 (1.4%)
TSS = 0 at baseline	1 (3.6%)	0	1 (1.7%)	0
TSS > 0 at baseline	27 (96.4%)	24 (100.0%)	56 (96.6%)	69 (98.6%)
Response Rate of Total Symptom Score at Week 24				
Subjects Evaluable at Week 24, n	28	24	56	69
TSS = 0 at baseline and TSS >0 or missing at Week 24	1 (3.6%)	0	0	0
Responder, n(%)	11 (39.3%)	8 (33.3%)	10 (17.9%)	25 (36.2%)
95% Exact CI	0.2150, 0.5942	0.1563, 0.5532	0.0891, 0.3040	0.2499, 0.4869
Noninferior Proportion Difference - Stratified CMH (95% CI)	0.15 (-0.11, 0.42)		-0.07 (-0.21, 0.06)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	0.17 (-0.06, 0.40)		-0.06 (-0.19, 0.06)	
Superior Proportion Difference - Stratified CMH (95% CI)	0.04 (-0.28, 0.36)		-0.19 (-0.36, -0.03)	
Superior Proportion Difference - Unstratified CMH (95% CI)	0.06 (-0.21, 0.33)		-0.18 (-0.34, -0.03)	
Superior Proportion Difference - Unstratified Exact (95% CI)	0.06 (-0.21, 0.32)		-0.18 (-0.35, -0.01)	
Non-Responder, n(%)	17 (60.7%)	16 (66.7%)	46 (82.1%)	44 (63.8%)
Last participation date < Day 162 in DB phase	4 (14.3%)	2 (8.3%)	12 (21.4%)	6 (8.7%)
Last participation date >= Day 162 and TSS at Week 24 not available	1 (3.6%)	1 (4.2%)	2 (3.6%)	5 (7.2%)
>0% increase from baseline at Week 24	5 (17.9%)	6 (25.0%)	12 (21.4%)	7 (10.1%)
<50% reduction from baseline at Week 24	11 (39.3%)	13 (54.2%)	32 (57.1%)	33 (47.8%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;
IPSS = International Prognostic Scoring System

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-dipss.pdf 29AUG2023: 9:04

Table 2.0724: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by IPSS
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk	
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)
Response Rate of Total Symptom Score at Week 12				
Subjects Evaluable at Week 12, n	28	24	56	69
TSS = 0 at baseline and TSS >0 or missing at Week 12	1 (3.6%)	0	0	0
Responder, n(%)	10 (35.7%)	8 (33.3%)	10 (17.9%)	20 (29.0%)
95% Exact CI	0.1864, 0.5593	0.1563, 0.5532	0.0891, 0.3040	0.1869, 0.4116
Noninferior Proportion Difference - Stratified CMH (95% CI)	0.10 (-0.15, 0.36)		-0.01 (-0.15, 0.12)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	0.13 (-0.09, 0.36)		-0.02 (-0.14, 0.11)	
Superior Proportion Difference - Stratified CMH (95% CI)	-0.01 (-0.33, 0.31)		-0.11 (-0.27, 0.05)	
Superior Proportion Difference - Unstratified CMH (95% CI)	0.02 (-0.24, 0.29)		-0.11 (-0.26, 0.04)	
Superior Proportion Difference - Unstratified Exact (95% CI)	0.02 (-0.25, 0.29)		-0.11 (-0.28, 0.06)	
Non-Responder, n(%)	18 (64.3%)	16 (66.7%)	46 (82.1%)	49 (71.0%)
Last participation date < Day 78 in DB phase	3 (10.7%)	0	7 (12.5%)	0
Last participation date >= Day 78 and TSS at Week 12 not available	1 (3.6%)	1 (4.2%)	1 (1.8%)	2 (2.9%)
>0% increase from baseline at Week 12	6 (21.4%)	5 (20.8%)	15 (26.8%)	13 (18.8%)
<50% reduction from baseline at Week 12	13 (46.4%)	15 (62.5%)	38 (67.9%)	47 (68.1%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;
IPSS = International Prognostic Scoring System

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-dipss.pdf 29AUG2023: 9:04

Table 2.0728: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by Geographic Area
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Europe		Eastern Europe		Asia	
	MMB (N=53)	RUX (N=51)	MMB (N=25)	RUX (N=36)	MMB (N=8)	RUX (N=7)
Total Symptom Score Status						
Missing TSS at baseline (excluded from rate calculation)	0	1 (2.0%)	1 (4.0%)	0	0	0
TSS = 0 at baseline	2 (3.8%)	0	0	0	0	0
TSS > 0 at baseline	51 (96.2%)	50 (98.0%)	24 (96.0%)	36 (100.0%)	8 (100.0%)	7 (100.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-geo.pdf 29AUG2023: 9:05

Table 2.0728: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by Geographic Area
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Europe		Eastern Europe		Asia	
	MMB (N=53)	RUX (N=51)	MMB (N=25)	RUX (N=36)	MMB (N=8)	RUX (N=7)
Response Rate of Total Symptom Score at Week 24						
Subjects Evaluable at Week 24, n	52	50	24	36	8	7
TSS = 0 at baseline and TSS >0 or missing at Week 24	1 (1.9%)	0	0	0	0	0
Responder, n(%)	15 (28.8%)	17 (34.0%)	4 (16.7%)	15 (41.7%)	2 (25.0%)	1 (14.3%)
95% Exact CI	0.1713, 0.4308	0.2121, 0.4877	0.0474, 0.3738	0.2551, 0.5924	0.0319, 0.6509	0.0036, 0.5787
Noninferior Proportion Difference - Stratified CMH (95% CI)	0.06 (-0.11, 0.23)		-0.12 (-0.35, 0.12)		0.11 (-0.38, 0.60)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	0.06 (-0.09, 0.21)		-0.11 (-0.30, 0.08)		0.15 (-0.24, 0.55)	
Superior Proportion Difference - Stratified CMH (95% CI)	-0.05 (-0.25, 0.15)		-0.26 (-0.53, 0.01)		0.03 (-0.50, 0.56)	
Superior Proportion Difference - Unstratified CMH (95% CI)	-0.05 (-0.23, 0.13)		-0.25 (-0.48, -0.02)		0.11 (-0.35, 0.56)	
Superior Proportion Difference - Unstratified Exact (95% CI)	-0.05 (-0.24, 0.14)		-0.25 (-0.49, 0.02)		0.11 (-0.36, 0.58)	
Non-Responder, n(%)	37 (71.2%)	33 (66.0%)	20 (83.3%)	21 (58.3%)	6 (75.0%)	6 (85.7%)
Last participation date < Day 162 in DB phase	10 (19.2%)	5 (10.0%)	4 (16.7%)	3 (8.3%)	2 (25.0%)	0
Last participation date >= Day 162 and TSS at Week 24 not available	3 (5.8%)	5 (10.0%)	0	1 (2.8%)	0	0
>0% increase from baseline at Week 24	11 (21.2%)	10 (20.0%)	6 (25.0%)	3 (8.3%)	0	0
<50% reduction from baseline at Week 24	23 (44.2%)	23 (46.0%)	16 (66.7%)	17 (47.2%)	4 (50.0%)	6 (85.7%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-geo.pdf 29AUG2023: 9:05

Table 2.0728: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by Geographic Area
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Europe		Eastern Europe		Asia	
	MMB (N=53)	RUX (N=51)	MMB (N=25)	RUX (N=36)	MMB (N=8)	RUX (N=7)
Response Rate of Total Symptom Score at Week 12						
Subjects Evaluable at Week 12, n	52	50	24	36	8	7
TSS = 0 at baseline and TSS >0 or missing at Week 12	1 (1.9%)	0	0	0	0	0
Responder, n(%)	15 (28.8%)	16 (32.0%)	3 (12.5%)	10 (27.8%)	2 (25.0%)	2 (28.6%)
95% Exact CI	0.1713, 0.4308	0.1952, 0.4670	0.0266, 0.3236	0.1420, 0.4519	0.0319, 0.6509	0.0367, 0.7096
Noninferior Proportion Difference - Stratified CMH (95% CI)	0.06 (-0.10, 0.23)		-0.05 (-0.27, 0.17)		0.03 (-0.48, 0.53)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	0.07 (-0.08, 0.23)		-0.06 (-0.23, 0.11)		0.06 (-0.36, 0.47)	
Superior Proportion Difference - Stratified CMH (95% CI)	-0.05 (-0.25, 0.15)		-0.14 (-0.40, 0.11)		-0.10 (-0.65, 0.46)	
Superior Proportion Difference - Unstratified CMH (95% CI)	-0.03 (-0.21, 0.15)		-0.15 (-0.36, 0.05)		-0.04 (-0.53, 0.46)	
Superior Proportion Difference - Unstratified Exact (95% CI)	-0.03 (-0.22, 0.16)		-0.15 (-0.40, 0.11)		-0.04 (-0.51, 0.47)	
Non-Responder, n(%)	37 (71.2%)	34 (68.0%)	21 (87.5%)	26 (72.2%)	6 (75.0%)	5 (71.4%)
Last participation date < Day 78 in DB phase	6 (11.5%)	0	3 (12.5%)	0	1 (12.5%)	0
Last participation date >= Day 78 and TSS at Week 12 not available	2 (3.8%)	3 (6.0%)	0	0	0	0
>0% increase from baseline at Week 12	12 (23.1%)	9 (18.0%)	8 (33.3%)	8 (22.2%)	1 (12.5%)	1 (14.3%)
<50% reduction from baseline at Week 12	28 (53.8%)	31 (62.0%)	18 (75.0%)	26 (72.2%)	5 (62.5%)	5 (71.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-geo.pdf 29AUG2023: 9:05

Table 2.0723: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by HGB at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	<8 g/dL		>=8 g/dL	
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)
Total Symptom Score Status				
Missing TSS at baseline (excluded from rate calculation)	0	1 (4.8%)	1 (1.7%)	0
TSS = 0 at baseline	1 (3.6%)	0	1 (1.7%)	0
TSS > 0 at baseline	27 (96.4%)	20 (95.2%)	56 (96.6%)	73 (100.0%)
Response Rate of Total Symptom Score at Week 24				
Subjects Evaluable at Week 24, n	27	20	57	73
TSS = 0 at baseline and TSS >0 or missing at Week 24	0	0	1 (1.8%)	0
Responder, n(%)	5 (18.5%)	7 (35.0%)	16 (28.1%)	26 (35.6%)
95% Exact CI	0.0630, 0.3808	0.1539, 0.5922	0.1697, 0.4154	0.2475, 0.4769
Noninferior Proportion Difference - Stratified CMH (95% CI)	-0.05 (-0.27, 0.18)		0.03 (-0.11, 0.18)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	-0.05 (-0.26, 0.16)		0.04 (-0.10, 0.18)	
Superior Proportion Difference - Stratified CMH (95% CI)	-0.16 (-0.45, 0.12)		-0.09 (-0.26, 0.08)	
Superior Proportion Difference - Unstratified CMH (95% CI)	-0.16 (-0.43, 0.10)		-0.08 (-0.24, 0.09)	
Superior Proportion Difference - Unstratified Exact (95% CI)	-0.16 (-0.43, 0.13)		-0.08 (-0.25, 0.10)	
Non-Responder, n(%)	22 (81.5%)	13 (65.0%)	41 (71.9%)	47 (64.4%)
Last participation date < Day 162 in DB phase	6 (22.2%)	4 (20.0%)	10 (17.5%)	4 (5.5%)
Last participation date >= Day 162 and TSS at Week 24 not available	1 (3.7%)	2 (10.0%)	2 (3.5%)	4 (5.5%)
>0% increase from baseline at Week 24	6 (22.2%)	2 (10.0%)	11 (19.3%)	11 (15.1%)
<50% reduction from baseline at Week 24	15 (55.6%)	7 (35.0%)	28 (49.1%)	39 (53.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-hgb.pdf 29AUG2023: 9:04

Table 2.0723: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by HGB at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	<8 g/dL		>=8 g/dL	
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)
Response Rate of Total Symptom Score at Week 12				
Subjects Evaluable at Week 12, n	27	20	57	73
TSS = 0 at baseline and TSS >0 or missing at Week 12	0	0	1 (1.8%)	0
Responder, n(%)	6 (22.2%)	5 (25.0%)	14 (24.6%)	23 (31.5%)
95% Exact CI	0.0862, 0.4226	0.0866, 0.4910	0.1413, 0.3776	0.2113, 0.4344
Noninferior Proportion Difference - Stratified CMH (95% CI)	0.05 (-0.17, 0.28)		0.03 (-0.11, 0.17)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	0.05 (-0.15, 0.26)		0.03 (-0.10, 0.17)	
Superior Proportion Difference - Stratified CMH (95% CI)	-0.03 (-0.30, 0.24)		-0.08 (-0.24, 0.08)	
Superior Proportion Difference - Unstratified CMH (95% CI)	-0.03 (-0.28, 0.23)		-0.07 (-0.23, 0.09)	
Superior Proportion Difference - Unstratified Exact (95% CI)	-0.03 (-0.31, 0.26)		-0.07 (-0.24, 0.10)	
Non-Responder, n(%)	21 (77.8%)	15 (75.0%)	43 (75.4%)	50 (68.5%)
Last participation date < Day 78 in DB phase	5 (18.5%)	0	5 (8.8%)	0
Last participation date >= Day 78 and TSS at Week 12 not available	1 (3.7%)	1 (5.0%)	1 (1.8%)	2 (2.7%)
>0% increase from baseline at Week 12	5 (18.5%)	3 (15.0%)	16 (28.1%)	15 (20.5%)
<50% reduction from baseline at Week 12	15 (55.6%)	14 (70.0%)	36 (63.2%)	48 (65.8%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-hgb.pdf 29AUG2023: 9:04

Table 2.0725: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by JAK2V617F Mutation
Double-Blind Phase
ITT-Anemic Analysis Set

	Positive		Negative	
	MMB (N=39)	RUX (N=56)	MMB (N=36)	RUX (N=29)
Total Symptom Score Status				
Missing TSS at baseline (excluded from rate calculation)	0	1 (1.8%)	1 (2.8%)	0
TSS = 0 at baseline	2 (5.1%)	0	0	0
TSS > 0 at baseline	37 (94.9%)	55 (98.2%)	35 (97.2%)	29 (100.0%)
Response Rate of Total Symptom Score at Week 24				
Subjects Evaluable at Week 24, n	38	55	35	29
TSS = 0 at baseline and TSS >0 or missing at Week 24	1 (2.6%)	0	0	0
Responder, n(%)	11 (28.9%)	20 (36.4%)	9 (25.7%)	11 (37.9%)
95% Exact CI	0.1542, 0.4590	0.2381, 0.5044	0.1249, 0.4326	0.2069, 0.5774
Noninferior Proportion Difference - Stratified CMH (95% CI)	0.03 (-0.16, 0.22)		-0.03 (-0.23, 0.17)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	0.05 (-0.12, 0.22)		0.00 (-0.19, 0.19)	
Superior Proportion Difference - Stratified CMH (95% CI)	-0.10 (-0.32, 0.12)		-0.16 (-0.41, 0.08)	
Superior Proportion Difference - Unstratified CMH (95% CI)	-0.07 (-0.27, 0.12)		-0.12 (-0.36, 0.11)	
Superior Proportion Difference - Unstratified Exact (95% CI)	-0.07 (-0.28, 0.13)		-0.12 (-0.36, 0.13)	
Non-Responder, n(%)	27 (71.1%)	35 (63.6%)	26 (74.3%)	18 (62.1%)
Last participation date < Day 162 in DB phase	8 (21.1%)	6 (10.9%)	6 (17.1%)	2 (6.9%)
Last participation date >= Day 162 and TSS at Week 24 not available	0	3 (5.5%)	3 (8.6%)	3 (10.3%)
>0% increase from baseline at Week 24	7 (18.4%)	6 (10.9%)	7 (20.0%)	5 (17.2%)
<50% reduction from baseline at Week 24	18 (47.4%)	26 (47.3%)	17 (48.6%)	13 (44.8%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-jak.pdf 29AUG2023: 9:04

Table 2.0725: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by JAK2V617F Mutation
Double-Blind Phase
ITT-Anemic Analysis Set

	Positive		Negative	
	MMB (N=39)	RUX (N=56)	MMB (N=36)	RUX (N=29)
Response Rate of Total Symptom Score at Week 12				
Subjects Evaluable at Week 12, n	38	55	35	29
TSS = 0 at baseline and TSS >0 or missing at Week 12	1 (2.6%)	0	0	0
Responder, n(%)	10 (26.3%)	18 (32.7%)	9 (25.7%)	8 (27.6%)
95% Exact CI	0.1340, 0.4310	0.2068, 0.4671	0.1249, 0.4326	0.1273, 0.4724
Noninferior Proportion Difference - Stratified CMH (95% CI)	0.01 (-0.17, 0.19)		0.05 (-0.15, 0.25)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	0.04 (-0.12, 0.21)		0.07 (-0.11, 0.26)	
Superior Proportion Difference - Stratified CMH (95% CI)	-0.10 (-0.31, 0.11)		-0.05 (-0.29, 0.19)	
Superior Proportion Difference - Unstratified CMH (95% CI)	-0.06 (-0.25, 0.13)		-0.02 (-0.24, 0.20)	
Superior Proportion Difference - Unstratified Exact (95% CI)	-0.06 (-0.27, 0.14)		-0.02 (-0.26, 0.23)	
Non-Responder, n(%)	28 (73.7%)	37 (67.3%)	26 (74.3%)	21 (72.4%)
Last participation date < Day 78 in DB phase	5 (13.2%)	0	3 (8.6%)	0
Last participation date >= Day 78 and TSS at Week 12 not available	0	2 (3.6%)	2 (5.7%)	1 (3.4%)
>0% increase from baseline at Week 12	10 (26.3%)	10 (18.2%)	7 (20.0%)	5 (17.2%)
<50% reduction from baseline at Week 12	22 (57.9%)	35 (63.6%)	21 (60.0%)	20 (69.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-jak.pdf 29AUG2023: 9:04

Table 2.0727: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by Disease Type
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis		Post-PV Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)	MMB (N=11)	RUX (N=12)
Total Symptom Score Status						
Missing TSS at baseline (excluded from rate calculation)	1 (1.7%)	0	0	1 (3.6%)	0	0
TSS = 0 at baseline	1 (1.7%)	0	0	0	1 (9.1%)	0
TSS > 0 at baseline	57 (96.6%)	54 (100.0%)	16 (100.0%)	27 (96.4%)	10 (90.9%)	12 (100.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-mf.pdf 29AUG2023: 9:04

Table 2.0727: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by Disease Type
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis		Post-PV Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)	MMB (N=11)	RUX (N=12)
Response Rate of Total Symptom Score at Week 24						
Subjects Evaluable at Week 24, n	58	54	16	27	10	12
TSS = 0 at baseline and TSS >0 or missing at Week 24	1 (1.7%)	0	0	0	0	0
Responder, n(%)	14 (24.1%)	25 (46.3%)	4 (25.0%)	4 (14.8%)	3 (30.0%)	4 (33.3%)
95% Exact CI	0.1387, 0.3717	0.3262, 0.6039	0.0727, 0.5238	0.0419, 0.3373	0.0667, 0.6525	0.0992, 0.6511
Noninferior Proportion Difference - Stratified CMH (95% CI)	-0.07 (-0.21, 0.08)		0.13 (-0.15, 0.40)		0.01 (-0.35, 0.38)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	-0.07 (-0.21, 0.07)		0.15 (-0.09, 0.39)		0.08 (-0.28, 0.43)	
Superior Proportion Difference - Stratified CMH (95% CI)	-0.22 (-0.40, -0.04)		0.08 (-0.22, 0.38)		-0.10 (-0.56, 0.37)	
Superior Proportion Difference - Unstratified CMH (95% CI)	-0.22 (-0.40, -0.05)		0.10 (-0.16, 0.37)		-0.03 (-0.45, 0.38)	
Superior Proportion Difference - Unstratified Exact (95% CI)	-0.22 (-0.40, -0.04)		0.10 (-0.21, 0.39)		-0.03 (-0.44, 0.37)	
Non-Responder, n(%)	44 (75.9%)	29 (53.7%)	12 (75.0%)	23 (85.2%)	7 (70.0%)	8 (66.7%)
Last participation date < Day 162 in DB phase	10 (17.2%)	4 (7.4%)	3 (18.8%)	2 (7.4%)	3 (30.0%)	2 (16.7%)
Last participation date >= Day 162 and TSS at Week 24 not available	0	2 (3.7%)	2 (12.5%)	2 (7.4%)	1 (10.0%)	2 (16.7%)
>0% increase from baseline at Week 24	10 (17.2%)	6 (11.1%)	5 (31.3%)	6 (22.2%)	2 (20.0%)	1 (8.3%)
<50% reduction from baseline at Week 24	33 (56.9%)	23 (42.6%)	7 (43.8%)	19 (70.4%)	3 (30.0%)	4 (33.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-mf.pdf 29AUG2023: 9:04

Table 2.0727: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by Disease Type
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis		Post-PV Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)	MMB (N=11)	RUX (N=12)
Response Rate of Total Symptom Score at Week 12						
Subjects Evaluable at Week 12, n	58	54	16	27	10	12
TSS = 0 at baseline and TSS >0 or missing at Week 12	1 (1.7%)	0	0	0	0	0
Responder, n(%)	13 (22.4%)	23 (42.6%)	4 (25.0%)	2 (7.4%)	3 (30.0%)	3 (25.0%)
95% Exact CI	0.1251, 0.3527	0.2923, 0.5679	0.0727, 0.5238	0.0091, 0.2429	0.0667, 0.6525	0.0549, 0.5719
Noninferior Proportion Difference - Stratified CMH (95% CI)	-0.05 (-0.20, 0.09)		0.18 (-0.09, 0.45)		0.07 (-0.29, 0.43)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	-0.06 (-0.20, 0.08)		0.20 (-0.03, 0.44)		0.13 (-0.22, 0.48)	
Superior Proportion Difference - Stratified CMH (95% CI)	-0.19 (-0.37, -0.02)		0.16 (-0.13, 0.45)		-0.02 (-0.48, 0.45)	
Superior Proportion Difference - Unstratified CMH (95% CI)	-0.20 (-0.37, -0.03)		0.18 (-0.07, 0.42)		0.05 (-0.35, 0.45)	
Superior Proportion Difference - Unstratified Exact (95% CI)	-0.20 (-0.38, -0.02)		0.18 (-0.14, 0.46)		0.05 (-0.36, 0.44)	
Non-Responder, n(%)	45 (77.6%)	31 (57.4%)	12 (75.0%)	25 (92.6%)	7 (70.0%)	9 (75.0%)
Last participation date < Day 78 in DB phase	5 (8.6%)	0	2 (12.5%)	0	3 (30.0%)	0
Last participation date >= Day 78 and TSS at Week 12 not available	0	1 (1.9%)	1 (6.3%)	2 (7.4%)	1 (10.0%)	0
>0% increase from baseline at Week 12	15 (25.9%)	11 (20.4%)	6 (37.5%)	6 (22.2%)	0	1 (8.3%)
<50% reduction from baseline at Week 12	39 (67.2%)	30 (55.6%)	9 (56.3%)	23 (85.2%)	3 (30.0%)	9 (75.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-mf.pdf 29AUG2023: 9:04

Table 2.0726: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by Platelet Count at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	<100X10E9/L		>=100X10E9/L and <=200X10E9/L		>200X10E9/L	
	MMB (N=13)	RUX (N=13)	MMB (N=36)	RUX (N=34)	MMB (N=37)	RUX (N=47)
Total Symptom Score Status						
Missing TSS at baseline (excluded from rate calculation)	1 (7.7%)	0	0	0	0	1 (2.1%)
TSS = 0 at baseline	0	0	1 (2.8%)	0	1 (2.7%)	0
TSS > 0 at baseline	12 (92.3%)	13 (100.0%)	35 (97.2%)	34 (100.0%)	36 (97.3%)	46 (97.9%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Stratification factor is transfusion dependence (Yes vs. No) at baseline.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
CMH = Cochran-Mantel-Haenszel
TSS = Total Symptom Score

Data Extracted: CRF data: 01JUL2019

Table 2.0726: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by Platelet Count at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	<100X10E9/L		>=100X10E9/L and <=200X10E9/L		>200X10E9/L	
	MMB (N=13)	RUX (N=13)	MMB (N=36)	RUX (N=34)	MMB (N=37)	RUX (N=47)
Response Rate of Total Symptom Score at Week 24						
Subjects Evaluable at Week 24, n	12	13	35	34	37	46
TSS = 0 at baseline and TSS >0 or missing at Week 24	0	0	0	0	1 (2.7%)	0
Responder, n(%)	4 (33.3%)	5 (38.5%)	10 (28.6%)	14 (41.2%)	7 (18.9%)	14 (30.4%)
95% Exact CI	0.0992, 0.6511	0.1386, 0.6842	0.1464, 0.4630	0.2465, 0.5930	0.0796, 0.3516	0.1774, 0.4575
Noninferior Proportion Difference - Stratified CMH (95% CI)	0.09 (-0.25, 0.43)		0.01 (-0.18, 0.20)		-0.03 (-0.19, 0.14)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	0.08 (-0.26, 0.41)		0.01 (-0.18, 0.20)		-0.01 (-0.17, 0.14)	
Superior Proportion Difference - Stratified CMH (95% CI)	-0.03 (-0.44, 0.37)		-0.13 (-0.36, 0.10)		-0.13 (-0.33, 0.06)	
Superior Proportion Difference - Unstratified CMH (95% CI)	-0.05 (-0.45, 0.34)		-0.13 (-0.35, 0.10)		-0.12 (-0.30, 0.07)	
Superior Proportion Difference - Unstratified Exact (95% CI)	-0.05 (-0.44, 0.33)		-0.13 (-0.35, 0.12)		-0.12 (-0.32, 0.10)	
Non-Responder, n(%)	8 (66.7%)	8 (61.5%)	25 (71.4%)	20 (58.8%)	30 (81.1%)	32 (69.6%)
Last participation date < Day 162 in DB phase	1 (8.3%)	4 (30.8%)	7 (20.0%)	4 (11.8%)	8 (21.6%)	0
Last participation date >= Day 162 and TSS at Week 24 not available	0	1 (7.7%)	1 (2.9%)	0	2 (5.4%)	5 (10.9%)
>0% increase from baseline at Week 24	5 (41.7%)	0	5 (14.3%)	6 (17.6%)	7 (18.9%)	7 (15.2%)
<50% reduction from baseline at Week 24	7 (58.3%)	3 (23.1%)	17 (48.6%)	16 (47.1%)	19 (51.4%)	27 (58.7%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Stratification factor is transfusion dependence (Yes vs. No) at baseline.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
CMH = Cochran-Mantel-Haenszel
TSS = Total Symptom Score

Data Extracted: CRF data: 01JUL2019

Table 2.0726: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by Platelet Count at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	<100X10E9/L		>=100X10E9/L and <=200X10E9/L		>200X10E9/L	
	MMB (N=13)	RUX (N=13)	MMB (N=36)	RUX (N=34)	MMB (N=37)	RUX (N=47)
Response Rate of Total Symptom Score at Week 12						
Subjects Evaluable at Week 12, n	12	13	35	34	37	46
TSS = 0 at baseline and TSS >0 or missing at Week 12	0	0	0	0	1 (2.7%)	0
Responder, n(%)	4 (33.3%)	5 (38.5%)	9 (25.7%)	11 (32.4%)	7 (18.9%)	12 (26.1%)
95% Exact CI	0.0992, 0.6511	0.1386, 0.6842	0.1249, 0.4326	0.1739, 0.5053	0.0796, 0.3516	0.1427, 0.4113
Noninferior Proportion Difference - Stratified CMH (95% CI)	0.09 (-0.25, 0.43)		0.04 (-0.15, 0.22)		0.00 (-0.16, 0.16)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	0.08 (-0.26, 0.41)		0.04 (-0.14, 0.22)		0.01 (-0.14, 0.17)	
Superior Proportion Difference - Stratified CMH (95% CI)	-0.03 (-0.44, 0.37)		-0.07 (-0.29, 0.15)		-0.09 (-0.27, 0.10)	
Superior Proportion Difference - Unstratified CMH (95% CI)	-0.05 (-0.45, 0.34)		-0.07 (-0.28, 0.15)		-0.07 (-0.25, 0.11)	
Superior Proportion Difference - Unstratified Exact (95% CI)	-0.05 (-0.44, 0.33)		-0.07 (-0.29, 0.18)		-0.07 (-0.28, 0.15)	
Non-Responder, n(%)	8 (66.7%)	8 (61.5%)	26 (74.3%)	23 (67.6%)	30 (81.1%)	34 (73.9%)
Last participation date < Day 78 in DB phase	1 (8.3%)	0	4 (11.4%)	0	5 (13.5%)	0
Last participation date >= Day 78 and TSS at Week 12 not available	0	1 (7.7%)	1 (2.9%)	0	1 (2.7%)	2 (4.3%)
>0% increase from baseline at Week 12	6 (50.0%)	2 (15.4%)	6 (17.1%)	8 (23.5%)	9 (24.3%)	8 (17.4%)
<50% reduction from baseline at Week 12	7 (58.3%)	7 (53.8%)	21 (60.0%)	23 (67.6%)	23 (62.2%)	32 (69.6%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Stratification factor is transfusion dependence (Yes vs. No) at baseline.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
CMH = Cochran-Mantel-Haenszel
TSS = Total Symptom Score

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-plate.pdf 29AUG2023: 9:04

Table 2.0719: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by Race
Double-Blind Phase
ITT-Anemic Analysis Set

	White		All Other Races	
	MMB (N=69)	RUX (N=76)	MMB (N=11)	RUX (N=8)
Total Symptom Score Status				
Missing TSS at baseline (excluded from rate calculation)	1 (1.4%)	1 (1.3%)	0	0
TSS = 0 at baseline	2 (2.9%)	0	0	0
TSS > 0 at baseline	66 (95.7%)	75 (98.7%)	11 (100.0%)	8 (100.0%)
Response Rate of Total Symptom Score at Week 24				
Subjects Evaluable at Week 24, n	67	75	11	8
TSS = 0 at baseline and TSS >0 or missing at Week 24	1 (1.5%)	0	0	0
Responder, n(%)	14 (20.9%)	27 (36.0%)	4 (36.4%)	2 (25.0%)
95% Exact CI	0.1192, 0.3257	0.2523, 0.4791	0.1093, 0.6921	0.0319, 0.6509
Noninferior Proportion Difference - Stratified CMH (95% CI)	-0.03 (-0.16, 0.10)		0.19 (-0.23, 0.61)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	-0.03 (-0.16, 0.09)		0.20 (-0.18, 0.57)	
Superior Proportion Difference - Stratified CMH (95% CI)	-0.15 (-0.30, 0.01)		0.11 (-0.34, 0.57)	
Superior Proportion Difference - Unstratified CMH (95% CI)	-0.15 (-0.30, -0.00)		0.11 (-0.33, 0.56)	
Superior Proportion Difference - Unstratified Exact (95% CI)	-0.15 (-0.31, 0.01)		0.11 (-0.34, 0.53)	
Non-Responder, n(%)	53 (79.1%)	48 (64.0%)	7 (63.6%)	6 (75.0%)
Last participation date < Day 162 in DB phase	13 (19.4%)	7 (9.3%)	2 (18.2%)	0
Last participation date >= Day 162 and TSS at Week 24 not available	2 (3.0%)	4 (5.3%)	1 (9.1%)	0
>0% increase from baseline at Week 24	15 (22.4%)	12 (16.0%)	0	0
<50% reduction from baseline at Week 24	37 (55.2%)	37 (49.3%)	4 (36.4%)	6 (75.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-race.pdf 29AUG2023: 9:03

Table 2.0719: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by Race
Double-Blind Phase
ITT-Anemic Analysis Set

	White		All Other Races	
	MMB (N=69)	RUX (N=76)	MMB (N=11)	RUX (N=8)
Response Rate of Total Symptom Score at Week 12				
Subjects Evaluable at Week 12, n	67	75	11	8
TSS = 0 at baseline and TSS >0 or missing at Week 12	1 (1.5%)	0	0	0
Responder, n(%)	13 (19.4%)	22 (29.3%)	4 (36.4%)	3 (37.5%)
95% Exact CI	0.1076, 0.3089	0.1938, 0.4098	0.1093, 0.6921	0.0852, 0.7551
Noninferior Proportion Difference - Stratified CMH (95% CI)	-0.00 (-0.12, 0.12)		0.11 (-0.32, 0.54)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	-0.00 (-0.12, 0.12)		0.11 (-0.27, 0.50)	
Superior Proportion Difference - Stratified CMH (95% CI)	-0.10 (-0.25, 0.05)		-0.00 (-0.49, 0.49)	
Superior Proportion Difference - Unstratified CMH (95% CI)	-0.10 (-0.24, 0.04)		-0.01 (-0.48, 0.46)	
Superior Proportion Difference - Unstratified Exact (95% CI)	-0.10 (-0.26, 0.07)		-0.01 (-0.46, 0.43)	
Non-Responder, n(%)	54 (80.6%)	53 (70.7%)	7 (63.6%)	5 (62.5%)
Last participation date < Day 78 in DB phase	9 (13.4%)	0	1 (9.1%)	0
Last participation date >= Day 78 and TSS at Week 12 not available	1 (1.5%)	2 (2.7%)	1 (9.1%)	0
>0% increase from baseline at Week 12	18 (26.9%)	15 (20.0%)	1 (9.1%)	1 (12.5%)
<50% reduction from baseline at Week 12	43 (64.2%)	51 (68.0%)	5 (45.5%)	5 (62.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-race.pdf 29AUG2023: 9:03

Table 2.0718: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female	
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)
Total Symptom Score Status				
Missing TSS at baseline (excluded from rate calculation)	0	0	1 (2.8%)	1 (2.6%)
TSS = 0 at baseline	2 (4.0%)	0	0	0
TSS > 0 at baseline	48 (96.0%)	56 (100.0%)	35 (97.2%)	37 (97.4%)
Response Rate of Total Symptom Score at Week 24				
Subjects Evaluable at Week 24, n	49	56	35	37
TSS = 0 at baseline and TSS >0 or missing at Week 24	1 (2.0%)	0	0	0
Responder, n(%)	14 (28.6%)	18 (32.1%)	7 (20.0%)	15 (40.5%)
95% Exact CI	0.1658, 0.4326	0.2029, 0.4596	0.0844, 0.3694	0.2475, 0.5790
Noninferior Proportion Difference - Stratified CMH (95% CI)	0.06 (-0.10, 0.23)		-0.08 (-0.27, 0.12)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	0.07 (-0.08, 0.22)		-0.07 (-0.25, 0.10)	
Superior Proportion Difference - Stratified CMH (95% CI)	-0.05 (-0.24, 0.15)		-0.21 (-0.45, 0.02)	
Superior Proportion Difference - Unstratified CMH (95% CI)	-0.04 (-0.21, 0.14)		-0.21 (-0.42, 0.01)	
Superior Proportion Difference - Unstratified Exact (95% CI)	-0.04 (-0.23, 0.16)		-0.21 (-0.42, 0.02)	
Non-Responder, n(%)	35 (71.4%)	38 (67.9%)	28 (80.0%)	22 (59.5%)
Last participation date < Day 162 in DB phase	6 (12.2%)	6 (10.7%)	10 (28.6%)	2 (5.4%)
Last participation date >= Day 162 and TSS at Week 24 not available	2 (4.1%)	1 (1.8%)	1 (2.9%)	5 (13.5%)
>0% increase from baseline at Week 24	10 (20.4%)	11 (19.6%)	7 (20.0%)	2 (5.4%)
<50% reduction from baseline at Week 24	26 (53.1%)	31 (55.4%)	17 (48.6%)	15 (40.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-sex.pdf 29AUG2023: 9:03

Table 2.0718: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female	
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)
Response Rate of Total Symptom Score at Week 12				
Subjects Evaluable at Week 12, n	49	56	35	37
TSS = 0 at baseline and TSS >0 or missing at Week 12	1 (2.0%)	0	0	0
Responder, n(%)	15 (30.6%)	14 (25.0%)	5 (14.3%)	14 (37.8%)
95% Exact CI	0.1825, 0.4542	0.1439, 0.3837	0.0481, 0.3026	0.2246, 0.5524
Noninferior Proportion Difference - Stratified CMH (95% CI)	0.13 (-0.03, 0.29)		-0.11 (-0.30, 0.08)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	0.14 (-0.01, 0.29)		-0.11 (-0.27, 0.05)	
Superior Proportion Difference - Stratified CMH (95% CI)	0.05 (-0.13, 0.23)		-0.23 (-0.46, -0.00)	
Superior Proportion Difference - Unstratified CMH (95% CI)	0.06 (-0.12, 0.23)		-0.24 (-0.44, -0.04)	
Superior Proportion Difference - Unstratified Exact (95% CI)	0.06 (-0.14, 0.25)		-0.24 (-0.45, -0.00)	
Non-Responder, n(%)	34 (69.4%)	42 (75.0%)	30 (85.7%)	23 (62.2%)
Last participation date < Day 78 in DB phase	3 (6.1%)	0	7 (20.0%)	0
Last participation date >= Day 78 and TSS at Week 12 not available	2 (4.1%)	2 (3.6%)	0	1 (2.7%)
>0% increase from baseline at Week 12	13 (26.5%)	13 (23.2%)	8 (22.9%)	5 (13.5%)
<50% reduction from baseline at Week 12	28 (57.1%)	40 (71.4%)	23 (65.7%)	22 (59.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-sex.pdf 29AUG2023: 9:03

Table 2.0721: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by Spleen Volume at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3	
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)
Total Symptom Score Status				
Missing TSS at baseline (excluded from rate calculation)	0	1 (2.3%)	1 (2.6%)	0
TSS = 0 at baseline	2 (4.3%)	0	0	0
TSS > 0 at baseline	45 (95.7%)	42 (97.7%)	38 (97.4%)	51 (100.0%)
Response Rate of Total Symptom Score at Week 24				
Subjects Evaluable at Week 24, n	46	42	38	51
TSS = 0 at baseline and TSS >0 or missing at Week 24	1 (2.2%)	0	0	0
Responder, n(%)	13 (28.3%)	14 (33.3%)	8 (21.1%)	19 (37.3%)
95% Exact CI	0.1599, 0.4346	0.1957, 0.4955	0.0955, 0.3732	0.2413, 0.5192
Noninferior Proportion Difference - Stratified CMH (95% CI)	0.05 (-0.13, 0.24)		-0.08 (-0.26, 0.09)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	0.06 (-0.10, 0.22)		-0.04 (-0.20, 0.12)	
Superior Proportion Difference - Stratified CMH (95% CI)	-0.06 (-0.27, 0.16)		-0.22 (-0.42, -0.01)	
Superior Proportion Difference - Unstratified CMH (95% CI)	-0.05 (-0.25, 0.15)		-0.16 (-0.35, 0.03)	
Superior Proportion Difference - Unstratified Exact (95% CI)	-0.05 (-0.26, 0.16)		-0.16 (-0.36, 0.05)	
Non-Responder, n(%)	33 (71.7%)	28 (66.7%)	30 (78.9%)	32 (62.7%)
Last participation date < Day 162 in DB phase	7 (15.2%)	4 (9.5%)	9 (23.7%)	4 (7.8%)
Last participation date >= Day 162 and TSS at Week 24 not available	1 (2.2%)	4 (9.5%)	2 (5.3%)	2 (3.9%)
>0% increase from baseline at Week 24	10 (21.7%)	8 (19.0%)	7 (18.4%)	5 (9.8%)
<50% reduction from baseline at Week 24	24 (52.2%)	20 (47.6%)	19 (50.0%)	26 (51.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
CMH = Cochran-Mantel-Haenszel
TSS = Total Symptom Score

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-svb.pdf 29AUG2023: 9:03

Table 2.0721: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by Spleen Volume at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3	
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)
Response Rate of Total Symptom Score at Week 12				
Subjects Evaluable at Week 12, n	46	42	38	51
TSS = 0 at baseline and TSS >0 or missing at Week 12	1 (2.2%)	0	0	0
Responder, n(%)	11 (23.9%)	12 (28.6%)	9 (23.7%)	16 (31.4%)
95% Exact CI	0.1259, 0.3877	0.1572, 0.4458	0.1144, 0.4024	0.1911, 0.4589
Noninferior Proportion Difference - Stratified CMH (95% CI)	0.05 (-0.13, 0.23)		-0.00 (-0.18, 0.17)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	0.05 (-0.11, 0.20)		0.03 (-0.14, 0.19)	
Superior Proportion Difference - Stratified CMH (95% CI)	-0.04 (-0.26, 0.17)		-0.11 (-0.32, 0.09)	
Superior Proportion Difference - Unstratified CMH (95% CI)	-0.05 (-0.23, 0.14)		-0.08 (-0.27, 0.11)	
Superior Proportion Difference - Unstratified Exact (95% CI)	-0.05 (-0.25, 0.16)		-0.08 (-0.28, 0.13)	
Non-Responder, n(%)	35 (76.1%)	30 (71.4%)	29 (76.3%)	35 (68.6%)
Last participation date < Day 78 in DB phase	6 (13.0%)	0	4 (10.5%)	0
Last participation date >= Day 78 and TSS at Week 12 not available	0	1 (2.4%)	2 (5.3%)	2 (3.9%)
>0% increase from baseline at Week 12	12 (26.1%)	10 (23.8%)	9 (23.7%)	8 (15.7%)
<50% reduction from baseline at Week 12	28 (60.9%)	29 (69.0%)	23 (60.5%)	33 (64.7%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
CMH = Cochran-Mantel-Haenszel
TSS = Total Symptom Score

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-svb.pdf 29AUG2023: 9:03

Table 2.0720: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by Transfusion Dependence at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	Yes		No	
	MMB (N=49)	RUX (N=43)	MMB (N=37)	RUX (N=51)
Total Symptom Score Status				
Missing TSS at baseline (excluded from rate calculation)	1 (2.0%)	1 (2.3%)	0	0
TSS = 0 at baseline	1 (2.0%)	0	1 (2.7%)	0
TSS > 0 at baseline	47 (95.9%)	42 (97.7%)	36 (97.3%)	51 (100.0%)
Response Rate of Total Symptom Score at Week 24				
Subjects Evaluable at Week 24, n	47	42	37	51
TSS = 0 at baseline and TSS >0 or missing at Week 24	0	0	1 (2.7%)	0
Responder, n(%)	12 (25.5%)	16 (38.1%)	9 (24.3%)	17 (33.3%)
95% Exact CI	0.1394, 0.4035	0.2357, 0.5436	0.1177, 0.4120	0.2076, 0.4792
Noninferior Proportion Difference - Stratified CMH (95% CI)	0.00 (-0.17, 0.17)		0.01 (-0.16, 0.18)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	0.00 (-0.16, 0.16)		0.02 (-0.15, 0.19)	
Superior Proportion Difference - Stratified CMH (95% CI)	-0.12 (-0.33, 0.08)		-0.11 (-0.30, 0.09)	
Superior Proportion Difference - Unstratified CMH (95% CI)	-0.13 (-0.32, 0.07)		-0.09 (-0.28, 0.10)	
Superior Proportion Difference - Unstratified Exact (95% CI)	-0.13 (-0.33, 0.08)		-0.09 (-0.30, 0.12)	
Non-Responder, n(%)	35 (74.5%)	26 (61.9%)	28 (75.7%)	34 (66.7%)
Last participation date < Day 162 in DB phase	9 (19.1%)	7 (16.7%)	7 (18.9%)	1 (2.0%)
Last participation date >= Day 162 and TSS at Week 24 not available	1 (2.1%)	3 (7.1%)	2 (5.4%)	3 (5.9%)
>0% increase from baseline at Week 24	12 (25.5%)	4 (9.5%)	5 (13.5%)	9 (17.6%)
<50% reduction from baseline at Week 24	25 (53.2%)	16 (38.1%)	18 (48.6%)	30 (58.8%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Stratification factor is platelet count (<100X10^9/L, =100X10^9/L and = 200X10^9/L, or > 200X10^9/L) at baseline.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-tf.pdf 29AUG2023: 9:03

Table 2.0720: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by Transfusion Dependence at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	Yes		No	
	MMB (N=49)	RUX (N=43)	MMB (N=37)	RUX (N=51)
Response Rate of Total Symptom Score at Week 12				
Subjects Evaluable at Week 12, n	47	42	37	51
TSS = 0 at baseline and TSS >0 or missing at Week 12	0	0	1 (2.7%)	0
Responder, n(%)	13 (27.7%)	14 (33.3%)	7 (18.9%)	14 (27.5%)
95% Exact CI	0.1562, 0.4264	0.1957, 0.4955	0.0796, 0.3516	0.1589, 0.4174
Noninferior Proportion Difference - Stratified CMH (95% CI)	0.05 (-0.11, 0.22)		0.00 (-0.15, 0.16)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	0.05 (-0.11, 0.22)		0.01 (-0.15, 0.16)	
Superior Proportion Difference - Stratified CMH (95% CI)	-0.05 (-0.25, 0.15)		-0.09 (-0.27, 0.09)	
Superior Proportion Difference - Unstratified CMH (95% CI)	-0.06 (-0.25, 0.14)		-0.09 (-0.27, 0.09)	
Superior Proportion Difference - Unstratified Exact (95% CI)	-0.06 (-0.26, 0.15)		-0.09 (-0.29, 0.12)	
Non-Responder, n(%)	34 (72.3%)	28 (66.7%)	30 (81.1%)	37 (72.5%)
Last participation date < Day 78 in DB phase	7 (14.9%)	0	3 (8.1%)	0
Last participation date >= Day 78 and TSS at Week 12 not available	1 (2.1%)	1 (2.4%)	1 (2.7%)	2 (3.9%)
>0% increase from baseline at Week 12	12 (25.5%)	6 (14.3%)	9 (24.3%)	12 (23.5%)
<50% reduction from baseline at Week 12	26 (55.3%)	27 (64.3%)	25 (67.6%)	35 (68.6%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Stratification factor is platelet count (<100X10^9/L, =100X10^9/L and = 200X10^9/L, or > 200X10^9/L) at baseline.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-tf.pdf 29AUG2023: 9:03

Table 2.0722: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by TSS at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	< Q1 7.8		>= Q1 7.8 and < Median 16.8	
	MMB (N=24)	RUX (N=20)	MMB (N=16)	RUX (N=29)
Total Symptom Score Status				
Missing TSS at baseline (excluded from rate calculation)	0	0	0	0
TSS = 0 at baseline	2 (8.3%)	0	0	0
TSS > 0 at baseline	22 (91.7%)	20 (100.0%)	16 (100.0%)	29 (100.0%)
Response Rate of Total Symptom Score at Week 24				
Subjects Evaluable at Week 24, n	23	20	16	29
TSS = 0 at baseline and TSS >0 or missing at Week 24	1 (4.3%)	0	0	0
Responder, n(%)	5 (21.7%)	10 (50.0%)	5 (31.3%)	8 (27.6%)
95% Exact CI	0.0746, 0.4370	0.2720, 0.7280	0.1102, 0.5866	0.1273, 0.4724
Noninferior Proportion Difference - Stratified CMH (95% CI)	-0.13 (-0.37, 0.11)		0.09 (-0.20, 0.38)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	-0.12 (-0.35, 0.11)		0.13 (-0.13, 0.39)	
Superior Proportion Difference - Stratified CMH (95% CI)	-0.30 (-0.59, -0.00)		-0.01 (-0.34, 0.31)	
Superior Proportion Difference - Unstratified CMH (95% CI)	-0.28 (-0.57, 0.00)		0.04 (-0.25, 0.33)	
Superior Proportion Difference - Unstratified Exact (95% CI)	-0.28 (-0.55, 0.02)		0.04 (-0.27, 0.34)	
Non-Responder, n(%)	18 (78.3%)	10 (50.0%)	11 (68.8%)	21 (72.4%)
Last participation date < Day 162 in DB phase	1 (4.3%)	0	2 (12.5%)	3 (10.3%)
Last participation date >= Day 162 and TSS at Week 24 not available	1 (4.3%)	0	0	1 (3.4%)
>0% increase from baseline at Week 24	9 (39.1%)	5 (25.0%)	3 (18.8%)	5 (17.2%)
<50% reduction from baseline at Week 24	15 (65.2%)	10 (50.0%)	9 (56.3%)	17 (58.6%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Stratification factor is total symptom score (< 18 vs. >=18) at baseline.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-tss.pdf 29AUG2023: 9:03

Table 2.0722: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by TSS at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

(Continued)	>= Median 16.8 and < Q3 25.7		>= Q3 25.7	
	MMB (N=21)	RUX (N=23)	MMB (N=24)	RUX (N=21)
Total Symptom Score Status				
Missing TSS at baseline (excluded from rate calculation)	0	0	0	0
TSS = 0 at baseline	0	0	0	0
TSS > 0 at baseline	21 (100.0%)	23 (100.0%)	24 (100.0%)	21 (100.0%)
Response Rate of Total Symptom Score at Week 24				
Subjects Evaluable at Week 24, n	21	23	24	21
TSS = 0 at baseline and TSS >0 or missing at Week 24	0	0	0	0
Responder, n(%)	8 (38.1%)	7 (30.4%)	3 (12.5%)	8 (38.1%)
95% Exact CI	0.1811, 0.6156	0.1321, 0.5292	0.0266, 0.3236	0.1811, 0.6156
Noninferior Proportion Difference - Stratified CMH (95% CI)	0.22 (-0.05, 0.49)		-0.13 (-0.35, 0.09)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	0.18 (-0.07, 0.43)		-0.13 (-0.33, 0.07)	
Superior Proportion Difference - Stratified CMH (95% CI)	0.12 (-0.19, 0.43)		-0.26 (-0.53, 0.01)	
Superior Proportion Difference - Unstratified CMH (95% CI)	0.08 (-0.21, 0.36)		-0.26 (-0.51, 0.00)	
Superior Proportion Difference - Unstratified Exact (95% CI)	0.08 (-0.22, 0.36)		-0.26 (-0.52, 0.04)	
Non-Responder, n(%)	13 (61.9%)	16 (69.6%)	21 (87.5%)	13 (61.9%)
Last participation date < Day 162 in DB phase	4 (19.0%)	2 (8.7%)	9 (37.5%)	3 (14.3%)
Last participation date >= Day 162 and TSS at Week 24 not available	1 (4.8%)	1 (4.3%)	1 (4.2%)	4 (19.0%)
>0% increase from baseline at Week 24	1 (4.8%)	2 (8.7%)	4 (16.7%)	1 (4.8%)
<50% reduction from baseline at Week 24	8 (38.1%)	13 (56.5%)	11 (45.8%)	6 (28.6%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Stratification factor is total symptom score (< 18 vs. >=18) at baseline.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-tss.pdf 29AUG2023: 9:03

Table 2.0722: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by TSS at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	< Q1 7.8		>= Q1 7.8 and < Median 16.8	
	MMB (N=24)	RUX (N=20)	MMB (N=16)	RUX (N=29)
Response Rate of Total Symptom Score at Week 12				
Subjects Evaluable at Week 12, n	23	20	16	29
TSS = 0 at baseline and TSS >0 or missing at Week 12	1 (4.3%)	0	0	0
Responder, n(%)	5 (21.7%)	10 (50.0%)	2 (12.5%)	7 (24.1%)
95% Exact CI	0.0746, 0.4370	0.2720, 0.7280	0.0155, 0.3835	0.1030, 0.4354
Noninferior Proportion Difference - Stratified CMH (95% CI)	-0.13 (-0.37, 0.11)		-0.07 (-0.33, 0.19)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	-0.12 (-0.35, 0.11)		-0.04 (-0.25, 0.17)	
Superior Proportion Difference - Stratified CMH (95% CI)	-0.30 (-0.59, -0.01)		-0.16 (-0.46, 0.13)	
Superior Proportion Difference - Unstratified CMH (95% CI)	-0.28 (-0.57, 0.00)		-0.12 (-0.36, 0.12)	
Superior Proportion Difference - Unstratified Exact (95% CI)	-0.28 (-0.55, 0.02)		-0.12 (-0.41, 0.18)	
Non-Responder, n(%)	18 (78.3%)	10 (50.0%)	14 (87.5%)	22 (75.9%)
Last participation date < Day 78 in DB phase	1 (4.3%)	0	2 (12.5%)	0
Last participation date >= Day 78 and TSS at Week 12 not available	1 (4.3%)	0	0	1 (3.4%)
>0% increase from baseline at Week 12	8 (34.8%)	5 (25.0%)	5 (31.3%)	7 (24.1%)
<50% reduction from baseline at Week 12	15 (65.2%)	10 (50.0%)	12 (75.0%)	21 (72.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Stratification factor is total symptom score (< 18 vs. >=18) at baseline.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-tss.pdf 29AUG2023: 9:03

Table 2.0722: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by TSS at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

(Continued)	>= Median 16.8 and < Q3 25.7		>= Q3 25.7	
	MMB (N=21)	RUX (N=23)	MMB (N=24)	RUX (N=21)
Response Rate of Total Symptom Score at Week 12				
Subjects Evaluable at Week 12, n	21	23	24	21
TSS = 0 at baseline and TSS >0 or missing at Week 12	0	0	0	0
Responder, n(%)	9 (42.9%)	6 (26.1%)	4 (16.7%)	5 (23.8%)
95% Exact CI	0.2182, 0.6598	0.1023, 0.4841	0.0474, 0.3738	0.0822, 0.4717
Noninferior Proportion Difference - Stratified CMH (95% CI)	0.31 (0.03, 0.59)		0.04 (-0.20, 0.28)	
Noninferior Proportion Difference - Unstratified CMH (95% CI)	0.25 (0.00, 0.50)		0.01 (-0.19, 0.21)	
Superior Proportion Difference - Stratified CMH (95% CI)	0.23 (-0.08, 0.54)		-0.05 (-0.32, 0.23)	
Superior Proportion Difference - Unstratified CMH (95% CI)	0.17 (-0.12, 0.45)		-0.07 (-0.32, 0.17)	
Superior Proportion Difference - Unstratified Exact (95% CI)	0.17 (-0.14, 0.44)		-0.07 (-0.36, 0.22)	
Non-Responder, n(%)	12 (57.1%)	17 (73.9%)	20 (83.3%)	16 (76.2%)
Last participation date < Day 78 in DB phase	2 (9.5%)	0	5 (20.8%)	0
Last participation date >= Day 78 and TSS at Week 12 not available	1 (4.8%)	1 (4.3%)	0	1 (4.8%)
>0% increase from baseline at Week 12	3 (14.3%)	5 (21.7%)	5 (20.8%)	1 (4.8%)
<50% reduction from baseline at Week 12	9 (42.9%)	16 (69.6%)	15 (62.5%)	15 (71.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Stratification factor is total symptom score (< 18 vs. >=18) at baseline.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-tss.pdf 29AUG2023: 9:03

Table 2.1617: Subgroup Analysis of Rate of RBC Transfusion by Age
Double-Blind Phase
ITT-Anemic Analysis Set

	< 65 years		>= 65 years	
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)
RBC Transfusion Rate in DB phase (units/month)				
N	24	36	62	58
Mean (SD)	0.6 (0.83)	1.4 (1.95)	1.4 (1.96)	2.1 (2.00)
Median	0.1	0.7	0.4	1.8
Q1, Q3	0.0, 1.2	0.0, 1.5	0.0, 2.5	0.6, 3.2
Min, Max	0.0, 2.7	0.0, 7.8	0.0, 9.1	0.0, 8.2
Negative Binomial Model				
Adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	0.50 (0.26, 0.95)	1.35 (0.75, 2.41)	0.88 (0.59, 1.32)	2.17 (1.51, 3.11)
Ratio of Rate for RBC Transfusion with 95% CI	0.37 (0.15, 0.89)		0.41 (0.25, 0.67)	
p-value	0.027		< 0.001	
Un-adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	0.63 (0.32, 1.25)	1.35 (0.79, 2.32)	1.32 (0.92, 1.89)	2.13 (1.49, 3.04)
Ratio of Rate for RBC Transfusion with 95% CI	0.47 (0.20, 1.12)		0.62 (0.37, 1.03)	
p-value	0.088		0.062	
Proportional Means Model - Supportive Analysis				
Stratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	0.45 (0.25, 0.81)		0.50 (0.33, 0.75)	
p-value	0.008		< 0.001	
Unstratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	0.50 (0.25, 1.00)		0.61 (0.39, 0.96)	
p-value	0.051		0.033	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-age.pdf 29AUG2023: 9:03

Table 2.1617: Subgroup Analysis of Rate of RBC Transfusion by Age
Double-Blind Phase
ITT-Anemic Analysis Set

	< 65 years		>= 65 years	
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)
Total number of RBC Transfusion unit in DB phase				
N	24	36	62	58
Mean (SD)	3.3 (4.50)	6.7 (9.12)	6.1 (9.67)	11.3 (10.15)
Median	0.5	4.0	2.0	10.0
Q1, Q3	0.0, 5.5	0.0, 8.0	0.0, 7.0	3.0, 16.0
Min, Max	0.0, 15.0	0.0, 38.0	0.0, 47.0	0.0, 44.0
Duration of RBC Transfusion in DB phase (months)				
N	24	36	62	58
Mean (SD)	5.23 (1.037)	5.37 (0.614)	4.85 (1.625)	5.45 (0.511)
Median	5.55	5.52	5.55	5.55
Q1, Q3	5.50, 5.59	5.49, 5.57	5.45, 5.59	5.52, 5.62
Min, Max	1.22, 5.78	2.56, 5.75	0.30, 5.72	2.76, 5.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-age.pdf 29AUG2023: 9:03

Table 2.1624: Subgroup Analysis of Rate of RBC Transfusion by IPSS
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High risk	
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)
RBC Transfusion Rate in DB phase (units/month)				
N	28	24	58	70
Mean (SD)	0.6 (0.97)	1.7 (2.15)	1.4 (1.98)	1.9 (1.97)
Median	0.0	1.1	0.4	1.2
Q1, Q3	0.0, 1.2	0.0, 2.3	0.0, 2.5	0.4, 2.8
Min, Max	0.0, 3.3	0.0, 7.8	0.0, 9.1	0.0, 8.2
Negative Binomial Model				
Adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	0.54 (0.29, 1.01)	1.74 (0.91, 3.34)	0.75 (0.45, 1.23)	1.43 (0.93, 2.20)
Ratio of Rate for RBC Transfusion with 95% CI	0.31 (0.13, 0.77)		0.52 (0.32, 0.84)	
p-value	0.011		0.008	
Un-adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	0.64 (0.33, 1.25)	1.71 (0.86, 3.40)	1.36 (0.93, 1.97)	1.87 (1.35, 2.60)
Ratio of Rate for RBC Transfusion with 95% CI	0.38 (0.14, 0.97)		0.72 (0.44, 1.19)	
p-value	0.044		0.20	
Proportional Means Model - Supportive Analysis				
Stratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	0.36 (0.18, 0.73)		0.64 (0.42, 0.97)	
p-value	0.005		0.037	
Unstratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	0.42 (0.20, 0.89)		0.71 (0.45, 1.12)	
p-value	0.023		0.14	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell
IPSS = International Prognostic Scoring System

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-dipss.pdf 29AUG2023: 9:03

Table 2.1624: Subgroup Analysis of Rate of RBC Transfusion by IPSS
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High risk	
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)
Total number of RBC Transfusion unit in DB phase				
N	28	24	58	70
Mean (SD)	3.3 (5.32)	8.5 (10.01)	6.3 (9.71)	9.9 (10.01)
Median	0.0	6.0	2.0	6.5
Q1, Q3	0.0, 4.5	0.0, 11.0	0.0, 7.0	2.0, 15.0
Min, Max	0.0, 18.0	0.0, 38.0	0.0, 47.0	0.0, 44.0
Duration of RBC Transfusion in DB phase (months)				
N	28	24	58	70
Mean (SD)	5.05 (1.469)	5.34 (0.737)	4.91 (1.509)	5.45 (0.474)
Median	5.55	5.54	5.55	5.55
Q1, Q3	5.50, 5.59	5.49, 5.60	5.45, 5.59	5.49, 5.59
Min, Max	0.62, 5.65	2.56, 5.78	0.30, 5.78	2.76, 5.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell
IPSS = International Prognostic Scoring System

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-dipss.pdf 29AUG2023: 9:03

Table 2.1628: Subgroup Analysis of Rate of RBC Transfusion by Geographic Area
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Europe		Eastern Europe	
	MMB (N=53)	RUX (N=51)	MMB (N=25)	RUX (N=36)
RBC Transfusion Rate in DB phase (units/month)				
N	53	51	25	36
Mean (SD)	1.5 (2.00)	2.2 (2.13)	0.8 (1.20)	1.4 (1.86)
Median	0.5	1.6	0.0	0.7
Q1, Q3	0.0, 2.5	0.4, 3.6	0.0, 1.4	0.0, 1.8
Min, Max	0.0, 9.1	0.0, 7.8	0.0, 3.4	0.0, 8.2
Negative Binomial Model				
Adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	0.98 (0.68, 1.43)	2.04 (1.43, 2.91)	0.01 (0.00, -)	0.04 (0.00, -)
Ratio of Rate for RBC Transfusion with 95% CI	0.48 (0.29, 0.79)		0.38 (0.17, 0.89)	
p-value	0.004		0.026	
Un-adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	1.41 (0.96, 2.07)	2.17 (1.49, 3.16)	0.85 (0.45, 1.62)	1.40 (0.84, 2.35)
Ratio of Rate for RBC Transfusion with 95% CI	0.65 (0.38, 1.11)		0.61 (0.27, 1.38)	
p-value	0.12		0.24	
Proportional Means Model - Supportive Analysis				
Stratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	0.53 (0.35, 0.79)		0.58 (0.33, 1.01)	
p-value	0.002		0.055	
Unstratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	0.66 (0.41, 1.05)		0.61 (0.31, 1.22)	
p-value	0.079		0.16	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-geo.pdf 29AUG2023: 9:02

Table 2.1628: Subgroup Analysis of Rate of RBC Transfusion by Geographic Area
Double-Blind Phase
ITT-Anemic Analysis Set

(Continued)	Asia	
	MMB (N=8)	RUX (N=7)
RBC Transfusion Rate in DB phase (units/month)		
N	8	7
Mean (SD)	0.0 (0.13)	1.6 (1.54)
Median	0.0	1.1
Q1, Q3	0.0, 0.0	0.4, 2.8
Min, Max	0.0, 0.4	0.0, 4.3
Negative Binomial Model		
Adjusted for Strata		
Rate of RBC Transfusion with 95% CI(units/month)	0.00 (0.00, -)	0.01 (0.00, -)
Ratio of Rate for RBC Transfusion with 95% CI	0.04 (0.01, 0.26)	
p-value	< 0.001	
Un-adjusted for Strata		
Rate of RBC Transfusion with 95% CI(units/month)	0.05 (0.01, 0.24)	1.59 (0.71, 3.56)
Ratio of Rate for RBC Transfusion with 95% CI	0.03 (0.01, 0.18)	
p-value	< 0.001	
Proportional Means Model - Supportive Analysis		
Stratified		
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	0.04 (0.01, 0.30)	
p-value	0.002	
Unstratified		
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	0.03 (0.00, 0.22)	
p-value	< 0.001	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-geo.pdf 29AUG2023: 9:02

Table 2.1628: Subgroup Analysis of Rate of RBC Transfusion by Geographic Area
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Europe		Eastern Europe	
	MMB (N=53)	RUX (N=51)	MMB (N=25)	RUX (N=36)
Total number of RBC Transfusion unit in DB phase				
N	53	51	25	36
Mean (SD)	6.7 (9.94)	11.0 (10.43)	4.1 (5.87)	7.5 (9.42)
Median	2.0	9.0	0.0	4.0
Q1, Q3	0.0, 7.0	2.0, 18.0	0.0, 7.0	0.0, 10.0
Min, Max	0.0, 47.0	0.0, 44.0	0.0, 19.0	0.0, 38.0
Duration of RBC Transfusion in DB phase (months)				
N	53	51	25	36
Mean (SD)	4.94 (1.485)	5.36 (0.710)	5.00 (1.507)	5.49 (0.265)
Median	5.55	5.55	5.55	5.54
Q1, Q3	5.45, 5.59	5.52, 5.59	5.52, 5.59	5.47, 5.59
Min, Max	0.30, 5.78	2.56, 5.78	0.62, 5.72	4.63, 5.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-geo.pdf 29AUG2023: 9:02

Table 2.1628: Subgroup Analysis of Rate of RBC Transfusion by Geographic Area
Double-Blind Phase
ITT-Anemic Analysis Set

(Continued)	Asia	
	MMB (N=8)	RUX (N=7)
Total number of RBC Transfusion unit in DB phase		
N	8	7
Mean (SD)	0.3 (0.71)	8.9 (8.55)
Median	0.0	6.0
Q1, Q3	0.0, 0.0	2.0, 16.0
Min, Max	0.0, 2.0	0.0, 24.0
Duration of RBC Transfusion in DB phase (months)		
N	8	7
Mean (SD)	4.94 (1.656)	5.56 (0.072)
Median	5.55	5.55
Q1, Q3	5.42, 5.59	5.49, 5.62
Min, Max	0.85, 5.59	5.49, 5.68

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-geo.pdf 29AUG2023: 9:02

Table 2.1623: Subgroup Analysis of Rate of RBC Transfusion by HGB at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	< 8 g/dL		>= 8 g/dL	
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)
RBC Transfusion Rate in DB phase (units/month)				
N	28	21	58	73
Mean (SD)	1.6 (1.96)	2.8 (2.58)	1.0 (1.62)	1.6 (1.73)
Median	1.2	2.2	0.0	0.9
Q1, Q3	0.3, 2.3	0.7, 5.0	0.0, 1.6	0.2, 2.2
Min, Max	0.0, 9.1	0.0, 8.2	0.0, 6.8	0.0, 7.8
Negative Binomial Model				
Adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	1.57 (1.00, 2.46)	2.90 (1.78, 4.72)	0.82 (0.53, 1.25)	1.95 (1.30, 2.93)
Ratio of Rate for RBC Transfusion with 95% CI	0.54 (0.28, 1.05)		0.42 (0.24, 0.73)	
p-value	0.068		0.002	
Un-adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	1.57 (1.01, 2.42)	2.82 (1.74, 4.56)	0.91 (0.59, 1.41)	1.55 (1.07, 2.25)
Ratio of Rate for RBC Transfusion with 95% CI	0.56 (0.29, 1.07)		0.59 (0.33, 1.04)	
p-value	0.077		0.069	
Proportional Means Model - Supportive Analysis				
Stratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	0.57 (0.31, 1.05)		0.52 (0.33, 0.83)	
p-value	0.069		0.006	
Unstratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	0.57 (0.31, 1.07)		0.58 (0.35, 0.97)	
p-value	0.080		0.038	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-hgb.pdf 29AUG2023: 9:03

Table 2.1623: Subgroup Analysis of Rate of RBC Transfusion by HGB at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	< 8 g/dL		>= 8 g/dL	
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)
Total number of RBC Transfusion unit in DB phase				
N	28	21	58	73
Mean (SD)	7.3 (9.98)	13.9 (12.72)	4.4 (7.80)	8.2 (8.73)
Median	3.5	10.0	0.0	5.0
Q1, Q3	1.5, 9.0	4.0, 19.0	0.0, 5.0	1.0, 12.0
Min, Max	0.0, 47.0	0.0, 44.0	0.0, 36.0	0.0, 38.0
Duration of RBC Transfusion in DB phase (months)				
N	28	21	58	73
Mean (SD)	4.75 (1.760)	5.21 (0.875)	5.06 (1.344)	5.48 (0.403)
Median	5.55	5.52	5.55	5.55
Q1, Q3	5.47, 5.59	5.45, 5.55	5.45, 5.59	5.52, 5.59
Min, Max	0.30, 5.65	2.56, 5.68	0.30, 5.78	3.19, 5.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-hgb.pdf 29AUG2023: 9:03

Table 2.1625: Subgroup Analysis of Rate of RBC Transfusion by JAK2V617F Mutation
Double-Blind Phase
ITT-Anemic Analysis Set

	Positive		Negative	
	MMB (N=39)	RUX (N=56)	MMB (N=36)	RUX (N=29)
RBC Transfusion Rate in DB phase (units/month)				
N	39	56	36	29
Mean (SD)	1.3 (1.93)	2.0 (2.26)	1.0 (1.71)	1.4 (1.50)
Median	0.4	1.1	0.3	1.2
Q1, Q3	0.0, 2.5	0.2, 3.1	0.0, 1.3	0.5, 1.8
Min, Max	0.0, 9.1	0.0, 8.2	0.0, 6.8	0.0, 6.9
Negative Binomial Model				
Adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	1.03 (0.64, 1.67)	1.51 (1.01, 2.26)	0.59 (0.33, 1.06)	2.05 (1.15, 3.65)
Ratio of Rate for RBC Transfusion with 95% CI	0.68 (0.37, 1.24)		0.29 (0.14, 0.60)	
p-value	0.21		< 0.001	
Un-adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	1.32 (0.81, 2.17)	1.97 (1.32, 2.95)	0.93 (0.56, 1.54)	1.41 (0.82, 2.42)
Ratio of Rate for RBC Transfusion with 95% CI	0.67 (0.35, 1.27)		0.66 (0.31, 1.38)	
p-value	0.22		0.27	
Proportional Means Model - Supportive Analysis				
Stratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	0.65 (0.38, 1.11)		0.55 (0.31, 0.97)	
p-value	0.12		0.040	
Unstratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	0.68 (0.38, 1.20)		0.66 (0.35, 1.25)	
p-value	0.18		0.20	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-jak.pdf 29AUG2023: 9:03

Table 2.1625: Subgroup Analysis of Rate of RBC Transfusion by JAK2V617F Mutation
Double-Blind Phase
ITT-Anemic Analysis Set

	Positive		Negative	
	MMB (N=39)	RUX (N=56)	MMB (N=36)	RUX (N=29)
Total number of RBC Transfusion unit in DB phase				
N	39	56	36	29
Mean (SD)	6.3 (10.02)	10.2 (11.44)	4.4 (7.52)	7.1 (6.07)
Median	2.0	6.0	1.5	7.0
Q1, Q3	0.0, 12.0	1.0, 15.5	0.0, 6.0	3.0, 10.0
Min, Max	0.0, 47.0	0.0, 44.0	0.0, 36.0	0.0, 20.0
Duration of RBC Transfusion in DB phase (months)				
N	39	56	36	29
Mean (SD)	4.92 (1.510)	5.39 (0.592)	5.07 (1.369)	5.44 (0.551)
Median	5.55	5.55	5.55	5.55
Q1, Q3	5.45, 5.59	5.49, 5.59	5.45, 5.57	5.52, 5.62
Min, Max	0.30, 5.65	2.56, 5.78	0.30, 5.78	2.76, 5.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-jak.pdf 29AUG2023: 9:03

Table 2.1627: Subgroup Analysis of Rate of RBC Transfusion by Disease Type
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
RBC Transfusion Rate in DB phase (units/month)				
N	59	54	16	28
Mean (SD)	1.1 (1.83)	1.6 (1.84)	1.5 (1.79)	2.1 (2.17)
Median	0.3	0.7	1.1	1.7
Q1, Q3	0.0, 1.8	0.3, 2.1	0.0, 2.3	0.1, 3.4
Min, Max	0.0, 9.1	0.0, 7.8	0.0, 6.8	0.0, 7.8
Negative Binomial Model				
Adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	0.76 (0.49, 1.17)	1.42 (0.95, 2.10)	1.19 (0.61, 2.31)	3.10 (1.62, 5.93)
Ratio of Rate for RBC Transfusion with 95% CI	0.54 (0.31, 0.94)		0.38 (0.16, 0.91)	
p-value	0.028		0.029	
Un-adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	1.12 (0.74, 1.69)	1.55 (1.02, 2.36)	1.28 (0.63, 2.64)	2.13 (1.28, 3.54)
Ratio of Rate for RBC Transfusion with 95% CI	0.72 (0.40, 1.30)		0.60 (0.25, 1.46)	
p-value	0.27		0.26	
Proportional Means Model - Supportive Analysis				
Stratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	0.71 (0.43, 1.19)		0.42 (0.27, 0.67)	
p-value	0.19		< 0.001	
Unstratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	0.74 (0.44, 1.26)		0.55 (0.29, 1.04)	
p-value	0.27		0.065	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-mf.pdf 29AUG2023: 9:04

Table 2.1627: Subgroup Analysis of Rate of RBC Transfusion by Disease Type
Double-Blind Phase
ITT-Anemic Analysis Set

(Continued)	Post-PV Myelofibrosis MMB (N=11)	Post-PV Myelofibrosis RUX (N=12)
RBC Transfusion Rate in DB phase (units/month)		
N	11	12
Mean (SD)	0.9 (1.21)	2.4 (2.28)
Median	0.0	2.0
Q1, Q3	0.0, 1.6	1.0, 2.7
Min, Max	0.0, 3.6	0.0, 8.2
Negative Binomial Model		
Adjusted for Strata		
Rate of RBC Transfusion with 95% CI(units/month)	0.75 (0.27, 2.12)	2.20 (1.13, 4.30)
Ratio of Rate for RBC Transfusion with 95% CI	0.34 (0.09, 1.32)	
p-value	0.12	
Un-adjusted for Strata		
Rate of RBC Transfusion with 95% CI(units/month)	0.88 (0.39, 2.01)	2.40 (1.18, 4.91)
Ratio of Rate for RBC Transfusion with 95% CI	0.37 (0.12, 1.09)	
p-value	0.071	
Proportional Means Model - Supportive Analysis		
Stratified		
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	0.46 (0.18, 1.19)	
p-value	0.11	
Unstratified		
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	0.36 (0.12, 1.07)	
p-value	0.067	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-mf.pdf 29AUG2023: 9:04

Table 2.1627: Subgroup Analysis of Rate of RBC Transfusion by Disease Type
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)
Total number of RBC Transfusion unit in DB phase				
N	59	54	16	28
Mean (SD)	5.6 (9.56)	8.1 (9.09)	5.6 (6.09)	10.9 (11.00)
Median	2.0	4.0	4.5	9.0
Q1, Q3	0.0, 7.0	2.0, 12.0	0.0, 8.5	0.5, 17.0
Min, Max	0.0, 47.0	0.0, 38.0	0.0, 19.0	0.0, 44.0
Duration of RBC Transfusion in DB phase (months)				
N	59	54	16	28
Mean (SD)	5.05 (1.355)	5.45 (0.459)	5.01 (1.503)	5.39 (0.775)
Median	5.55	5.55	5.55	5.55
Q1, Q3	5.45, 5.59	5.49, 5.59	5.50, 5.59	5.52, 5.63
Min, Max	0.53, 5.72	3.19, 5.78	0.30, 5.78	2.56, 5.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-mf.pdf 29AUG2023: 9:04

Table 2.1627: Subgroup Analysis of Rate of RBC Transfusion by Disease Type
Double-Blind Phase
ITT-Anemic Analysis Set

(Continued)	Post-PV Myelofibrosis MMB (N=11)	Post-PV Myelofibrosis RUX (N=12)
Total number of RBC Transfusion unit in DB phase		
N	11	12
Mean (SD)	3.6 (6.48)	12.6 (10.98)
Median	0.0	11.0
Q1, Q3	0.0, 3.0	5.5, 14.5
Min, Max	0.0, 20.0	0.0, 38.0
Duration of RBC Transfusion in DB phase (months)		
N	11	12
Mean (SD)	4.37 (2.089)	5.40 (0.266)
Median	5.55	5.47
Q1, Q3	2.00, 5.59	5.34, 5.55
Min, Max	0.30, 5.65	4.63, 5.65

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-mf.pdf 29AUG2023: 9:04

Table 2.1626: Subgroup Analysis of Rate of RBC Transfusion by Platelet Count at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	< 100X10E9/L		>= 100X10E9/L and <= 200X10E9/L	
	MMB (N=13)	RUX (N=13)	MMB (N=36)	RUX (N=34)
RBC Transfusion Rate in DB phase (units/month)				
N	13	13	36	34
Mean (SD)	1.6 (1.57)	2.9 (2.88)	1.3 (2.24)	1.7 (1.87)
Median	1.3	2.1	0.0	0.9
Q1, Q3	0.4, 3.3	0.4, 4.6	0.0, 1.4	0.5, 2.2
Min, Max	0.0, 4.3	0.0, 8.2	0.0, 9.1	0.0, 6.9
Negative Binomial Model				
Adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	1.18 (0.58, 2.43)	2.10 (1.03, 4.26)	0.70 (0.39, 1.23)	1.61 (0.97, 2.65)
Ratio of Rate for RBC Transfusion with 95% CI	0.56 (0.22, 1.45)		0.43 (0.20, 0.95)	
p-value	0.23		0.037	
Un-adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	1.60 (0.79, 3.25)	2.87 (1.43, 5.74)	1.18 (0.67, 2.05)	1.70 (0.98, 2.95)
Ratio of Rate for RBC Transfusion with 95% CI	0.56 (0.21, 1.51)		0.69 (0.32, 1.51)	
p-value	0.25		0.35	
Proportional Means Model - Supportive Analysis				
Stratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	0.55 (0.27, 1.13)		0.65 (0.32, 1.29)	
p-value	0.10		0.22	
Unstratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	0.58 (0.28, 1.23)		0.66 (0.32, 1.40)	
p-value	0.16		0.28	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratification factor is transfusion dependence (Yes vs. No) at baseline.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-plate.pdf 29AUG2023: 9:04

Table 2.1626: Subgroup Analysis of Rate of RBC Transfusion by Platelet Count at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

(Continued)	> 200X10E9/L MMB (N=37)	> 200X10E9/L RUX (N=47)
RBC Transfusion Rate in DB phase (units/month)		
N	37	47
Mean (SD)	0.9 (1.16)	1.6 (1.76)
Median	0.3	1.2
Q1, Q3	0.0, 1.8	0.0, 2.6
Min, Max	0.0, 3.6	0.0, 7.8
Negative Binomial Model		
Adjusted for Strata		
Rate of RBC Transfusion with 95% CI(units/month)	0.76 (0.49, 1.19)	1.73 (1.18, 2.54)
Ratio of Rate for RBC Transfusion with 95% CI	0.44 (0.24, 0.80)	
p-value	0.007	
Un-adjusted for Strata		
Rate of RBC Transfusion with 95% CI(units/month)	0.91 (0.57, 1.47)	1.64 (1.09, 2.46)
Ratio of Rate for RBC Transfusion with 95% CI	0.56 (0.30, 1.04)	
p-value	0.065	
Proportional Means Model - Supportive Analysis		
Stratified		
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	0.47 (0.29, 0.76)	
p-value	0.002	
Unstratified		
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	0.56 (0.33, 0.95)	
p-value	0.033	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratification factor is transfusion dependence (Yes vs. No) at baseline.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-plate.pdf 29AUG2023: 9:04

Table 2.1626: Subgroup Analysis of Rate of RBC Transfusion by Platelet Count at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	< 100X10E9/L		>= 100X10E9/L and <= 200X10E9/L	
	MMB (N=13)	RUX (N=13)	MMB (N=36)	RUX (N=34)
Total number of RBC Transfusion unit in DB phase				
N	13	13	36	34
Mean (SD)	8.1 (8.34)	13.4 (12.93)	5.2 (10.62)	8.5 (8.75)
Median	6.0	9.0	0.0	5.0
Q1, Q3	2.0, 15.0	2.0, 26.0	0.0, 6.0	3.0, 12.0
Min, Max	0.0, 24.0	0.0, 38.0	0.0, 47.0	0.0, 38.0
Duration of RBC Transfusion in DB phase (months)				
N	13	13	36	34
Mean (SD)	5.27 (1.033)	5.04 (0.973)	4.87 (1.590)	5.36 (0.635)
Median	5.55	5.52	5.55	5.54
Q1, Q3	5.52, 5.59	4.80, 5.55	5.45, 5.59	5.45, 5.59
Min, Max	1.84, 5.65	2.56, 5.72	0.30, 5.65	2.76, 5.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratification factor is transfusion dependence (Yes vs. No) at baseline.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-plate.pdf 29AUG2023: 9:04

Table 2.1626: Subgroup Analysis of Rate of RBC Transfusion by Platelet Count at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

(Continued)	> 200X10E9/L MMB (N=37)	> 200X10E9/L RUX (N=47)
Total number of RBC Transfusion unit in DB phase		
N	37	47
Mean (SD)	4.5 (6.25)	9.1 (9.88)
Median	2.0	7.0
Q1, Q3	0.0, 5.0	0.0, 14.0
Min, Max	0.0, 20.0	0.0, 44.0
Duration of RBC Transfusion in DB phase (months)		
N	37	47
Mean (SD)	4.93 (1.541)	5.57 (0.101)
Median	5.55	5.55
Q1, Q3	5.45, 5.59	5.52, 5.62
Min, Max	0.30, 5.78	5.32, 5.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratification factor is transfusion dependence (Yes vs. No) at baseline.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-plate.pdf 29AUG2023: 9:04

Table 2.1619: Subgroup Analysis of Rate of RBC Transfusion by Race
Double-Blind Phase
ITT-Anemic Analysis Set

	White		All Other Races	
	MMB (N=69)	RUX (N=76)	MMB (N=11)	RUX (N=8)
RBC Transfusion Rate in DB phase (units/month)				
N	69	76	11	8
Mean (SD)	1.3 (1.86)	1.7 (2.04)	0.4 (0.80)	1.4 (1.51)
Median	0.4	1.1	0.0	0.9
Q1, Q3	0.0, 2.1	0.4, 2.3	0.0, 0.4	0.3, 2.3
Min, Max	0.0, 9.1	0.0, 8.2	0.0, 2.5	0.0, 4.3
Negative Binomial Model				
Adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	0.96 (0.68, 1.36)	1.79 (1.29, 2.49)	0.00 (0.00, -)	0.01 (0.00, -)
Ratio of Rate for RBC Transfusion with 95% CI	0.53 (0.34, 0.84)		0.30 (0.04, 2.16)	
p-value	0.006		0.23	
Un-adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	1.28 (0.90, 1.82)	1.74 (1.26, 2.40)	0.39 (0.14, 1.12)	1.42 (0.45, 4.48)
Ratio of Rate for RBC Transfusion with 95% CI	0.74 (0.46, 1.19)		0.28 (0.06, 1.31)	
p-value	0.21		0.10	
Proportional Means Model - Supportive Analysis				
Stratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	0.60 (0.39, 0.91)		0.37 (0.10, 1.38)	
p-value	0.016		0.14	
Unstratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	0.74 (0.48, 1.14)		0.29 (0.07, 1.15)	
p-value	0.18		0.078	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-race.pdf 29AUG2023: 9:02

Table 2.1619: Subgroup Analysis of Rate of RBC Transfusion by Race
Double-Blind Phase
ITT-Anemic Analysis Set

	White		All Other Races	
	MMB (N=69)	RUX (N=76)	MMB (N=11)	RUX (N=8)
Total number of RBC Transfusion unit in DB phase				
N	69	76	11	8
Mean (SD)	6.0 (9.12)	9.0 (9.90)	2.1 (4.48)	7.9 (8.39)
Median	2.0	6.0	0.0	5.0
Q1, Q3	0.0, 7.0	2.0, 12.5	0.0, 2.0	1.5, 13.0
Min, Max	0.0, 47.0	0.0, 44.0	0.0, 14.0	0.0, 24.0
Duration of RBC Transfusion in DB phase (months)				
N	69	76	11	8
Mean (SD)	4.90 (1.563)	5.43 (0.512)	5.11 (1.414)	5.55 (0.068)
Median	5.55	5.55	5.55	5.54
Q1, Q3	5.45, 5.59	5.49, 5.59	5.49, 5.59	5.50, 5.59
Min, Max	0.30, 5.78	2.76, 5.78	0.85, 5.62	5.49, 5.68

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-race.pdf 29AUG2023: 9:02

Table 2.1618: Subgroup Analysis of Rate of RBC Transfusion by Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female	
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)
RBC Transfusion Rate in DB phase (units/month)				
N	50	56	36	38
Mean (SD)	1.5 (1.88)	2.2 (2.19)	0.7 (1.45)	1.3 (1.57)
Median	0.8	1.5	0.0	0.9
Q1, Q3	0.0, 2.5	0.5, 3.7	0.0, 0.5	0.0, 1.8
Min, Max	0.0, 9.1	0.0, 8.2	0.0, 6.8	0.0, 7.8
Negative Binomial Model				
Adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	0.91 (0.57, 1.44)	1.86 (1.24, 2.77)	0.61 (0.32, 1.15)	1.47 (0.81, 2.66)
Ratio of Rate for RBC Transfusion with 95% CI	0.49 (0.30, 0.80)		0.41 (0.17, 1.00)	
p-value	0.004		0.051	
Un-adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	1.46 (1.00, 2.12)	2.19 (1.55, 3.10)	0.61 (0.33, 1.13)	1.31 (0.77, 2.24)
Ratio of Rate for RBC Transfusion with 95% CI	0.67 (0.40, 1.11)		0.47 (0.21, 1.06)	
p-value	0.12		0.068	
Proportional Means Model - Supportive Analysis				
Stratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	0.57 (0.37, 0.88)		0.45 (0.22, 0.89)	
p-value	0.011		0.022	
Unstratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	0.69 (0.44, 1.08)		0.40 (0.19, 0.84)	
p-value	0.10		0.016	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-sex.pdf 29AUG2023: 9:03

Table 2.1618: Subgroup Analysis of Rate of RBC Transfusion by Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female	
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)
Total number of RBC Transfusion unit in DB phase				
N	50	56	36	38
Mean (SD)	7.5 (10.08)	11.1 (10.56)	2.4 (4.73)	7.2 (8.66)
Median	3.0	8.0	0.0	5.0
Q1, Q3	0.0, 12.0	3.0, 18.5	0.0, 2.0	0.0, 10.0
Min, Max	0.0, 47.0	0.0, 38.0	0.0, 20.0	0.0, 44.0
Duration of RBC Transfusion in DB phase (months)				
N	50	56	36	38
Mean (SD)	5.27 (0.996)	5.36 (0.688)	4.53 (1.915)	5.51 (0.214)
Median	5.55	5.55	5.54	5.55
Q1, Q3	5.52, 5.59	5.49, 5.59	4.98, 5.55	5.49, 5.62
Min, Max	0.53, 5.72	2.56, 5.78	0.30, 5.78	4.67, 5.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-sex.pdf 29AUG2023: 9:03

Table 2.1621: Subgroup Analysis of Rate of RBC Transfusion by Spleen Volume at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3	
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)
RBC Transfusion Rate in DB phase (units/month)				
N	47	43	39	51
Mean (SD)	1.0 (1.61)	2.0 (1.67)	1.3 (1.91)	1.7 (2.26)
Median	0.2	1.8	0.4	0.7
Q1, Q3	0.0, 1.8	0.7, 2.8	0.0, 2.1	0.2, 2.2
Min, Max	0.0, 6.8	0.0, 7.8	0.0, 9.1	0.0, 8.2
Negative Binomial Model				
Adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	0.63 (0.38, 1.07)	2.17 (1.34, 3.50)	0.97 (0.59, 1.59)	1.50 (1.00, 2.25)
Ratio of Rate for RBC Transfusion with 95% CI	0.29 (0.16, 0.55)		0.65 (0.35, 1.20)	
p-value	< 0.001		0.17	
Un-adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	0.94 (0.60, 1.48)	1.95 (1.25, 3.04)	1.33 (0.83, 2.13)	1.73 (1.16, 2.60)
Ratio of Rate for RBC Transfusion with 95% CI	0.48 (0.25, 0.91)		0.77 (0.41, 1.43)	
p-value	0.024		0.40	
Proportional Means Model - Supportive Analysis				
Stratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	0.38 (0.25, 0.60)		0.74 (0.42, 1.31)	
p-value	< 0.001		0.30	
Unstratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	0.45 (0.26, 0.76)		0.83 (0.46, 1.48)	
p-value	0.003		0.53	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-svb.pdf 29AUG2023: 9:03

Table 2.1621: Subgroup Analysis of Rate of RBC Transfusion by Spleen Volume at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3	
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)
Total number of RBC Transfusion unit in DB phase				
N	47	43	39	51
Mean (SD)	4.2 (6.96)	10.6 (9.09)	6.7 (10.19)	8.6 (10.67)
Median	1.0	10.0	2.0	4.0
Q1, Q3	0.0, 6.0	4.0, 15.0	0.0, 8.0	1.0, 12.0
Min, Max	0.0, 26.0	0.0, 44.0	0.0, 47.0	0.0, 38.0
Duration of RBC Transfusion in DB phase (months)				
N	47	43	39	51
Mean (SD)	4.91 (1.609)	5.47 (0.416)	5.02 (1.348)	5.38 (0.644)
Median	5.55	5.55	5.55	5.55
Q1, Q3	5.49, 5.59	5.49, 5.62	5.45, 5.59	5.49, 5.59
Min, Max	0.30, 5.78	3.19, 5.78	0.30, 5.72	2.56, 5.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-svb.pdf 29AUG2023: 9:03

Table 2.1620: Subgroup Analysis of Rate of RBC Transfusion by Transfusion Dependence at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	Yes		No	
	MMB (N=49)	RUX (N=43)	MMB (N=37)	RUX (N=51)
RBC Transfusion Rate in DB phase (units/month)				
N	49	43	37	51
Mean (SD)	1.7 (1.87)	2.8 (2.42)	0.5 (1.31)	1.1 (1.10)
Median	1.3	2.3	0.0	0.7
Q1, Q3	0.4, 2.5	0.7, 4.3	0.0, 0.2	0.0, 1.8
Min, Max	0.0, 9.1	0.0, 8.2	0.0, 6.8	0.0, 4.3
Negative Binomial Model				
Adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	1.72 (1.23, 2.42)	2.82 (2.00, 3.97)	0.38 (0.19, 0.74)	1.20 (0.66, 2.18)
Ratio of Rate for RBC Transfusion with 95% CI	0.61 (0.38, 0.98)		0.31 (0.14, 0.69)	
p-value	0.041		0.004	
Un-adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	1.68 (1.21, 2.33)	2.76 (1.97, 3.88)	0.36 (0.19, 0.67)	1.05 (0.66, 1.68)
Ratio of Rate for RBC Transfusion with 95% CI	0.61 (0.38, 0.97)		0.34 (0.16, 0.75)	
p-value	0.038		0.007	
Proportional Means Model - Supportive Analysis				
Stratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	0.63 (0.41, 0.96)		0.31 (0.13, 0.72)	
p-value	0.032		0.006	
Unstratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	0.63 (0.41, 0.96)		0.31 (0.13, 0.72)	
p-value	0.031		0.006	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratification factor is platelet count (<100X10^9/L, =100X10^9/L and = 200X10^9/L, or > 200X10^9/L) at baseline.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell
CMH = Cochran-Mantel-Haenszel

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-tf.pdf 29AUG2023: 9:02

Table 2.1620: Subgroup Analysis of Rate of RBC Transfusion by Transfusion Dependence at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	Yes		No	
	MMB (N=49)	RUX (N=43)	MMB (N=37)	RUX (N=51)
Total number of RBC Transfusion unit in DB phase				
N	49	43	37	51
Mean (SD)	8.1 (10.04)	13.8 (11.85)	1.6 (4.02)	5.9 (6.11)
Median	4.0	12.0	0.0	4.0
Q1, Q3	2.0, 12.0	4.0, 24.0	0.0, 1.0	0.0, 10.0
Min, Max	0.0, 47.0	0.0, 44.0	0.0, 15.0	0.0, 24.0
Duration of RBC Transfusion in DB phase (months)				
N	49	43	37	51
Mean (SD)	4.91 (1.541)	5.26 (0.771)	5.02 (1.435)	5.56 (0.148)
Median	5.55	5.52	5.55	5.55
Q1, Q3	5.52, 5.59	5.45, 5.59	5.45, 5.59	5.52, 5.62
Min, Max	0.30, 5.65	2.56, 5.78	0.30, 5.78	4.80, 5.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratification factor is platelet count (<100X10^9/L, =100X10^9/L and = 200X10^9/L, or > 200X10^9/L) at baseline.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell
CMH = Cochran-Mantel-Haenszel

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-tf.pdf 29AUG2023: 9:02

Table 2.1622: Subgroup Analysis of Rate of RBC Transfusion by TSS at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	< Q1 7.8		>= Q1 7.8 and < Median 16.8	
	MMB (N=24)	RUX (N=20)	MMB (N=16)	RUX (N=29)
RBC Transfusion Rate in DB phase (units/month)				
N	24	20	16	29
Mean (SD)	0.9 (1.35)	2.1 (1.71)	0.9 (1.20)	1.6 (1.80)
Median	0.3	1.6	0.4	0.9
Q1, Q3	0.0, 1.8	0.7, 3.5	0.0, 1.4	0.4, 2.4
Min, Max	0.0, 3.6	0.0, 5.2	0.0, 3.8	0.0, 8.2
Negative Binomial Model				
Adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	0.73 (0.41, 1.30)	2.40 (1.27, 4.53)	0.81 (0.43, 1.55)	1.62 (1.02, 2.56)
Ratio of Rate for RBC Transfusion with 95% CI	0.31 (0.13, 0.72)		0.50 (0.22, 1.13)	
p-value	0.007		0.098	
Un-adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	0.94 (0.53, 1.65)	2.13 (1.17, 3.88)	0.88 (0.45, 1.73)	1.57 (0.99, 2.50)
Ratio of Rate for RBC Transfusion with 95% CI	0.44 (0.19, 1.00)		0.56 (0.25, 1.28)	
p-value	0.050		0.17	
Proportional Means Model - Supportive Analysis				
Stratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	0.43 (0.23, 0.80)		0.60 (0.36, 1.01)	
p-value	0.008		0.054	
Unstratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	0.46 (0.24, 0.88)		0.56 (0.28, 1.15)	
p-value	0.019		0.11	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell
TSS = Total Symptom Score

Data Extracted: CRF data: 01JUL2019

Table 2.1622: Subgroup Analysis of Rate of RBC Transfusion by TSS at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

(Continued)	>= Median 16.8 and < Q3 25.7		>= Q3 25.7	
	MMB (N=21)	RUX (N=23)	MMB (N=24)	RUX (N=21)
RBC Transfusion Rate in DB phase (units/month)				
N	21	23	24	21
Mean (SD)	1.1 (1.31)	1.2 (1.56)	1.7 (2.58)	2.4 (2.45)
Median	0.4	0.6	0.1	1.3
Q1, Q3	0.0, 1.9	0.0, 2.1	0.0, 2.7	0.4, 4.3
Min, Max	0.0, 4.7	0.0, 6.9	0.0, 9.1	0.0, 7.8
Negative Binomial Model				
Adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	0.56 (0.28, 1.12)	1.39 (0.66, 2.93)	1.18 (0.59, 2.38)	1.57 (0.87, 2.82)
Ratio of Rate for RBC Transfusion with 95% CI	0.40 (0.13, 1.26)		0.76 (0.33, 1.75)	
p-value	0.12		0.51	
Un-adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	1.05 (0.53, 2.09)	1.17 (0.61, 2.23)	1.59 (0.80, 3.15)	2.35 (1.16, 4.78)
Ratio of Rate for RBC Transfusion with 95% CI	0.90 (0.35, 2.32)		0.67 (0.25, 1.81)	
p-value	0.83		0.43	
Proportional Means Model - Supportive Analysis				
Stratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	0.57 (0.28, 1.19)		0.94 (0.52, 1.70)	
p-value	0.14		0.83	
Unstratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	0.86 (0.40, 1.87)		0.69 (0.30, 1.58)	
p-value	0.70		0.38	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell
TSS = Total Symptom Score

Data Extracted: CRF data: 01JUL2019

Table 2.1622: Subgroup Analysis of Rate of RBC Transfusion by TSS at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	< Q1 7.8		>= Q1 7.8 and < Median 16.8	
	MMB (N=24)	RUX (N=20)	MMB (N=16)	RUX (N=29)
Total number of RBC Transfusion unit in DB phase				
N	24	20	16	29
Mean (SD)	5.2 (7.53)	11.9 (9.60)	4.0 (5.13)	7.9 (8.40)
Median	1.5	9.0	2.0	5.0
Q1, Q3	0.0, 10.0	4.0, 19.5	0.0, 6.5	2.0, 12.0
Min, Max	0.0, 20.0	0.0, 29.0	0.0, 18.0	0.0, 38.0
Duration of RBC Transfusion in DB phase (months)				
N	24	20	16	29
Mean (SD)	5.37 (0.962)	5.56 (0.085)	4.89 (1.751)	5.36 (0.719)
Median	5.57	5.55	5.54	5.55
Q1, Q3	5.54, 5.59	5.52, 5.59	5.45, 5.55	5.52, 5.59
Min, Max	0.85, 5.65	5.39, 5.78	0.30, 5.72	2.56, 5.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell
TSS = Total Symptom Score

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-tss.pdf 29AUG2023: 9:02

Table 2.1622: Subgroup Analysis of Rate of RBC Transfusion by TSS at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

(Continued)	>= Median 16.8 and < Q3 25.7		>= Q3 25.7	
	MMB (N=21)	RUX (N=23)	MMB (N=24)	RUX (N=21)
Total number of RBC Transfusion unit in DB phase				
N	21	23	24	21
Mean (SD)	5.1 (7.12)	6.5 (8.61)	6.7 (12.36)	11.2 (10.58)
Median	2.0	3.0	0.5	7.0
Q1, Q3	0.0, 7.0	0.0, 12.0	0.0, 6.0	2.0, 20.0
Min, Max	0.0, 26.0	0.0, 38.0	0.0, 47.0	0.0, 29.0
Duration of RBC Transfusion in DB phase (months)				
N	21	23	24	21
Mean (SD)	4.99 (1.297)	5.53 (0.204)	4.54 (1.851)	5.26 (0.753)
Median	5.59	5.55	5.52	5.52
Q1, Q3	5.49, 5.59	5.45, 5.62	4.73, 5.55	5.45, 5.55
Min, Max	1.22, 5.65	4.80, 5.78	0.30, 5.78	2.76, 5.75

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell
TSS = Total Symptom Score

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-tss.pdf 29AUG2023: 9:02

Table 2.3817: Subgroup Analysis of RBC TD Response Rate at Week 24 and at Week 12 by Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years	
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)
RBC Transfusion Dependent Rate at Week 24				
Non-Dependent, n(%)	13 (54.2%)	15 (41.7%)	32 (51.6%)	21 (36.2%)
Transfusion Requiring, n(%)	2 (8.3%)	2 (5.6%)	3 (4.8%)	9 (15.5%)
Transfusion Independent, n(%)	11 (45.8%)	13 (36.1%)	29 (46.8%)	12 (20.7%)
Dependent, n(%)	11 (45.8%)	21 (58.3%)	30 (48.4%)	37 (63.8%)
95% Exact CI	0.2555, 0.6718	0.4076, 0.7449	0.3550, 0.6144	0.5012, 0.7601
Proportion Difference - Stratified CMH Method(95% CI)	-0.11(-0.41, 0.20)		-0.17(-0.35, 0.01)	
Proportion Difference - Unstratified CMH Method(95% CI)	-0.13(-0.39, 0.14)		-0.15(-0.33, 0.02)	
Proportion Difference - Unstratified Exact Method(95% CI)	-0.13(-0.38, 0.14)		-0.15(-0.33, 0.03)	
>=4 units transfused in the last 8 weeks	4 (16.7%)	6 (16.7%)	10 (16.1%)	23 (39.7%)
Any Hgb assessment < 8g/dL in the last 8 weeks	6 (25.0%)	18 (50.0%)	14 (22.6%)	25 (43.1%)
Last Participation date < Day 162 in DB phase	4 (16.7%)	3 (8.3%)	12 (19.4%)	5 (8.6%)
Other	4 (16.7%)	10 (27.8%)	7 (11.3%)	16 (27.6%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-td.sas V.03.05 Output file: t-subgrp-rbctd24-age.pdf 29AUG2023: 9:02

Table 2.3817: Subgroup Analysis of RBC TD Response Rate at Week 24 and at Week 12 by Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years	
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)
RBC Transfusion Dependent Rate at Week 12				
Non-Dependent, n(%)	14 (58.3%)	12 (33.3%)	36 (58.1%)	15 (25.9%)
Transfusion Requiring, n(%)	3 (12.5%)	3 (8.3%)	12 (19.4%)	4 (6.9%)
Transfusion Independent, n(%)	11 (45.8%)	9 (25.0%)	24 (38.7%)	11 (19.0%)
Dependent, n(%)	10 (41.7%)	24 (66.7%)	26 (41.9%)	43 (74.1%)
95% Exact CI	0.2211, 0.6336	0.4903, 0.8144	0.2951, 0.5515	0.6096, 0.8474
Proportion Difference - Stratified CMH Method(95% CI)	-0.27(-0.54, 0.01)		-0.40(-0.57, -0.24)	
Proportion Difference - Unstratified CMH Method(95% CI)	-0.25(-0.51, 0.01)		-0.32(-0.49, -0.15)	
Proportion Difference - Unstratified Exact Method(95% CI)	-0.25(-0.49, 0.02)		-0.32(-0.49, -0.15)	
>=4 units transfused in the last 8 weeks	4 (16.7%)	8 (22.2%)	17 (27.4%)	30 (51.7%)
Any Hgb assessment < 8g/dL in the last 8 weeks	7 (29.2%)	24 (66.7%)	14 (22.6%)	39 (67.2%)
Last Participation date < Day 78 in DB phase	1 (4.2%)	0	9 (14.5%)	0
Other	3 (12.5%)	14 (38.9%)	8 (12.9%)	21 (36.2%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-td.sas V.03.05 Output file: t-subgrp-rbctd24-age.pdf 29AUG2023: 9:02

Table 2.3824: Subgroup Analysis of RBC TD Response Rate at Week 24 and at Week 12 by IPSS
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk	
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)
RBC Transfusion Dependent Rate at Week 24				
Non-Dependent, n(%)	17 (60.7%)	9 (37.5%)	28 (48.3%)	27 (38.6%)
Transfusion Requiring, n(%)	3 (10.7%)	1 (4.2%)	2 (3.4%)	10 (14.3%)
Transfusion Independent, n(%)	14 (50.0%)	8 (33.3%)	26 (44.8%)	17 (24.3%)
Dependent, n(%)	11 (39.3%)	15 (62.5%)	30 (51.7%)	43 (61.4%)
95% Exact CI	0.2150, 0.5942	0.4059, 0.8120	0.3822, 0.6505	0.4903, 0.7283
Proportion Difference - Stratified CMH Method(95% CI)	-0.29(-0.58, 0.00)		-0.10(-0.27, 0.08)	
Proportion Difference - Unstratified CMH Method(95% CI)	-0.23(-0.50, 0.04)		-0.10(-0.27, 0.08)	
Proportion Difference - Unstratified Exact Method(95% CI)	-0.23(-0.48, 0.05)		-0.10(-0.27, 0.08)	
>=4 units transfused in the last 8 weeks	5 (17.9%)	8 (33.3%)	9 (15.5%)	21 (30.0%)
Any Hgb assessment < 8g/dL in the last 8 weeks	4 (14.3%)	11 (45.8%)	16 (27.6%)	32 (45.7%)
Last Participation date < Day 162 in DB phase	4 (14.3%)	2 (8.3%)	12 (20.7%)	6 (8.6%)
Other	3 (10.7%)	7 (29.2%)	8 (13.8%)	19 (27.1%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel
RBC = Red Blood Cell
IPSS = International Prognostic Scoring System

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-td.sas V.03.05 Output file: t-subgrp-rbctd24-dipss.pdf 29AUG2023: 9:04

Table 2.3824: Subgroup Analysis of RBC TD Response Rate at Week 24 and at Week 12 by IPSS
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk	
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)
RBC Transfusion Dependent Rate at Week 12				
Non-Dependent, n(%)	17 (60.7%)	9 (37.5%)	33 (56.9%)	18 (25.7%)
Transfusion Requiring, n(%)	4 (14.3%)	3 (12.5%)	11 (19.0%)	4 (5.7%)
Transfusion Independent, n(%)	13 (46.4%)	6 (25.0%)	22 (37.9%)	14 (20.0%)
Dependent, n(%)	11 (39.3%)	15 (62.5%)	25 (43.1%)	52 (74.3%)
95% Exact CI	0.2150, 0.5942	0.4059, 0.8120	0.3016, 0.5677	0.6244, 0.8399
Proportion Difference - Stratified CMH Method(95% CI)	-0.28(-0.59, 0.02)		-0.35(-0.52, -0.19)	
Proportion Difference - Unstratified CMH Method(95% CI)	-0.23(-0.50, 0.04)		-0.31(-0.48, -0.15)	
Proportion Difference - Unstratified Exact Method(95% CI)	-0.23(-0.48, 0.05)		-0.31(-0.47, -0.14)	
>=4 units transfused in the last 8 weeks	5 (17.9%)	9 (37.5%)	16 (27.6%)	29 (41.4%)
Any Hgb assessment < 8g/dL in the last 8 weeks	5 (17.9%)	14 (58.3%)	16 (27.6%)	49 (70.0%)
Last Participation date < Day 78 in DB phase	3 (10.7%)	0	7 (12.1%)	0
Other	2 (7.1%)	6 (25.0%)	9 (15.5%)	29 (41.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel
RBC = Red Blood Cell
IPSS = International Prognostic Scoring System

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-td.sas V.03.05 Output file: t-subgrp-rbctd24-dipss.pdf 29AUG2023: 9:04

Table 2.3828: Subgroup Analysis of RBC TD Response Rate at Week 24 and at Week 12 by Geographic Area
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Europe		Eastern Europe		Asia	
	MMB (N=53)	RUX (N=51)	MMB (N=25)	RUX (N=36)	MMB (N=8)	RUX (N=7)
RBC Transfusion Dependent Rate at Week 24						
Non-Dependent, n(%)	25 (47.2%)	21 (41.2%)	16 (64.0%)	15 (41.7%)	4 (50.0%)	0
Transfusion Requiring, n(%)	4 (7.5%)	8 (15.7%)	1 (4.0%)	3 (8.3%)	0	0
Transfusion Independent, n(%)	21 (39.6%)	13 (25.5%)	15 (60.0%)	12 (33.3%)	4 (50.0%)	0
Dependent, n(%)	28 (52.8%)	30 (58.8%)	9 (36.0%)	21 (58.3%)	4 (50.0%)	7 (100.0%)
95% Exact CI	0.3864, 0.6670	0.4417, 0.7242	0.1797, 0.5748	0.4076, 0.7449	0.1570, 0.8430	0.5904, 1.0000
Proportion Difference - Stratified CMH Method(95% CI)	-0.11(-0.31, 0.08)		-0.28(-0.54, -0.02)		-0.46(-1.04, 0.12)	
Proportion Difference - Unstratified CMH Method(95% CI)	-0.06(-0.25, 0.13)		-0.22(-0.48, 0.03)		-0.50(-0.92, -0.08)	
Proportion Difference - Unstratified Exact Method(95% CI)	-0.06(-0.25, 0.13)		-0.22(-0.46, 0.04)		-0.50(-0.85, -0.02)	
>=4 units transfused in the last 8 weeks	11 (20.8%)	19 (37.3%)	3 (12.0%)	7 (19.4%)	0	3 (42.9%)
Any Hgb assessment < 8g/dL in the last 8 weeks	14 (26.4%)	19 (37.3%)	4 (16.0%)	17 (47.2%)	2 (25.0%)	7 (100.0%)
Last Participation date < Day 162 in DB phase	10 (18.9%)	5 (9.8%)	4 (16.0%)	3 (8.3%)	2 (25.0%)	0
Other	5 (9.4%)	9 (17.6%)	4 (16.0%)	10 (27.8%)	2 (25.0%)	7 (100.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-td.sas V.03.05 Output file: t-subgrp-rbctd24-geo.pdf 29AUG2023: 9:06

Table 2.3828: Subgroup Analysis of RBC TD Response Rate at Week 24 and at Week 12 by Geographic Area
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Europe		Eastern Europe		Asia	
	MMB (N=53)	RUX (N=51)	MMB (N=25)	RUX (N=36)	MMB (N=8)	RUX (N=7)
RBC Transfusion Dependent Rate at Week 12						
Non-Dependent, n(%)	31 (58.5%)	16 (31.4%)	14 (56.0%)	11 (30.6%)	5 (62.5%)	0
Transfusion Requiring, n(%)	12 (22.6%)	4 (7.8%)	3 (12.0%)	3 (8.3%)	0	0
Transfusion Independent, n(%)	19 (35.8%)	12 (23.5%)	11 (44.0%)	8 (22.2%)	5 (62.5%)	0
Dependent, n(%)	22 (41.5%)	35 (68.6%)	11 (44.0%)	25 (69.4%)	3 (37.5%)	7 (100.0%)
95% Exact CI	0.2814, 0.5587	0.5411, 0.8089	0.2440, 0.6507	0.5189, 0.8365	0.0852, 0.7551	0.5904, 1.0000
Proportion Difference - Stratified CMH Method(95% CI)	-0.35(-0.53, -0.17)		-0.28(-0.53, -0.03)		-0.65(-1.18, -0.12)	
Proportion Difference - Unstratified CMH Method(95% CI)	-0.27(-0.46, -0.09)		-0.25(-0.51, 0.00)		-0.63(-1.03, -0.22)	
Proportion Difference - Unstratified Exact Method(95% CI)	-0.27(-0.45, -0.08)		-0.25(-0.49, 0.00)		-0.63(-0.92, -0.14)	
>=4 units transfused in the last 8 weeks	15 (28.3%)	24 (47.1%)	6 (24.0%)	11 (30.6%)	0	3 (42.9%)
Any Hgb assessment < 8g/dL in the last 8 weeks	11 (20.8%)	32 (62.7%)	8 (32.0%)	24 (66.7%)	2 (25.0%)	7 (100.0%)
Last Participation date < Day 78 in DB phase	6 (11.3%)	0	3 (12.0%)	0	1 (12.5%)	0
Other	7 (13.2%)	18 (35.3%)	2 (8.0%)	10 (27.8%)	2 (25.0%)	7 (100.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-td.sas V.03.05 Output file: t-subgrp-rbctd24-geo.pdf 29AUG2023: 9:06

Table 2.3823: Subgroup Analysis of RBC TD Response Rate at Week 24 and at Week 12 by HGB at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	< 8 g/dL		>= 8 g/dL	
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)
RBC Transfusion Dependent Rate at Week 24				
Non-Dependent, n(%)	11 (39.3%)	5 (23.8%)	34 (58.6%)	31 (42.5%)
Transfusion Requiring, n(%)	3 (10.7%)	2 (9.5%)	2 (3.4%)	9 (12.3%)
Transfusion Independent, n(%)	8 (28.6%)	3 (14.3%)	32 (55.2%)	22 (30.1%)
Dependent, n(%)	17 (60.7%)	16 (76.2%)	24 (41.4%)	42 (57.5%)
95% Exact CI	0.4058, 0.7850	0.5283, 0.9178	0.2860, 0.5507	0.4541, 0.6903
Proportion Difference - Stratified CMH Method(95% CI)	-0.15(-0.41, 0.12)		-0.17(-0.35, 0.00)	
Proportion Difference - Unstratified CMH Method(95% CI)	-0.15(-0.42, 0.11)		-0.16(-0.33, 0.01)	
Proportion Difference - Unstratified Exact Method(95% CI)	-0.15(-0.42, 0.13)		-0.16(-0.33, 0.01)	
>=4 units transfused in the last 8 weeks	5 (17.9%)	7 (33.3%)	9 (15.5%)	22 (30.1%)
Any Hgb assessment < 8g/dL in the last 8 weeks	11 (39.3%)	10 (47.6%)	9 (15.5%)	33 (45.2%)
Last Participation date < Day 162 in DB phase	6 (21.4%)	4 (19.0%)	10 (17.2%)	4 (5.5%)
Other	9 (32.1%)	6 (28.6%)	2 (3.4%)	20 (27.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-td.sas V.03.05 Output file: t-subgrp-rbctd24-hgb.pdf 29AUG2023: 9:04

Table 2.3823: Subgroup Analysis of RBC TD Response Rate at Week 24 and at Week 12 by HGB at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	< 8 g/dL		>= 8 g/dL	
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)
RBC Transfusion Dependent Rate at Week 12				
Non-Dependent, n(%)	10 (35.7%)	3 (14.3%)	40 (69.0%)	24 (32.9%)
Transfusion Requiring, n(%)	5 (17.9%)	2 (9.5%)	10 (17.2%)	5 (6.8%)
Transfusion Independent, n(%)	5 (17.9%)	1 (4.8%)	30 (51.7%)	19 (26.0%)
Dependent, n(%)	18 (64.3%)	18 (85.7%)	18 (31.0%)	49 (67.1%)
95% Exact CI	0.4407, 0.8136	0.6366, 0.9695	0.1954, 0.4454	0.5513, 0.7767
Proportion Difference - Stratified CMH Method(95% CI)	-0.22(-0.48, 0.04)		-0.38(-0.54, -0.22)	
Proportion Difference - Unstratified CMH Method(95% CI)	-0.21(-0.46, 0.03)		-0.36(-0.52, -0.20)	
Proportion Difference - Unstratified Exact Method(95% CI)	-0.21(-0.48, 0.07)		-0.36(-0.51, -0.19)	
>=4 units transfused in the last 8 weeks	10 (35.7%)	13 (61.9%)	11 (19.0%)	25 (34.2%)
Any Hgb assessment < 8g/dL in the last 8 weeks	12 (42.9%)	17 (81.0%)	9 (15.5%)	46 (63.0%)
Last Participation date < Day 78 in DB phase	5 (17.9%)	0	5 (8.6%)	0
Other	5 (17.9%)	14 (66.7%)	6 (10.3%)	21 (28.8%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-td.sas V.03.05 Output file: t-subgrp-rbctd24-hgb.pdf 29AUG2023: 9:04

Table 2.3825: Subgroup Analysis of RBC TD Response Rate at Week 24 and at Week 12 by JAK2V617F Mutation
Double-Blind Phase
ITT-Anemic Analysis Set

	Positive		Negative	
	MMB (N=39)	RUX (N=56)	MMB (N=36)	RUX (N=29)
RBC Transfusion Dependent Rate at Week 24				
Non-Dependent, n(%)	19 (48.7%)	21 (37.5%)	20 (55.6%)	13 (44.8%)
Transfusion Requiring, n(%)	1 (2.6%)	5 (8.9%)	4 (11.1%)	5 (17.2%)
Transfusion Independent, n(%)	18 (46.2%)	16 (28.6%)	16 (44.4%)	8 (27.6%)
Dependent, n(%)	20 (51.3%)	35 (62.5%)	16 (44.4%)	16 (55.2%)
95% Exact CI	0.3478, 0.6758	0.4855, 0.7508	0.2794, 0.6190	0.3569, 0.7355
Proportion Difference - Stratified CMH Method(95% CI)	-0.14(-0.35, 0.08)		-0.11(-0.37, 0.14)	
Proportion Difference - Unstratified CMH Method(95% CI)	-0.11(-0.32, 0.09)		-0.11(-0.35, 0.14)	
Proportion Difference - Unstratified Exact Method(95% CI)	-0.11(-0.31, 0.09)		-0.11(-0.34, 0.14)	
>=4 units transfused in the last 8 weeks	8 (20.5%)	17 (30.4%)	4 (11.1%)	7 (24.1%)
Any Hgb assessment < 8g/dL in the last 8 weeks	8 (20.5%)	24 (42.9%)	9 (25.0%)	14 (48.3%)
Last Participation date < Day 162 in DB phase	8 (20.5%)	6 (10.7%)	6 (16.7%)	2 (6.9%)
Other	5 (12.8%)	16 (28.6%)	3 (8.3%)	7 (24.1%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-td.sas V.03.05 Output file: t-subgrp-rbctd24-jak.pdf 29AUG2023: 9:05

Table 2.3825: Subgroup Analysis of RBC TD Response Rate at Week 24 and at Week 12 by JAK2V617F Mutation
Double-Blind Phase
ITT-Anemic Analysis Set

	Positive		Negative	
	MMB (N=39)	RUX (N=56)	MMB (N=36)	RUX (N=29)
RBC Transfusion Dependent Rate at Week 12				
Non-Dependent, n(%)	22 (56.4%)	18 (32.1%)	22 (61.1%)	7 (24.1%)
Transfusion Requiring, n(%)	6 (15.4%)	4 (7.1%)	6 (16.7%)	2 (6.9%)
Transfusion Independent, n(%)	16 (41.0%)	14 (25.0%)	16 (44.4%)	5 (17.2%)
Dependent, n(%)	17 (43.6%)	38 (67.9%)	14 (38.9%)	22 (75.9%)
95% Exact CI	0.2781, 0.6038	0.5404, 0.7971	0.2314, 0.5654	0.5646, 0.8970
Proportion Difference - Stratified CMH Method(95% CI)	-0.26(-0.48, -0.05)		-0.43(-0.64, -0.22)	
Proportion Difference - Unstratified CMH Method(95% CI)	-0.24(-0.44, -0.04)		-0.37(-0.60, -0.14)	
Proportion Difference - Unstratified Exact Method(95% CI)	-0.24(-0.43, -0.04)		-0.37(-0.58, -0.13)	
>=4 units transfused in the last 8 weeks	11 (28.2%)	22 (39.3%)	8 (22.2%)	11 (37.9%)
Any Hgb assessment < 8g/dL in the last 8 weeks	10 (25.6%)	37 (66.1%)	8 (22.2%)	21 (72.4%)
Last Participation date < Day 78 in DB phase	5 (12.8%)	0	3 (8.3%)	0
Other	6 (15.4%)	20 (35.7%)	4 (11.1%)	11 (37.9%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-td.sas V.03.05 Output file: t-subgrp-rbctd24-jak.pdf 29AUG2023: 9:05

Table 2.3827: Subgroup Analysis of RBC TD Response Rate at Week 24 and at Week 12 by Disease Type
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis		Post-PV Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)	MMB (N=11)	RUX (N=12)
RBC Transfusion Dependent Rate at Week 24						
Non-Dependent, n(%)	32 (54.2%)	24 (44.4%)	7 (43.8%)	8 (28.6%)	6 (54.5%)	4 (33.3%)
Transfusion Requiring, n(%)	3 (5.1%)	6 (11.1%)	2 (12.5%)	2 (7.1%)	0	3 (25.0%)
Transfusion Independent, n(%)	29 (49.2%)	18 (33.3%)	5 (31.3%)	6 (21.4%)	6 (54.5%)	1 (8.3%)
Dependent, n(%)	27 (45.8%)	30 (55.6%)	9 (56.3%)	20 (71.4%)	5 (45.5%)	8 (66.7%)
95% Exact CI	0.3272, 0.5925	0.4140, 0.6908	0.2988, 0.8025	0.5133, 0.8678	0.1675, 0.7662	0.3489, 0.9008
Proportion Difference - Stratified CMH Method(95% CI)	-0.10(-0.28, 0.09)		-0.17(-0.49, 0.16)		-0.29(-0.75, 0.18)	
Proportion Difference - Unstratified CMH Method(95% CI)	-0.10(-0.28, 0.09)		-0.15(-0.46, 0.15)		-0.21(-0.63, 0.21)	
Proportion Difference - Unstratified Exact Method(95% CI)	-0.10(-0.28, 0.09)		-0.15(-0.44, 0.16)		-0.21(-0.59, 0.22)	
>=4 units transfused in the last 8 weeks	9 (15.3%)	15 (27.8%)	3 (18.8%)	10 (35.7%)	2 (18.2%)	4 (33.3%)
Any Hgb assessment < 8g/dL in the last 8 weeks	13 (22.0%)	23 (42.6%)	5 (31.3%)	15 (53.6%)	2 (18.2%)	5 (41.7%)
Last Participation date < Day 162 in DB phase	10 (16.9%)	4 (7.4%)	3 (18.8%)	2 (7.1%)	3 (27.3%)	2 (16.7%)
Other	7 (11.9%)	15 (27.8%)	2 (12.5%)	9 (32.1%)	2 (18.2%)	2 (16.7%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-td.sas V.03.05 Output file: t-subgrp-rbctd24-mf.pdf 29AUG2023: 9:05

Table 2.3827: Subgroup Analysis of RBC TD Response Rate at Week 24 and at Week 12 by Disease Type
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis		Post-PV Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)	MMB (N=11)	RUX (N=12)
RBC Transfusion Dependent Rate at Week 12						
Non-Dependent, n(%)	36 (61.0%)	17 (31.5%)	8 (50.0%)	7 (25.0%)	6 (54.5%)	3 (25.0%)
Transfusion Requiring, n(%)	12 (20.3%)	6 (11.1%)	2 (12.5%)	0	1 (9.1%)	1 (8.3%)
Transfusion Independent, n(%)	24 (40.7%)	11 (20.4%)	6 (37.5%)	7 (25.0%)	5 (45.5%)	2 (16.7%)
Dependent, n(%)	23 (39.0%)	37 (68.5%)	8 (50.0%)	21 (75.0%)	5 (45.5%)	9 (75.0%)
95% Exact CI	0.2655, 0.5256	0.5445, 0.8048	0.2465, 0.7535	0.5513, 0.8931	0.1675, 0.7662	0.4281, 0.9451
Proportion Difference - Stratified CMH Method(95% CI)	-0.32(-0.49, -0.15)		-0.31(-0.57, -0.05)		-0.33(-0.80, 0.13)	
Proportion Difference - Unstratified CMH Method(95% CI)	-0.30(-0.47, -0.12)		-0.25(-0.55, 0.05)		-0.30(-0.70, 0.11)	
Proportion Difference - Unstratified Exact Method(95% CI)	-0.30(-0.47, -0.11)		-0.25(-0.53, 0.06)		-0.30(-0.65, 0.14)	
>=4 units transfused in the last 8 weeks	14 (23.7%)	19 (35.2%)	5 (31.3%)	13 (46.4%)	2 (18.2%)	6 (50.0%)
Any Hgb assessment < 8g/dL in the last 8 weeks	13 (22.0%)	35 (64.8%)	6 (37.5%)	19 (67.9%)	2 (18.2%)	9 (75.0%)
Last Participation date < Day 78 in DB phase	5 (8.5%)	0	2 (12.5%)	0	3 (27.3%)	0
Other	10 (16.9%)	18 (33.3%)	1 (6.3%)	12 (42.9%)	0	5 (41.7%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-td.sas V.03.05 Output file: t-subgrp-rbctd24-mf.pdf 29AUG2023: 9:05

Table 2.3826: Subgroup Analysis of RBC TD Response Rate at Week 24 and at Week 12 by Platelet Count at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	< 100X10E9/L		>= 100X10E9/L and <= 200X10E9/L		> 200X10E9/L	
	MMB (N=13)	RUX (N=13)	MMB (N=36)	RUX (N=34)	MMB (N=37)	RUX (N=47)
RBC Transfusion Dependent Rate at Week 24						
Non-Dependent, n(%)	7 (53.8%)	2 (15.4%)	21 (58.3%)	16 (47.1%)	17 (45.9%)	18 (38.3%)
Transfusion Requiring, n(%)	0	0	3 (8.3%)	8 (23.5%)	2 (5.4%)	3 (6.4%)
Transfusion Independent, n(%)	7 (53.8%)	2 (15.4%)	18 (50.0%)	8 (23.5%)	15 (40.5%)	15 (31.9%)
Dependent, n(%)	6 (46.2%)	11 (84.6%)	15 (41.7%)	18 (52.9%)	20 (54.1%)	29 (61.7%)
95% Exact CI	0.1922, 0.7487	0.5455, 0.9808	0.2551, 0.5924	0.3513, 0.7022	0.3692, 0.7051	0.4638, 0.7549
Proportion Difference - Stratified CMH Method(95% CI)	-0.38(-0.76, 0.00)		-0.12(-0.35, 0.12)		-0.14(-0.34, 0.07)	
Proportion Difference - Unstratified CMH Method(95% CI)	-0.38(-0.74, -0.03)		-0.11(-0.35, 0.12)		-0.08(-0.29, 0.14)	
Proportion Difference - Unstratified Exact Method(95% CI)	-0.38(-0.71, 0.04)		-0.11(-0.34, 0.13)		-0.08(-0.29, 0.14)	
>=4 units transfused in the last 8 weeks	5 (38.5%)	5 (38.5%)	3 (8.3%)	6 (17.6%)	6 (16.2%)	18 (38.3%)
Any Hgb assessment < 8g/dL in the last 8 weeks	3 (23.1%)	6 (46.2%)	7 (19.4%)	13 (38.2%)	10 (27.0%)	24 (51.1%)
Last Participation date < Day 162 in DB phase	1 (7.7%)	4 (30.8%)	7 (19.4%)	4 (11.8%)	8 (21.6%)	0
Other	1 (7.7%)	4 (30.8%)	3 (8.3%)	6 (17.6%)	7 (18.9%)	16 (34.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Stratification factor is transfusion dependence (Yes vs. No) at baseline.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-td.sas V.03.05 Output file: t-subgrp-rbctd24-plate.pdf 29AUG2023: 9:06

Table 2.3826: Subgroup Analysis of RBC TD Response Rate at Week 24 and at Week 12 by Platelet Count at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	< 100X10E9/L		>= 100X10E9/L and <= 200X10E9/L		> 200X10E9/L	
	MMB (N=13)	RUX (N=13)	MMB (N=36)	RUX (N=34)	MMB (N=37)	RUX (N=47)
RBC Transfusion Dependent Rate at Week 12						
Non-Dependent, n(%)	6 (46.2%)	5 (38.5%)	21 (58.3%)	7 (20.6%)	23 (62.2%)	15 (31.9%)
Transfusion Requiring, n(%)	2 (15.4%)	3 (23.1%)	4 (11.1%)	2 (5.9%)	9 (24.3%)	2 (4.3%)
Transfusion Independent, n(%)	4 (30.8%)	2 (15.4%)	17 (47.2%)	5 (14.7%)	14 (37.8%)	13 (27.7%)
Dependent, n(%)	7 (53.8%)	8 (61.5%)	15 (41.7%)	27 (79.4%)	14 (37.8%)	32 (68.1%)
95% Exact CI	0.2513, 0.8078	0.3158, 0.8614	0.2551, 0.5924	0.6210, 0.9130	0.2246, 0.5524	0.5288, 0.8091
Proportion Difference - Stratified CMH Method(95% CI)	-0.11(-0.50, 0.29)		-0.39(-0.59, -0.18)		-0.35(-0.55, -0.16)	
Proportion Difference - Unstratified CMH Method(95% CI)	-0.08(-0.47, 0.32)		-0.38(-0.59, -0.16)		-0.30(-0.51, -0.09)	
Proportion Difference - Unstratified Exact Method(95% CI)	-0.08(-0.47, 0.33)		-0.38(-0.58, -0.15)		-0.30(-0.50, -0.09)	
>=4 units transfused in the last 8 weeks	6 (46.2%)	7 (53.8%)	8 (22.2%)	14 (41.2%)	7 (18.9%)	17 (36.2%)
Any Hgb assessment < 8g/dL in the last 8 weeks	4 (30.8%)	8 (61.5%)	9 (25.0%)	25 (73.5%)	8 (21.6%)	30 (63.8%)
Last Participation date < Day 78 in DB phase	1 (7.7%)	0	4 (11.1%)	0	5 (13.5%)	0
Other	1 (7.7%)	4 (30.8%)	6 (16.7%)	13 (38.2%)	4 (10.8%)	18 (38.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Stratification factor is transfusion dependence (Yes vs. No) at baseline.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-td.sas V.03.05 Output file: t-subgrp-rbctd24-plate.pdf 29AUG2023: 9:06

Table 2.3819: Subgroup Analysis of RBC TD Response Rate at Week 24 and at Week 12 by Race
Double-Blind Phase
ITT-Anemic Analysis Set

	White		All Other Races	
	MMB (N=69)	RUX (N=76)	MMB (N=11)	RUX (N=8)
RBC Transfusion Dependent Rate at Week 24				
Non-Dependent, n(%)	37 (53.6%)	32 (42.1%)	5 (45.5%)	1 (12.5%)
Transfusion Requiring, n(%)	5 (7.2%)	10 (13.2%)	0	0
Transfusion Independent, n(%)	32 (46.4%)	22 (28.9%)	5 (45.5%)	1 (12.5%)
Dependent, n(%)	32 (46.4%)	44 (57.9%)	6 (54.5%)	7 (87.5%)
95% Exact CI	0.3428, 0.5880	0.4602, 0.6914	0.2338, 0.8325	0.4735, 0.9968
Proportion Difference - Stratified CMH Method(95% CI)	-0.16(-0.32, 0.00)		-0.37(-0.88, 0.14)	
Proportion Difference - Unstratified CMH Method(95% CI)	-0.12(-0.28, 0.05)		-0.33(-0.74, 0.08)	
Proportion Difference - Unstratified Exact Method(95% CI)	-0.12(-0.27, 0.05)		-0.33(-0.70, 0.13)	
>=4 units transfused in the last 8 weeks	12 (17.4%)	20 (26.3%)	1 (9.1%)	3 (37.5%)
Any Hgb assessment < 8g/dL in the last 8 weeks	14 (20.3%)	31 (40.8%)	4 (36.4%)	7 (87.5%)
Last Participation date < Day 162 in DB phase	13 (18.8%)	7 (9.2%)	2 (18.2%)	0
Other	7 (10.1%)	18 (23.7%)	4 (36.4%)	7 (87.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-td.sas V.03.05 Output file: t-subgrp-rbctd24-race.pdf 29AUG2023: 9:02

Table 2.3819: Subgroup Analysis of RBC TD Response Rate at Week 24 and at Week 12 by Race
Double-Blind Phase
ITT-Anemic Analysis Set

	White		All Other Races	
	MMB (N=69)	RUX (N=76)	MMB (N=11)	RUX (N=8)
RBC Transfusion Dependent Rate at Week 12				
Non-Dependent, n(%)	38 (55.1%)	24 (31.6%)	7 (63.6%)	1 (12.5%)
Transfusion Requiring, n(%)	13 (18.8%)	6 (7.9%)	1 (9.1%)	1 (12.5%)
Transfusion Independent, n(%)	25 (36.2%)	18 (23.7%)	6 (54.5%)	0
Dependent, n(%)	31 (44.9%)	52 (68.4%)	4 (36.4%)	7 (87.5%)
95% Exact CI	0.3292, 0.5738	0.5675, 0.7861	0.1093, 0.6921	0.4735, 0.9968
Proportion Difference - Stratified CMH Method(95% CI)	-0.29(-0.45, -0.13)		-0.69(-1.14, -0.23)	
Proportion Difference - Unstratified CMH Method(95% CI)	-0.23(-0.39, -0.08)		-0.51(-0.92, -0.10)	
Proportion Difference - Unstratified Exact Method(95% CI)	-0.23(-0.39, -0.07)		-0.51(-0.84, -0.05)	
>=4 units transfused in the last 8 weeks	19 (27.5%)	28 (36.8%)	1 (9.1%)	3 (37.5%)
Any Hgb assessment < 8g/dL in the last 8 weeks	17 (24.6%)	49 (64.5%)	3 (27.3%)	7 (87.5%)
Last Participation date < Day 78 in DB phase	9 (13.0%)	0	1 (9.1%)	0
Other	8 (11.6%)	24 (31.6%)	3 (27.3%)	7 (87.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-td.sas V.03.05 Output file: t-subgrp-rbctd24-race.pdf 29AUG2023: 9:02

Table 2.3818: Subgroup Analysis of RBC TD Response Rate at Week 24 and at Week 12 by Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female	
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)
RBC Transfusion Dependent Rate at Week 24				
Non-Dependent, n(%)	24 (48.0%)	21 (37.5%)	21 (58.3%)	15 (39.5%)
Transfusion Requiring, n(%)	4 (8.0%)	5 (8.9%)	1 (2.8%)	6 (15.8%)
Transfusion Independent, n(%)	20 (40.0%)	16 (28.6%)	20 (55.6%)	9 (23.7%)
Dependent, n(%)	26 (52.0%)	35 (62.5%)	15 (41.7%)	23 (60.5%)
95% Exact CI	0.3742, 0.6634	0.4855, 0.7508	0.2551, 0.5924	0.4339, 0.7596
Proportion Difference - Stratified CMH Method(95% CI)	-0.17(-0.36, 0.03)		-0.14(-0.38, 0.11)	
Proportion Difference - Unstratified CMH Method(95% CI)	-0.11(-0.29, 0.08)		-0.19(-0.42, 0.04)	
Proportion Difference - Unstratified Exact Method(95% CI)	-0.11(-0.29, 0.09)		-0.19(-0.41, 0.05)	
>=4 units transfused in the last 8 weeks	12 (24.0%)	20 (35.7%)	2 (5.6%)	9 (23.7%)
Any Hgb assessment < 8g/dL in the last 8 weeks	16 (32.0%)	24 (42.9%)	4 (11.1%)	19 (50.0%)
Last Participation date < Day 162 in DB phase	6 (12.0%)	6 (10.7%)	10 (27.8%)	2 (5.3%)
Other	9 (18.0%)	14 (25.0%)	2 (5.6%)	12 (31.6%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-td.sas V.03.05 Output file: t-subgrp-rbctd24-sex.pdf 29AUG2023: 9:02

Table 2.3818: Subgroup Analysis of RBC TD Response Rate at Week 24 and at Week 12 by Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female	
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)
RBC Transfusion Dependent Rate at Week 12				
Non-Dependent, n(%)	28 (56.0%)	12 (21.4%)	22 (61.1%)	15 (39.5%)
Transfusion Requiring, n(%)	12 (24.0%)	2 (3.6%)	3 (8.3%)	5 (13.2%)
Transfusion Independent, n(%)	16 (32.0%)	10 (17.9%)	19 (52.8%)	10 (26.3%)
Dependent, n(%)	22 (44.0%)	44 (78.6%)	14 (38.9%)	23 (60.5%)
95% Exact CI	0.2999, 0.5875	0.6556, 0.8841	0.2314, 0.5654	0.4339, 0.7596
Proportion Difference - Stratified CMH Method(95% CI)	-0.41(-0.58, -0.25)		-0.20(-0.44, 0.05)	
Proportion Difference - Unstratified CMH Method(95% CI)	-0.35(-0.52, -0.17)		-0.22(-0.44, 0.01)	
Proportion Difference - Unstratified Exact Method(95% CI)	-0.35(-0.52, -0.16)		-0.22(-0.43, 0.02)	
>=4 units transfused in the last 8 weeks	17 (34.0%)	24 (42.9%)	4 (11.1%)	14 (36.8%)
Any Hgb assessment < 8g/dL in the last 8 weeks	15 (30.0%)	41 (73.2%)	6 (16.7%)	22 (57.9%)
Last Participation date < Day 78 in DB phase	3 (6.0%)	0	7 (19.4%)	0
Other	8 (16.0%)	23 (41.1%)	3 (8.3%)	12 (31.6%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-td.sas V.03.05 Output file: t-subgrp-rbctd24-sex.pdf 29AUG2023: 9:02

Table 2.3821: Subgroup Analysis of RBC TD Response Rate at Week 24 and at Week 12 by Spleen Volume at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3	
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)
RBC Transfusion Dependent Rate at Week 24				
Non-Dependent, n(%)	28 (59.6%)	12 (27.9%)	17 (43.6%)	24 (47.1%)
Transfusion Requiring, n(%)	2 (4.3%)	4 (9.3%)	3 (7.7%)	7 (13.7%)
Transfusion Independent, n(%)	26 (55.3%)	8 (18.6%)	14 (35.9%)	17 (33.3%)
Dependent, n(%)	19 (40.4%)	31 (72.1%)	22 (56.4%)	27 (52.9%)
95% Exact CI	0.2637, 0.5573	0.5633, 0.8467	0.3962, 0.7219	0.3846, 0.6707
Proportion Difference - Stratified CMH Method(95% CI)	-0.31(-0.52, -0.09)		-0.04(-0.26, 0.18)	
Proportion Difference - Unstratified CMH Method(95% CI)	-0.32(-0.51, -0.12)		0.03(-0.18, 0.24)	
Proportion Difference - Unstratified Exact Method(95% CI)	-0.32(-0.50, -0.11)		0.03(-0.17, 0.24)	
>=4 units transfused in the last 8 weeks	8 (17.0%)	17 (39.5%)	6 (15.4%)	12 (23.5%)
Any Hgb assessment < 8g/dL in the last 8 weeks	10 (21.3%)	23 (53.5%)	10 (25.6%)	20 (39.2%)
Last Participation date < Day 162 in DB phase	7 (14.9%)	4 (9.3%)	9 (23.1%)	4 (7.8%)
Other	5 (10.6%)	14 (32.6%)	6 (15.4%)	12 (23.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-td.sas V.03.05 Output file: t-subgrp-rbctd24-svb.pdf 29AUG2023: 9:03

Table 2.3821: Subgroup Analysis of RBC TD Response Rate at Week 24 and at Week 12 by Spleen Volume at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3	
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)
RBC Transfusion Dependent Rate at Week 12				
Non-Dependent, n(%)	31 (66.0%)	9 (20.9%)	19 (48.7%)	18 (35.3%)
Transfusion Requiring, n(%)	8 (17.0%)	2 (4.7%)	7 (17.9%)	5 (9.8%)
Transfusion Independent, n(%)	23 (48.9%)	7 (16.3%)	12 (30.8%)	13 (25.5%)
Dependent, n(%)	16 (34.0%)	34 (79.1%)	20 (51.3%)	33 (64.7%)
95% Exact CI	0.2086, 0.4931	0.6396, 0.8996	0.3478, 0.6758	0.5007, 0.7757
Proportion Difference - Stratified CMH Method(95% CI)	-0.52(-0.72, -0.32)		-0.17(-0.38, 0.04)	
Proportion Difference - Unstratified CMH Method(95% CI)	-0.45(-0.64, -0.27)		-0.13(-0.34, 0.07)	
Proportion Difference - Unstratified Exact Method(95% CI)	-0.45(-0.62, -0.25)		-0.13(-0.34, 0.07)	
>=4 units transfused in the last 8 weeks	7 (14.9%)	22 (51.2%)	14 (35.9%)	16 (31.4%)
Any Hgb assessment < 8g/dL in the last 8 weeks	6 (12.8%)	32 (74.4%)	15 (38.5%)	31 (60.8%)
Last Participation date < Day 78 in DB phase	6 (12.8%)	0	4 (10.3%)	0
Other	4 (8.5%)	14 (32.6%)	7 (17.9%)	21 (41.2%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-td.sas V.03.05 Output file: t-subgrp-rbctd24-svb.pdf 29AUG2023: 9:03

Table 2.3820: Subgroup Analysis of RBC TD Response Rate at Week 24 and at Week 12 by Transfusion Dependence at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	Yes		No	
	MMB (N=49)	RUX (N=43)	MMB (N=37)	RUX (N=51)
RBC Transfusion Dependent Rate at Week 24				
Non-Dependent, n(%)	20 (40.8%)	12 (27.9%)	25 (67.6%)	24 (47.1%)
Transfusion Requiring, n(%)	4 (8.2%)	4 (9.3%)	1 (2.7%)	7 (13.7%)
Transfusion Independent, n(%)	16 (32.7%)	8 (18.6%)	24 (64.9%)	17 (33.3%)
Dependent, n(%)	29 (59.2%)	31 (72.1%)	12 (32.4%)	27 (52.9%)
95% Exact CI	0.4421, 0.7300	0.5633, 0.8467	0.1801, 0.4979	0.3846, 0.6707
Proportion Difference - Stratified CMH Method(95% CI)	-0.13(-0.33, 0.06)		-0.20(-0.41, 0.01)	
Proportion Difference - Unstratified CMH Method(95% CI)	-0.13(-0.32, 0.07)		-0.21(-0.41, 0.00)	
Proportion Difference - Unstratified Exact Method(95% CI)	-0.13(-0.33, 0.08)		-0.21(-0.40, 0.01)	
>=4 units transfused in the last 8 weeks	12 (24.5%)	16 (37.2%)	2 (5.4%)	13 (25.5%)
Any Hgb assessment < 8g/dL in the last 8 weeks	17 (34.7%)	21 (48.8%)	3 (8.1%)	22 (43.1%)
Last Participation date < Day 162 in DB phase	9 (18.4%)	7 (16.3%)	7 (18.9%)	1 (2.0%)
Other	11 (22.4%)	15 (34.9%)	0	11 (21.6%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Stratification factor is platelet count (<100X10^9/L, =100X10^9/L and = 200X10^9/L, or > 200X10^9/L) at baseline.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-td.sas V.03.05 Output file: t-subgrp-rbctd24-tf.pdf 29AUG2023: 9:03

Table 2.3820: Subgroup Analysis of RBC TD Response Rate at Week 24 and at Week 12 by Transfusion Dependence at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	Yes		No	
	MMB (N=49)	RUX (N=43)	MMB (N=37)	RUX (N=51)
RBC Transfusion Dependent Rate at Week 12				
Non-Dependent, n(%)	20 (40.8%)	7 (16.3%)	30 (81.1%)	20 (39.2%)
Transfusion Requiring, n(%)	11 (22.4%)	3 (7.0%)	4 (10.8%)	4 (7.8%)
Transfusion Independent, n(%)	9 (18.4%)	4 (9.3%)	26 (70.3%)	16 (31.4%)
Dependent, n(%)	29 (59.2%)	36 (83.7%)	7 (18.9%)	31 (60.8%)
95% Exact CI	0.4421, 0.7300	0.6930, 0.9319	0.0796, 0.3516	0.4611, 0.7416
Proportion Difference - Stratified CMH Method(95% CI)	-0.24(-0.43, -0.06)		-0.42(-0.62, -0.23)	
Proportion Difference - Unstratified CMH Method(95% CI)	-0.25(-0.43, -0.07)		-0.42(-0.61, -0.23)	
Proportion Difference - Unstratified Exact Method(95% CI)	-0.25(-0.43, -0.04)		-0.42(-0.60, -0.21)	
>=4 units transfused in the last 8 weeks	18 (36.7%)	25 (58.1%)	3 (8.1%)	13 (25.5%)
Any Hgb assessment < 8g/dL in the last 8 weeks	19 (38.8%)	35 (81.4%)	2 (5.4%)	28 (54.9%)
Last Participation date < Day 78 in DB phase	7 (14.3%)	0	3 (8.1%)	0
Other	9 (18.4%)	25 (58.1%)	2 (5.4%)	10 (19.6%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Stratification factor is platelet count (<100X10^9/L, =100X10^9/L and = 200X10^9/L, or > 200X10^9/L) at baseline.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-td.sas V.03.05 Output file: t-subgrp-rbctd24-tf.pdf 29AUG2023: 9:03

Table 2.3822: Subgroup Analysis of RBC TD Response Rate at Week 24 and at Week 12 by TSS at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	< Q1 7.8		>= Q1 7.8 and < Median 16.8	
	MMB (N=24)	RUX (N=20)	MMB (N=16)	RUX (N=29)
RBC Transfusion Dependent Rate at Week 24				
Non-Dependent, n(%)	14 (58.3%)	5 (25.0%)	7 (43.8%)	13 (44.8%)
Transfusion Requiring, n(%)	1 (4.2%)	0	1 (6.3%)	3 (10.3%)
Transfusion Independent, n(%)	13 (54.2%)	5 (25.0%)	6 (37.5%)	10 (34.5%)
Dependent, n(%)	10 (41.7%)	15 (75.0%)	9 (56.3%)	16 (55.2%)
95% Exact CI	0.2211, 0.6336	0.5090, 0.9134	0.2988, 0.8025	0.3569, 0.7355
Proportion Difference - Stratified CMH Method(95% CI)	-0.34(-0.63, -0.06)		0.00(-0.30, 0.30)	
Proportion Difference - Unstratified CMH Method(95% CI)	-0.33(-0.62, -0.05)		0.01(-0.30, 0.32)	
Proportion Difference - Unstratified Exact Method(95% CI)	-0.33(-0.59, -0.04)		0.01(-0.29, 0.31)	
>=4 units transfused in the last 8 weeks	6 (25.0%)	11 (55.0%)	2 (12.5%)	6 (20.7%)
Any Hgb assessment < 8g/dL in the last 8 weeks	8 (33.3%)	12 (60.0%)	6 (37.5%)	12 (41.4%)
Last Participation date < Day 162 in DB phase	1 (4.2%)	0	2 (12.5%)	3 (10.3%)
Other	5 (20.8%)	9 (45.0%)	2 (12.5%)	5 (17.2%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel
TSS = Total Symptom Score
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-td.sas V.03.05 Output file: t-subgrp-rbctd24-tss.pdf 29AUG2023: 9:04

Table 2.3822: Subgroup Analysis of RBC TD Response Rate at Week 24 and at Week 12 by TSS at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	>= Median 16.8 and < Q3 25.7		>= Q3 25.7	
	MMB (N=21)	RUX (N=23)	MMB (N=24)	RUX (N=21)
RBC Transfusion Dependent Rate at Week 24				
Non-Dependent, n(%)	12 (57.1%)	11 (47.8%)	11 (45.8%)	7 (33.3%)
Transfusion Requiring, n(%)	2 (9.5%)	6 (26.1%)	1 (4.2%)	2 (9.5%)
Transfusion Independent, n(%)	10 (47.6%)	5 (21.7%)	10 (41.7%)	5 (23.8%)
Dependent, n(%)	9 (42.9%)	12 (52.2%)	13 (54.2%)	14 (66.7%)
95% Exact CI	0.2182, 0.6598	0.3059, 0.7318	0.3282, 0.7445	0.4303, 0.8541
Proportion Difference - Stratified CMH Method(95% CI)	-0.22(-0.56, 0.11)		0.00(-0.29, 0.30)	
Proportion Difference - Unstratified CMH Method(95% CI)	-0.09(-0.39, 0.21)		-0.13(-0.42, 0.17)	
Proportion Difference - Unstratified Exact Method(95% CI)	-0.09(-0.38, 0.21)		-0.13(-0.41, 0.17)	
>=4 units transfused in the last 8 weeks	3 (14.3%)	4 (17.4%)	3 (12.5%)	7 (33.3%)
Any Hgb assessment < 8g/dL in the last 8 weeks	3 (14.3%)	8 (34.8%)	3 (12.5%)	10 (47.6%)
Last Participation date < Day 162 in DB phase	4 (19.0%)	2 (8.7%)	9 (37.5%)	3 (14.3%)
Other	2 (9.5%)	7 (30.4%)	2 (8.3%)	5 (23.8%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel
TSS = Total Symptom Score
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-td.sas V.03.05 Output file: t-subgrp-rbctd24-tss.pdf 29AUG2023: 9:04

Table 2.3822: Subgroup Analysis of RBC TD Response Rate at Week 24 and at Week 12 by TSS at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	< Q1 7.8		>= Q1 7.8 and < Median 16.8	
	MMB (N=24)	RUX (N=20)	MMB (N=16)	RUX (N=29)
RBC Transfusion Dependent Rate at Week 12				
Non-Dependent, n(%)	15 (62.5%)	5 (25.0%)	9 (56.3%)	9 (31.0%)
Transfusion Requiring, n(%)	5 (20.8%)	2 (10.0%)	5 (31.3%)	2 (6.9%)
Transfusion Independent, n(%)	10 (41.7%)	3 (15.0%)	4 (25.0%)	7 (24.1%)
Dependent, n(%)	9 (37.5%)	15 (75.0%)	7 (43.8%)	20 (69.0%)
95% Exact CI	0.1880, 0.5941	0.5090, 0.9134	0.1975, 0.7012	0.4917, 0.8472
Proportion Difference - Stratified CMH Method(95% CI)	-0.39(-0.67, -0.11)		-0.29(-0.59, 0.00)	
Proportion Difference - Unstratified CMH Method(95% CI)	-0.38(-0.66, -0.09)		-0.25(-0.56, 0.05)	
Proportion Difference - Unstratified Exact Method(95% CI)	-0.38(-0.63, -0.08)		-0.25(-0.53, 0.05)	
>=4 units transfused in the last 8 weeks	6 (25.0%)	9 (45.0%)	4 (25.0%)	10 (34.5%)
Any Hgb assessment < 8g/dL in the last 8 weeks	6 (25.0%)	14 (70.0%)	4 (25.0%)	19 (65.5%)
Last Participation date < Day 78 in DB phase	1 (4.2%)	0	2 (12.5%)	0
Other	3 (12.5%)	10 (50.0%)	1 (6.3%)	6 (20.7%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel
TSS = Total Symptom Score
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-td.sas V.03.05 Output file: t-subgrp-rbctd24-tss.pdf 29AUG2023: 9:04

Table 2.3822: Subgroup Analysis of RBC TD Response Rate at Week 24 and at Week 12 by TSS at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	>= Median 16.8 and < Q3 25.7		>= Q3 25.7	
	MMB (N=21)	RUX (N=23)	MMB (N=24)	RUX (N=21)
RBC Transfusion Dependent Rate at Week 12				
Non-Dependent, n(%)	11 (52.4%)	8 (34.8%)	14 (58.3%)	5 (23.8%)
Transfusion Requiring, n(%)	1 (4.8%)	2 (8.7%)	3 (12.5%)	1 (4.8%)
Transfusion Independent, n(%)	10 (47.6%)	6 (26.1%)	11 (45.8%)	4 (19.0%)
Dependent, n(%)	10 (47.6%)	15 (65.2%)	10 (41.7%)	16 (76.2%)
95% Exact CI	0.2571, 0.7022	0.4273, 0.8362	0.2211, 0.6336	0.5283, 0.9178
Proportion Difference - Stratified CMH Method(95% CI)	-0.27(-0.60, 0.07)		-0.27(-0.55, 0.01)	
Proportion Difference - Unstratified CMH Method(95% CI)	-0.18(-0.47, 0.12)		-0.35(-0.62, -0.07)	
Proportion Difference - Unstratified Exact Method(95% CI)	-0.18(-0.46, 0.13)		-0.35(-0.60, -0.05)	
>=4 units transfused in the last 8 weeks	7 (33.3%)	8 (34.8%)	4 (16.7%)	10 (47.6%)
Any Hgb assessment < 8g/dL in the last 8 weeks	7 (33.3%)	14 (60.9%)	4 (16.7%)	15 (71.4%)
Last Participation date < Day 78 in DB phase	2 (9.5%)	0	5 (20.8%)	0
Other	4 (19.0%)	7 (30.4%)	3 (12.5%)	11 (52.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel
TSS = Total Symptom Score
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-td.sas V.03.05 Output file: t-subgrp-rbctd24-tss.pdf 29AUG2023: 9:04

Table 2.2807: Subgroup Analysis of RBC TI Response Rate at Week 24 and Week 12 by Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years	
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)
RBC Transfusion Independent Rate at Week 24				
Responder, n(%)	11 (45.8%)	13 (36.1%)	29 (46.8%)	12 (20.7%)
95% Exact CI	0.2555, 0.6718	0.2082, 0.5378	0.3398, 0.5988	0.1117, 0.3335
Proportion Difference - Stratified CMH Method (95% CI)	0.07 (-0.22, 0.37)		0.28 (0.11, 0.45)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.10 (-0.16, 0.36)		0.26 (0.10, 0.42)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.10 (-0.17, 0.35)		0.26 (0.08, 0.43)	
Non-Responder, n(%)	13 (54.2%)	23 (63.9%)	33 (53.2%)	46 (79.3%)
Transfusion (except bleeding) in the last 12 weeks	7 (29.2%)	16 (44.4%)	19 (30.6%)	39 (67.2%)
Any Hgb assessment < 8g/dL in the last 12 weeks	7 (29.2%)	18 (50.0%)	16 (25.8%)	27 (46.6%)
Last Participation date < Day 162 in DB phase	4 (16.7%)	3 (8.3%)	12 (19.4%)	5 (8.6%)
Other	3 (12.5%)	11 (30.6%)	9 (14.5%)	14 (24.1%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-age.pdf 29AUG2023: 9:02

Table 2.2807: Subgroup Analysis of RBC TI Response Rate at Week 24 and Week 12 by Age
Double-Blind Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years	
	MMB (N=24)	RUX (N=36)	MMB (N=62)	RUX (N=58)
RBC Transfusion Independent Rate at Week 12				
Responder, n(%)	11 (45.8%)	9 (25.0%)	24 (38.7%)	11 (19.0%)
95% Exact CI	0.2555, 0.6718	0.1212, 0.4220	0.2660, 0.5193	0.0987, 0.3141
Proportion Difference - Stratified CMH Method (95% CI)	0.20 (-0.08, 0.47)		0.26 (0.10, 0.42)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.21 (-0.04, 0.46)		0.20 (0.04, 0.36)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.21 (-0.06, 0.45)		0.20 (0.02, 0.37)	
Non-Responder, n(%)	13 (54.2%)	27 (75.0%)	38 (61.3%)	47 (81.0%)
Transfusion (except bleeding) in the last 12 weeks	10 (41.7%)	22 (61.1%)	28 (45.2%)	45 (77.6%)
Any Hgb assessment < 8g/dL in the last 12 weeks	7 (29.2%)	24 (66.7%)	16 (25.8%)	40 (69.0%)
Last Participation date < Day 78 in DB phase	1 (4.2%)	1 (2.8%)	9 (14.5%)	1 (1.7%)
Other	5 (20.8%)	9 (25.0%)	8 (12.9%)	11 (19.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-age.pdf 29AUG2023: 9:02

Table 2.2814: Subgroup Analysis of RBC TI Response Rate at Week 24 and Week 12 by IPSS
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk	
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)
RBC Transfusion Independent Rate at Week 24				
Responder, n(%)	14 (50.0%)	8 (33.3%)	26 (44.8%)	17 (24.3%)
95% Exact CI	0.3065, 0.6935	0.1563, 0.5532	0.3174, 0.5846	0.1483, 0.3601
Proportion Difference - Stratified CMH Method (95% CI)	0.26 (-0.04, 0.55)		0.21 (0.05, 0.38)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.17 (-0.10, 0.44)		0.21 (0.04, 0.37)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.17 (-0.11, 0.43)		0.21 (0.03, 0.37)	
Non-Responder, n(%)	14 (50.0%)	16 (66.7%)	32 (55.2%)	53 (75.7%)
Transfusion (except bleeding) in the last 12 weeks	8 (28.6%)	12 (50.0%)	18 (31.0%)	43 (61.4%)
Any Hgb assessment < 8g/dL in the last 12 weeks	5 (17.9%)	11 (45.8%)	18 (31.0%)	34 (48.6%)
Last Participation date < Day 162 in DB phase	4 (14.3%)	2 (8.3%)	12 (20.7%)	6 (8.6%)
Other	3 (10.7%)	6 (25.0%)	9 (15.5%)	19 (27.1%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel
RBC = Red Blood Cell
IPSS = International Prognostic Scoring System

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-dipss.pdf 29AUG2023: 9:04

Table 2.2814: Subgroup Analysis of RBC TI Response Rate at Week 24 and Week 12 by IPSS
Double-Blind Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk	
	MMB (N=28)	RUX (N=24)	MMB (N=58)	RUX (N=70)
RBC Transfusion Independent Rate at Week 12				
Responder, n(%)	13 (46.4%)	6 (25.0%)	22 (37.9%)	14 (20.0%)
95% Exact CI	0.2751, 0.6613	0.0977, 0.4671	0.2551, 0.5163	0.1139, 0.3127
Proportion Difference - Stratified CMH Method (95% CI)	0.31 (0.03, 0.59)		0.21 (0.06, 0.37)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.21 (-0.05, 0.47)		0.18 (0.02, 0.34)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.21 (-0.06, 0.47)		0.18 (0.01, 0.34)	
Non-Responder, n(%)	15 (53.6%)	18 (75.0%)	36 (62.1%)	56 (80.0%)
Transfusion (except bleeding) in the last 12 weeks	11 (39.3%)	16 (66.7%)	27 (46.6%)	51 (72.9%)
Any Hgb assessment < 8g/dL in the last 12 weeks	6 (21.4%)	14 (58.3%)	17 (29.3%)	50 (71.4%)
Last Participation date < Day 78 in DB phase	3 (10.7%)	1 (4.2%)	7 (12.1%)	1 (1.4%)
Other	4 (14.3%)	3 (12.5%)	9 (15.5%)	17 (24.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel
RBC = Red Blood Cell
IPSS = International Prognostic Scoring System

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-dipss.pdf 29AUG2023: 9:04

Table 2.2818: Subgroup Analysis of RBC TI Response Rate at Week 24 and Week 12 by Geographic Area
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Europe		Eastern Europe		Asia	
	MMB (N=53)	RUX (N=51)	MMB (N=25)	RUX (N=36)	MMB (N=8)	RUX (N=7)
RBC Transfusion Independent Rate at Week 24						
Responder, n(%)	21 (39.6%)	13 (25.5%)	15 (60.0%)	12 (33.3%)	4 (50.0%)	0
95% Exact CI	0.2645, 0.5400	0.1433, 0.3963	0.3867, 0.7887	0.1856, 0.5097	0.1570, 0.8430	0.0000, 0.4096
Proportion Difference - Stratified CMH Method (95% CI)	0.20 (0.01, 0.38)		0.28 (0.02, 0.54)		0.46 (-0.12, 1.04)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.14 (-0.04, 0.32)		0.27 (0.02, 0.52)		0.50 (0.08, 0.92)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.14 (-0.05, 0.33)		0.27 (0.01, 0.50)		0.50 (0.02, 0.85)	
Non-Responder, n(%)	32 (60.4%)	38 (74.5%)	10 (40.0%)	24 (66.7%)	4 (50.0%)	7 (100.0%)
Transfusion (except bleeding) in the last 12 weeks	21 (39.6%)	31 (60.8%)	5 (20.0%)	19 (52.8%)	0	5 (71.4%)
Any Hgb assessment < 8g/dL in the last 12 weeks	17 (32.1%)	20 (39.2%)	4 (16.0%)	18 (50.0%)	2 (25.0%)	7 (100.0%)
Last Participation date < Day 162 in DB phase	10 (18.9%)	5 (9.8%)	4 (16.0%)	3 (8.3%)	2 (25.0%)	0
Other	7 (13.2%)	10 (19.6%)	3 (12.0%)	9 (25.0%)	2 (25.0%)	6 (85.7%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-geo.pdf 29AUG2023: 9:05

Table 2.2818: Subgroup Analysis of RBC TI Response Rate at Week 24 and Week 12 by Geographic Area
Double-Blind Phase
ITT-Anemic Analysis Set

	Western Europe		Eastern Europe		Asia	
	MMB (N=53)	RUX (N=51)	MMB (N=25)	RUX (N=36)	MMB (N=8)	RUX (N=7)
RBC Transfusion Independent Rate at Week 12						
Responder, n(%)	19 (35.8%)	12 (23.5%)	11 (44.0%)	8 (22.2%)	5 (62.5%)	0
95% Exact CI	0.2314, 0.5020	0.1279, 0.3749	0.2440, 0.6507	0.1012, 0.3915	0.2449, 0.9148	0.0000, 0.4096
Proportion Difference - Stratified CMH Method (95% CI)	0.22 (0.05, 0.39)		0.25 (0.01, 0.48)		0.65 (0.12, 1.18)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.12 (-0.05, 0.30)		0.22 (-0.02, 0.46)		0.63 (0.22, 1.03)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.12 (-0.07, 0.31)		0.22 (-0.04, 0.46)		0.63 (0.14, 0.92)	
Non-Responder, n(%)	34 (64.2%)	39 (76.5%)	14 (56.0%)	28 (77.8%)	3 (37.5%)	7 (100.0%)
Transfusion (except bleeding) in the last 12 weeks	26 (49.1%)	37 (72.5%)	11 (44.0%)	25 (69.4%)	1 (12.5%)	5 (71.4%)
Any Hgb assessment < 8g/dL in the last 12 weeks	13 (24.5%)	32 (62.7%)	8 (32.0%)	25 (69.4%)	2 (25.0%)	7 (100.0%)
Last Participation date < Day 78 in DB phase	6 (11.3%)	2 (3.9%)	3 (12.0%)	0	1 (12.5%)	0
Other	9 (17.0%)	11 (21.6%)	2 (8.0%)	8 (22.2%)	2 (25.0%)	1 (14.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-geo.pdf 29AUG2023: 9:05

Table 2.2813: Subgroup Analysis of RBC TI Response Rate at Week 24 and Week 12 by HGB at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	< 8 g/dL		>= 8 g/dL	
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)
RBC Transfusion Independent Rate at Week 24				
Responder, n(%)	8 (28.6%)	3 (14.3%)	32 (55.2%)	22 (30.1%)
95% Exact CI	0.1322, 0.4867	0.0305, 0.3634	0.4154, 0.6826	0.1994, 0.4200
Proportion Difference - Stratified CMH Method (95% CI)	0.14 (-0.11, 0.39)		0.27 (0.10, 0.44)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.14 (-0.09, 0.38)		0.25 (0.08, 0.42)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.14 (-0.15, 0.41)		0.25 (0.08, 0.41)	
Non-Responder, n(%)	20 (71.4%)	18 (85.7%)	26 (44.8%)	51 (69.9%)
Transfusion (except bleeding) in the last 12 weeks	11 (39.3%)	13 (61.9%)	15 (25.9%)	42 (57.5%)
Any Hgb assessment < 8g/dL in the last 12 weeks	13 (46.4%)	12 (57.1%)	10 (17.2%)	33 (45.2%)
Last Participation date < Day 162 in DB phase	6 (21.4%)	4 (19.0%)	10 (17.2%)	4 (5.5%)
Other	7 (25.0%)	8 (38.1%)	5 (8.6%)	17 (23.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-hgb.pdf 29AUG2023: 9:04

Table 2.2813: Subgroup Analysis of RBC TI Response Rate at Week 24 and Week 12 by HGB at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	< 8 g/dL		>= 8 g/dL	
	MMB (N=28)	RUX (N=21)	MMB (N=58)	RUX (N=73)
RBC Transfusion Independent Rate at Week 12				
Responder, n(%)	5 (17.9%)	1 (4.8%)	30 (51.7%)	19 (26.0%)
95% Exact CI	0.0606, 0.3689	0.0012, 0.2382	0.3822, 0.6505	0.1645, 0.3762
Proportion Difference - Stratified CMH Method (95% CI)	0.13 (-0.08, 0.35)		0.28 (0.12, 0.44)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.13 (-0.05, 0.32)		0.26 (0.09, 0.42)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.13 (-0.16, 0.40)		0.26 (0.08, 0.42)	
Non-Responder, n(%)	23 (82.1%)	20 (95.2%)	28 (48.3%)	54 (74.0%)
Transfusion (except bleeding) in the last 12 weeks	16 (57.1%)	16 (76.2%)	22 (37.9%)	51 (69.9%)
Any Hgb assessment < 8g/dL in the last 12 weeks	13 (46.4%)	16 (76.2%)	10 (17.2%)	48 (65.8%)
Last Participation date < Day 78 in DB phase	5 (17.9%)	2 (9.5%)	5 (8.6%)	0
Other	9 (32.1%)	10 (47.6%)	4 (6.9%)	10 (13.7%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-hgb.pdf 29AUG2023: 9:04

Table 2.2815: Subgroup Analysis of RBC TI Response Rate at Week 24 and Week 12 by JAK2V617F Mutation
Double-blind Phase
ITT-Anemic Analysis Set

	Positive		Negative	
	MMB (N=39)	RUX (N=56)	MMB (N=36)	RUX (N=29)
RBC Transfusion Independent Rate at Week 24				
Responder, n(%)	18 (46.2%)	16 (28.6%)	16 (44.4%)	8 (27.6%)
95% Exact CI	0.3009, 0.6282	0.1730, 0.4221	0.2794, 0.6190	0.1273, 0.4724
Proportion Difference - Stratified CMH Method (95% CI)	0.20 (-0.02, 0.42)		0.18 (-0.06, 0.41)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.18 (-0.02, 0.37)		0.17 (-0.07, 0.40)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.18 (-0.03, 0.37)		0.17 (-0.08, 0.40)	
Non-Responder, n(%)	21 (53.8%)	40 (71.4%)	20 (55.6%)	21 (72.4%)
Transfusion (except bleeding) in the last 12 weeks	12 (30.8%)	29 (51.8%)	11 (30.6%)	18 (62.1%)
Any Hgb assessment < 8g/dL in the last 12 weeks	9 (23.1%)	25 (44.6%)	11 (30.6%)	15 (51.7%)
Last Participation date < Day 162 in DB phase	8 (20.5%)	6 (10.7%)	6 (16.7%)	2 (6.9%)
Other	3 (7.7%)	13 (23.2%)	7 (19.4%)	7 (24.1%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-jak.pdf 29AUG2023: 9:04

Table 2.2815: Subgroup Analysis of RBC TI Response Rate at Week 24 and Week 12 by JAK2V617F Mutation
Double-blind Phase
ITT-Anemic Analysis Set

	Positive		Negative	
	MMB (N=39)	RUX (N=56)	MMB (N=36)	RUX (N=29)
RBC Transfusion Independent Rate at Week 12				
Responder, n(%)	16 (41.0%)	14 (25.0%)	16 (44.4%)	5 (17.2%)
95% Exact CI	0.2557, 0.5790	0.1439, 0.3837	0.2794, 0.6190	0.0585, 0.3577
Proportion Difference - Stratified CMH Method (95% CI)	0.20 (0.00, 0.41)		0.34 (0.13, 0.55)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.16 (-0.03, 0.35)		0.27 (0.05, 0.49)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.16 (-0.05, 0.36)		0.27 (0.03, 0.49)	
Non-Responder, n(%)	23 (59.0%)	42 (75.0%)	20 (55.6%)	24 (82.8%)
Transfusion (except bleeding) in the last 12 weeks	16 (41.0%)	39 (69.6%)	16 (44.4%)	21 (72.4%)
Any Hgb assessment < 8g/dL in the last 12 weeks	10 (25.6%)	38 (67.9%)	9 (25.0%)	21 (72.4%)
Last Participation date < Day 78 in DB phase	5 (12.8%)	1 (1.8%)	3 (8.3%)	1 (3.4%)
Other	6 (15.4%)	13 (23.2%)	4 (11.1%)	5 (17.2%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-jak.pdf 29AUG2023: 9:04

Table 2.2817: Subgroup Analysis of RBC TI Response Rate at Week 24 and Week 12 by Disease Type
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis		Post-PV Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)	MMB (N=11)	RUX (N=12)
RBC Transfusion Independent Rate at Week 24						
Responder, n(%)	29 (49.2%)	18 (33.3%)	5 (31.3%)	6 (21.4%)	6 (54.5%)	1 (8.3%)
95% Exact CI	0.3589, 0.6250	0.2109, 0.4747	0.1102, 0.5866	0.0830, 0.4095	0.2338, 0.8325	0.0021, 0.3848
Proportion Difference - Stratified CMH Method (95% CI)	0.16 (-0.02, 0.34)		0.10 (-0.18, 0.39)		0.55 (0.14, 0.96)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.16 (-0.02, 0.34)		0.10 (-0.19, 0.38)		0.46 (0.10, 0.82)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.16 (-0.03, 0.34)		0.10 (-0.21, 0.39)		0.46 (0.03, 0.77)	
Non-Responder, n(%)	30 (50.8%)	36 (66.7%)	11 (68.8%)	22 (78.6%)	5 (45.5%)	11 (91.7%)
Transfusion (except bleeding) in the last 12 weeks	16 (27.1%)	27 (50.0%)	8 (50.0%)	19 (67.9%)	2 (18.2%)	9 (75.0%)
Any Hgb assessment < 8g/dL in the last 12 weeks	15 (25.4%)	24 (44.4%)	6 (37.5%)	16 (57.1%)	2 (18.2%)	5 (41.7%)
Last Participation date < Day 162 in DB phase	10 (16.9%)	4 (7.4%)	3 (18.8%)	2 (7.1%)	3 (27.3%)	2 (16.7%)
Other	6 (10.2%)	11 (20.4%)	5 (31.3%)	10 (35.7%)	1 (9.1%)	4 (33.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-mf.pdf 29AUG2023: 9:04

Table 2.2817: Subgroup Analysis of RBC TI Response Rate at Week 24 and Week 12 by Disease Type
Double-Blind Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis		Post-PV Myelofibrosis	
	MMB (N=59)	RUX (N=54)	MMB (N=16)	RUX (N=28)	MMB (N=11)	RUX (N=12)
RBC Transfusion Independent Rate at Week 12						
Responder, n(%)	24 (40.7%)	11 (20.4%)	6 (37.5%)	7 (25.0%)	5 (45.5%)	2 (16.7%)
95% Exact CI	0.2807, 0.5425	0.1063, 0.3353	0.1520, 0.6457	0.1069, 0.4487	0.1675, 0.7662	0.0209, 0.4841
Proportion Difference - Stratified CMH Method (95% CI)	0.22 (0.07, 0.38)		0.16 (-0.11, 0.43)		0.43 (0.03, 0.84)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.20 (0.04, 0.37)		0.13 (-0.17, 0.42)		0.29 (-0.10, 0.67)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.20 (0.02, 0.38)		0.13 (-0.19, 0.42)		0.29 (-0.15, 0.64)	
Non-Responder, n(%)	35 (59.3%)	43 (79.6%)	10 (62.5%)	21 (75.0%)	6 (54.5%)	10 (83.3%)
Transfusion (except bleeding) in the last 12 weeks	27 (45.8%)	40 (74.1%)	8 (50.0%)	17 (60.7%)	3 (27.3%)	10 (83.3%)
Any Hgb assessment < 8g/dL in the last 12 weeks	15 (25.4%)	38 (70.4%)	6 (37.5%)	17 (60.7%)	2 (18.2%)	9 (75.0%)
Last Participation date < Day 78 in DB phase	5 (8.5%)	0	2 (12.5%)	2 (7.1%)	3 (27.3%)	0
Other	10 (16.9%)	12 (22.2%)	2 (12.5%)	5 (17.9%)	1 (9.1%)	3 (25.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-mf.pdf 29AUG2023: 9:04

Table 2.2816: Subgroup Analysis of RBC TI Response Rate at Week 24 and Week 12 by Platelet Count at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	< 100X10E9/L		>= 100X10E9/L and <= 200X10E9/L		> 200X10E9/L	
	MMB (N=13)	RUX (N=13)	MMB (N=36)	RUX (N=34)	MMB (N=37)	RUX (N=47)
RBC Transfusion Independent Rate at Week 24						
Responder, n(%)	7 (53.8%)	2 (15.4%)	18 (50.0%)	8 (23.5%)	15 (40.5%)	15 (31.9%)
95% Exact CI	0.2513, 0.8078	0.0192, 0.4545	0.3292, 0.6708	0.1075, 0.4117	0.2475, 0.5790	0.1909, 0.4712
Proportion Difference - Stratified CMH Method (95% CI)	0.38 (0.00, 0.76)		0.27 (0.05, 0.49)		0.15 (-0.06, 0.35)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.38 (0.03, 0.74)		0.26 (0.04, 0.49)		0.09 (-0.12, 0.30)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.38 (-0.04, 0.71)		0.26 (0.04, 0.48)		0.09 (-0.13, 0.30)	
Non-Responder, n(%)	6 (46.2%)	11 (84.6%)	18 (50.0%)	26 (76.5%)	22 (59.5%)	32 (68.1%)
Transfusion (except bleeding) in the last 12 weeks	5 (38.5%)	6 (46.2%)	9 (25.0%)	18 (52.9%)	12 (32.4%)	31 (66.0%)
Any Hgb assessment < 8g/dL in the last 12 weeks	3 (23.1%)	6 (46.2%)	9 (25.0%)	14 (41.2%)	11 (29.7%)	25 (53.2%)
Last Participation date < Day 162 in DB phase	1 (7.7%)	4 (30.8%)	7 (19.4%)	4 (11.8%)	8 (21.6%)	0
Other	1 (7.7%)	3 (23.1%)	5 (13.9%)	8 (23.5%)	6 (16.2%)	14 (29.8%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Stratification factor is transfusion dependence (Yes vs. No) at baseline.
CMH = Cochran-Mantel-Haenszel
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-plate.pdf 29AUG2023: 9:05

Table 2.2816: Subgroup Analysis of RBC TI Response Rate at Week 24 and Week 12 by Platelet Count at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	< 100X10E9/L		>= 100X10E9/L and <= 200X10E9/L		> 200X10E9/L	
	MMB (N=13)	RUX (N=13)	MMB (N=36)	RUX (N=34)	MMB (N=37)	RUX (N=47)
RBC Transfusion Independent Rate at Week 12						
Responder, n(%)	4 (30.8%)	2 (15.4%)	17 (47.2%)	5 (14.7%)	14 (37.8%)	13 (27.7%)
95% Exact CI	0.0909, 0.6143	0.0192, 0.4545	0.3041, 0.6451	0.0495, 0.3106	0.2246, 0.5524	0.1562, 0.4264
Proportion Difference - Stratified CMH Method (95% CI)	0.18 (-0.18, 0.53)		0.33 (0.15, 0.52)		0.17 (-0.02, 0.36)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.15 (-0.19, 0.50)		0.33 (0.12, 0.53)		0.10 (-0.10, 0.31)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.15 (-0.26, 0.53)		0.33 (0.10, 0.53)		0.10 (-0.11, 0.31)	
Non-Responder, n(%)	9 (69.2%)	11 (84.6%)	19 (52.8%)	29 (85.3%)	23 (62.2%)	34 (72.3%)
Transfusion (except bleeding) in the last 12 weeks	8 (61.5%)	10 (76.9%)	13 (36.1%)	25 (73.5%)	17 (45.9%)	32 (68.1%)
Any Hgb assessment < 8g/dL in the last 12 weeks	5 (38.5%)	8 (61.5%)	9 (25.0%)	25 (73.5%)	9 (24.3%)	31 (66.0%)
Last Participation date < Day 78 in DB phase	1 (7.7%)	1 (7.7%)	4 (11.1%)	1 (2.9%)	5 (13.5%)	0
Other	1 (7.7%)	3 (23.1%)	7 (19.4%)	9 (26.5%)	5 (13.5%)	8 (17.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Stratification factor is transfusion dependence (Yes vs. No) at baseline.
CMH = Cochran-Mantel-Haenszel
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-plate.pdf 29AUG2023: 9:05

Table 2.2809: Subgroup Analysis of RBC TI Response Rate at Week 24 and Week 12 by Race
Double-Blind Phase
ITT-Anemic Analysis Set

	White		All Other Races	
	MMB (N=69)	RUX (N=76)	MMB (N=11)	RUX (N=8)
RBC Transfusion Independent Rate at Week 24				
Responder, n(%)	32 (46.4%)	22 (28.9%)	5 (45.5%)	1 (12.5%)
95% Exact CI	0.3428, 0.5880	0.1911, 0.4049	0.1675, 0.7662	0.0032, 0.5265
Proportion Difference - Stratified CMH Method (95% CI)	0.22 (0.06, 0.38)		0.37 (-0.14, 0.88)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.17 (0.02, 0.33)		0.33 (-0.08, 0.74)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.17 (0.01, 0.33)		0.33 (-0.13, 0.70)	
Non-Responder, n(%)	37 (53.6%)	54 (71.1%)	6 (54.5%)	7 (87.5%)
Transfusion (except bleeding) in the last 12 weeks	23 (33.3%)	43 (56.6%)	2 (18.2%)	5 (62.5%)
Any Hgb assessment < 8g/dL in the last 12 weeks	17 (24.6%)	33 (43.4%)	4 (36.4%)	7 (87.5%)
Last Participation date < Day 162 in DB phase	13 (18.8%)	7 (9.2%)	2 (18.2%)	0
Other	8 (11.6%)	15 (19.7%)	3 (27.3%)	6 (75.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-race.pdf 29AUG2023: 9:02

Table 2.2809: Subgroup Analysis of RBC TI Response Rate at Week 24 and Week 12 by Race
Double-Blind Phase
ITT-Anemic Analysis Set

	White		All Other Races	
	MMB (N=69)	RUX (N=76)	MMB (N=11)	RUX (N=8)
RBC Transfusion Independent Rate at Week 12				
Responder, n(%)	25 (36.2%)	18 (23.7%)	6 (54.5%)	0
95% Exact CI	0.2499, 0.4869	0.1468, 0.3482	0.2338, 0.8325	0.0000, 0.3694
Proportion Difference - Stratified CMH Method (95% CI)	0.19 (0.04, 0.33)		0.54 (0.09, 1.00)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.13 (-0.02, 0.28)		0.55 (0.19, 0.90)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.13 (-0.04, 0.28)		0.55 (0.09, 0.85)	
Non-Responder, n(%)	44 (63.8%)	58 (76.3%)	5 (45.5%)	8 (100.0%)
Transfusion (except bleeding) in the last 12 weeks	33 (47.8%)	54 (71.1%)	3 (27.3%)	6 (75.0%)
Any Hgb assessment < 8g/dL in the last 12 weeks	18 (26.1%)	51 (67.1%)	4 (36.4%)	7 (87.5%)
Last Participation date < Day 78 in DB phase	9 (13.0%)	1 (1.3%)	1 (9.1%)	0
Other	9 (13.0%)	16 (21.1%)	4 (36.4%)	1 (12.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-race.pdf 29AUG2023: 9:02

Table 2.2808: Subgroup Analysis of RBC TI Response Rate at Week 24 and Week 12 by Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female	
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)
RBC Transfusion Independent Rate at Week 24				
Responder, n(%)	20 (40.0%)	16 (28.6%)	20 (55.6%)	9 (23.7%)
95% Exact CI	0.2641, 0.5482	0.1730, 0.4221	0.3810, 0.7206	0.1144, 0.4024
Proportion Difference - Stratified CMH Method (95% CI)	0.18 (0.00, 0.37)		0.29 (0.06, 0.53)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.11 (-0.07, 0.30)		0.32 (0.10, 0.53)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.11 (-0.08, 0.30)		0.32 (0.09, 0.52)	
Non-Responder, n(%)	30 (60.0%)	40 (71.4%)	16 (44.4%)	29 (76.3%)
Transfusion (except bleeding) in the last 12 weeks	21 (42.0%)	32 (57.1%)	5 (13.9%)	23 (60.5%)
Any Hgb assessment < 8g/dL in the last 12 weeks	18 (36.0%)	26 (46.4%)	5 (13.9%)	19 (50.0%)
Last Participation date < Day 162 in DB phase	6 (12.0%)	6 (10.7%)	10 (27.8%)	2 (5.3%)
Other	9 (18.0%)	15 (26.8%)	3 (8.3%)	10 (26.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-sex.pdf 29AUG2023: 9:02

Table 2.2808: Subgroup Analysis of RBC TI Response Rate at Week 24 and Week 12 by Gender
Double-Blind Phase
ITT-Anemic Analysis Set

	Male		Female	
	MMB (N=50)	RUX (N=56)	MMB (N=36)	RUX (N=38)
RBC Transfusion Independent Rate at Week 12				
Responder, n(%)	16 (32.0%)	10 (17.9%)	19 (52.8%)	10 (26.3%)
95% Exact CI	0.1952, 0.4670	0.0891, 0.3040	0.3549, 0.6959	0.1340, 0.4310
Proportion Difference - Stratified CMH Method (95% CI)	0.21 (0.05, 0.37)		0.24 (0.01, 0.47)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.14 (-0.02, 0.31)		0.26 (0.05, 0.48)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.14 (-0.05, 0.32)		0.26 (0.03, 0.47)	
Non-Responder, n(%)	34 (68.0%)	46 (82.1%)	17 (47.2%)	28 (73.7%)
Transfusion (except bleeding) in the last 12 weeks	29 (58.0%)	42 (75.0%)	9 (25.0%)	25 (65.8%)
Any Hgb assessment < 8g/dL in the last 12 weeks	17 (34.0%)	39 (69.6%)	6 (16.7%)	25 (65.8%)
Last Participation date < Day 78 in DB phase	3 (6.0%)	2 (3.6%)	7 (19.4%)	0
Other	9 (18.0%)	17 (30.4%)	4 (11.1%)	3 (7.9%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-sex.pdf 29AUG2023: 9:02

Table 2.2811: Subgroup Analysis of RBC TI Response Rate at Week 24 and Week 12 by Spleen Volume at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3	
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)
RBC Transfusion Independent Rate at Week 24				
Responder, n(%)	26 (55.3%)	8 (18.6%)	14 (35.9%)	17 (33.3%)
95% Exact CI	0.4012, 0.6983	0.0839, 0.3340	0.2120, 0.5282	0.2076, 0.4792
Proportion Difference - Stratified CMH Method (95% CI)	0.38 (0.18, 0.59)		0.10 (-0.11, 0.31)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.37 (0.18, 0.55)		0.03 (-0.18, 0.23)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.37 (0.16, 0.55)		0.03 (-0.18, 0.23)	
Non-Responder, n(%)	21 (44.7%)	35 (81.4%)	25 (64.1%)	34 (66.7%)
Transfusion (except bleeding) in the last 12 weeks	14 (29.8%)	29 (67.4%)	12 (30.8%)	26 (51.0%)
Any Hgb assessment < 8g/dL in the last 12 weeks	12 (25.5%)	24 (55.8%)	11 (28.2%)	21 (41.2%)
Last Participation date < Day 162 in DB phase	7 (14.9%)	4 (9.3%)	9 (23.1%)	4 (7.8%)
Other	4 (8.5%)	15 (34.9%)	8 (20.5%)	10 (19.6%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-svb.pdf 29AUG2023: 9:03

Table 2.2811: Subgroup Analysis of RBC TI Response Rate at Week 24 and Week 12 by Spleen Volume at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	< Median 1837.09 cm^3		>= Median 1837.09 cm^3	
	MMB (N=47)	RUX (N=43)	MMB (N=39)	RUX (N=51)
RBC Transfusion Independent Rate at Week 12				
Responder, n(%)	23 (48.9%)	7 (16.3%)	12 (30.8%)	13 (25.5%)
95% Exact CI	0.3408, 0.6394	0.0681, 0.3070	0.1702, 0.4757	0.1433, 0.3963
Proportion Difference - Stratified CMH Method (95% CI)	0.39 (0.21, 0.57)		0.09 (-0.11, 0.29)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.33 (0.14, 0.51)		0.05 (-0.14, 0.24)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.33 (0.12, 0.51)		0.05 (-0.16, 0.26)	
Non-Responder, n(%)	24 (51.1%)	36 (83.7%)	27 (69.2%)	38 (74.5%)
Transfusion (except bleeding) in the last 12 weeks	16 (34.0%)	34 (79.1%)	22 (56.4%)	33 (64.7%)
Any Hgb assessment < 8g/dL in the last 12 weeks	8 (17.0%)	33 (76.7%)	15 (38.5%)	31 (60.8%)
Last Participation date < Day 78 in DB phase	6 (12.8%)	0	4 (10.3%)	2 (3.9%)
Other	8 (17.0%)	7 (16.3%)	5 (12.8%)	13 (25.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-svb.pdf 29AUG2023: 9:03

Table 2.2810: Subgroup Analysis of RBC TI Response Rate at Week 24 and Week 12 by Transfusion Dependence at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	Yes		No	
	MMB (N=49)	RUX (N=43)	MMB (N=37)	RUX (N=51)
RBC Transfusion Independent Rate at Week 24				
Responder, n(%)	16 (32.7%)	8 (18.6%)	24 (64.9%)	17 (33.3%)
95% Exact CI	0.1995, 0.4754	0.0839, 0.3340	0.4746, 0.7979	0.2076, 0.4792
Proportion Difference - Stratified CMH Method (95% CI)	0.14 (-0.04, 0.33)		0.32 (0.11, 0.53)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.14 (-0.04, 0.32)		0.32 (0.11, 0.52)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.14 (-0.07, 0.34)		0.32 (0.10, 0.51)	
Non-Responder, n(%)	33 (67.3%)	35 (81.4%)	13 (35.1%)	34 (66.7%)
Transfusion (except bleeding) in the last 12 weeks	21 (42.9%)	25 (58.1%)	5 (13.5%)	30 (58.8%)
Any Hgb assessment < 8g/dL in the last 12 weeks	19 (38.8%)	23 (53.5%)	4 (10.8%)	22 (43.1%)
Last Participation date < Day 162 in DB phase	9 (18.4%)	7 (16.3%)	7 (18.9%)	1 (2.0%)
Other	11 (22.4%)	14 (32.6%)	1 (2.7%)	11 (21.6%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Stratification factor is platelet count (<100X10^9/L, =100X10^9/L and = 200X10^9/L, or > 200X10^9/L) at baseline.
CMH = Cochran-Mantel-Haenszel
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-tf.pdf 29AUG2023: 9:03

Table 2.2810: Subgroup Analysis of RBC TI Response Rate at Week 24 and Week 12 by Transfusion Dependence at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	Yes		No	
	MMB (N=49)	RUX (N=43)	MMB (N=37)	RUX (N=51)
RBC Transfusion Independent Rate at Week 12				
Responder, n(%)	9 (18.4%)	4 (9.3%)	26 (70.3%)	16 (31.4%)
95% Exact CI	0.0876, 0.3202	0.0259, 0.2214	0.5302, 0.8413	0.1911, 0.4589
Proportion Difference - Stratified CMH Method (95% CI)	0.09 (-0.06, 0.24)		0.39 (0.19, 0.60)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.09 (-0.05, 0.23)		0.39 (0.19, 0.59)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.09 (-0.11, 0.29)		0.39 (0.18, 0.57)	
Non-Responder, n(%)	40 (81.6%)	39 (90.7%)	11 (29.7%)	35 (68.6%)
Transfusion (except bleeding) in the last 12 weeks	31 (63.3%)	35 (81.4%)	7 (18.9%)	32 (62.7%)
Any Hgb assessment < 8g/dL in the last 12 weeks	21 (42.9%)	34 (79.1%)	2 (5.4%)	30 (58.8%)
Last Participation date < Day 78 in DB phase	7 (14.3%)	2 (4.7%)	3 (8.1%)	0
Other	12 (24.5%)	18 (41.9%)	1 (2.7%)	2 (3.9%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Stratification factor is platelet count (<100X10^9/L, =100X10^9/L and = 200X10^9/L, or > 200X10^9/L) at baseline.
CMH = Cochran-Mantel-Haenszel
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-tf.pdf 29AUG2023: 9:03

Table 2.2812: Subgroup Analysis of RBC TI Response Rate at Week 24 and Week 12 by TSS at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	< Q1 7.8		>= Q1 7.8 and < Median 16.8	
	MMB (N=24)	RUX (N=20)	MMB (N=16)	RUX (N=29)
RBC Transfusion Independent Rate at Week 24				
Responder, n(%)	13 (54.2%)	5 (25.0%)	6 (37.5%)	10 (34.5%)
95% Exact CI	0.3282, 0.7445	0.0866, 0.4910	0.1520, 0.6457	0.1794, 0.5433
Proportion Difference - Stratified CMH Method (95% CI)	0.30 (0.01, 0.59)		0.10 (-0.20, 0.40)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.29 (0.01, 0.58)		0.03 (-0.27, 0.33)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.29 (-0.01, 0.55)		0.03 (-0.27, 0.33)	
Non-Responder, n(%)	11 (45.8%)	15 (75.0%)	10 (62.5%)	19 (65.5%)
Transfusion (except bleeding) in the last 12 weeks	9 (37.5%)	13 (65.0%)	6 (37.5%)	16 (55.2%)
Any Hgb assessment < 8g/dL in the last 12 weeks	9 (37.5%)	12 (60.0%)	6 (37.5%)	12 (41.4%)
Last Participation date < Day 162 in DB phase	1 (4.2%)	0	2 (12.5%)	3 (10.3%)
Other	7 (29.2%)	10 (50.0%)	2 (12.5%)	5 (17.2%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel
TSS = Total Symptom Score
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-tss.pdf 29AUG2023: 9:03

Table 2.2812: Subgroup Analysis of RBC TI Response Rate at Week 24 and Week 12 by TSS at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	>= Median 16.8 and < Q3 25.7		>= Q3 25.7	
	MMB (N=21)	RUX (N=23)	MMB (N=24)	RUX (N=21)
RBC Transfusion Independent Rate at Week 24				
Responder, n(%)	10 (47.6%)	5 (21.7%)	10 (41.7%)	5 (23.8%)
95% Exact CI	0.2571, 0.7022	0.0746, 0.4370	0.2211, 0.6336	0.0822, 0.4717
Proportion Difference - Stratified CMH Method (95% CI)	0.42 (0.10, 0.73)		0.08 (-0.21, 0.38)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.26 (-0.02, 0.54)		0.18 (-0.10, 0.46)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.26 (-0.05, 0.52)		0.18 (-0.12, 0.45)	
Non-Responder, n(%)	11 (52.4%)	18 (78.3%)	14 (58.3%)	16 (76.2%)
Transfusion (except bleeding) in the last 12 weeks	6 (28.6%)	13 (56.5%)	5 (20.8%)	12 (57.1%)
Any Hgb assessment < 8g/dL in the last 12 weeks	4 (19.0%)	10 (43.5%)	4 (16.7%)	10 (47.6%)
Last Participation date < Day 162 in DB phase	4 (19.0%)	2 (8.7%)	9 (37.5%)	3 (14.3%)
Other	3 (14.3%)	5 (21.7%)	0	4 (19.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel
TSS = Total Symptom Score
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-tss.pdf 29AUG2023: 9:03

Table 2.2812: Subgroup Analysis of RBC TI Response Rate at Week 24 and Week 12 by TSS at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	< Q1 7.8		>= Q1 7.8 and < Median 16.8	
	MMB (N=24)	RUX (N=20)	MMB (N=16)	RUX (N=29)
RBC Transfusion Independent Rate at Week 12				
Responder, n(%)	10 (41.7%)	3 (15.0%)	4 (25.0%)	7 (24.1%)
95% Exact CI	0.2211, 0.6336	0.0321, 0.3789	0.0727, 0.5238	0.1030, 0.4354
Proportion Difference - Stratified CMH Method (95% CI)	0.31 (0.06, 0.57)		0.06 (-0.24, 0.37)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.27 (0.00, 0.53)		0.01 (-0.27, 0.28)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.27 (-0.04, 0.54)		0.01 (-0.29, 0.31)	
Non-Responder, n(%)	14 (58.3%)	17 (85.0%)	12 (75.0%)	22 (75.9%)
Transfusion (except bleeding) in the last 12 weeks	11 (45.8%)	17 (85.0%)	10 (62.5%)	19 (65.5%)
Any Hgb assessment < 8g/dL in the last 12 weeks	7 (29.2%)	14 (70.0%)	4 (25.0%)	19 (65.5%)
Last Participation date < Day 78 in DB phase	1 (4.2%)	0	2 (12.5%)	1 (3.4%)
Other	5 (20.8%)	6 (30.0%)	1 (6.3%)	4 (13.8%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel
TSS = Total Symptom Score
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-tss.pdf 29AUG2023: 9:03

Table 2.2812: Subgroup Analysis of RBC TI Response Rate at Week 24 and Week 12 by TSS at Baseline
Double-Blind Phase
ITT-Anemic Analysis Set

	>= Median 16.8 and < Q3 25.7		>= Q3 25.7	
	MMB (N=21)	RUX (N=23)	MMB (N=24)	RUX (N=21)
RBC Transfusion Independent Rate at Week 12				
Responder, n(%)	10 (47.6%)	6 (26.1%)	11 (45.8%)	4 (19.0%)
95% Exact CI	0.2571, 0.7022	0.1023, 0.4841	0.2555, 0.6718	0.0545, 0.4191
Proportion Difference - Stratified CMH Method (95% CI)	0.35 (0.03, 0.67)		0.17 (-0.11, 0.44)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.22 (-0.07, 0.50)		0.27 (0.00, 0.54)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.22 (-0.09, 0.48)		0.27 (-0.03, 0.53)	
Non-Responder, n(%)	11 (52.4%)	17 (73.9%)	13 (54.2%)	17 (81.0%)
Transfusion (except bleeding) in the last 12 weeks	8 (38.1%)	15 (65.2%)	8 (33.3%)	15 (71.4%)
Any Hgb assessment < 8g/dL in the last 12 weeks	7 (33.3%)	15 (65.2%)	5 (20.8%)	15 (71.4%)
Last Participation date < Day 78 in DB phase	2 (9.5%)	0	5 (20.8%)	1 (4.8%)
Other	3 (14.3%)	3 (13.0%)	4 (16.7%)	6 (28.6%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel
TSS = Total Symptom Score
RBC = Red Blood Cell

Data Extracted: CRF data: 01JUL2019
Source: t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-tss.pdf 29AUG2023: 9:03

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders	12 (50.0%)	12 (33.3%)	24 (40.0%)	6 (31.6%)	16 (50.0%)	22 (43.1%)
Grade 1	7 (29.2%)	7 (19.4%)	14 (23.3%)	5 (26.3%)	9 (28.1%)	14 (27.5%)
Grade 2	3 (12.5%)	5 (13.9%)	8 (13.3%)	1 (5.3%)	5 (15.6%)	6 (11.8%)
Grade 3	1 (4.2%)	0	1 (1.7%)	0	2 (6.3%)	2 (3.9%)
Grade 4	0	0	0	0	0	0
Grade 5	1 (4.2%)	0	1 (1.7%)	0	0	0
Nausea and vomiting symptoms	8 (33.3%)	2 (5.6%)	10 (16.7%)	1 (5.3%)	4 (12.5%)	5 (9.8%)
Grade 1	4 (16.7%)	1 (2.8%)	5 (8.3%)	1 (5.3%)	2 (6.3%)	3 (5.9%)
Grade 2	2 (8.3%)	1 (2.8%)	3 (5.0%)	0	2 (6.3%)	2 (3.9%)
Grade 3	2 (8.3%)	0	2 (3.3%)	0	0	0
Nausea	8 (33.3%)	1 (2.8%)	9 (15.0%)	0	2 (6.3%)	2 (3.9%)
Grade 1	6 (25.0%)	0	6 (10.0%)	0	1 (3.1%)	1 (2.0%)
Grade 2	1 (4.2%)	1 (2.8%)	2 (3.3%)	0	1 (3.1%)	1 (2.0%)
Grade 3	1 (4.2%)	0	1 (1.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders	34 (54.8%)	25 (43.1%)	59 (49.2%)	10 (22.2%)	27 (51.9%)	37 (38.1%)
Grade 1	21 (33.9%)	13 (22.4%)	34 (28.3%)	6 (13.3%)	11 (21.2%)	17 (17.5%)
Grade 2	9 (14.5%)	8 (13.8%)	17 (14.2%)	4 (8.9%)	12 (23.1%)	16 (16.5%)
Grade 3	4 (6.5%)	3 (5.2%)	7 (5.8%)	0	4 (7.7%)	4 (4.1%)
Grade 4	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 5	0	0	0	0	0	0
Nausea and vomiting symptoms	13 (21.0%)	6 (10.3%)	19 (15.8%)	3 (6.7%)	7 (13.5%)	10 (10.3%)
Grade 1	10 (16.1%)	2 (3.4%)	12 (10.0%)	2 (4.4%)	5 (9.6%)	7 (7.2%)
Grade 2	3 (4.8%)	3 (5.2%)	6 (5.0%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 3	0	1 (1.7%)	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Nausea	11 (17.7%)	2 (3.4%)	13 (10.8%)	2 (4.4%)	5 (9.6%)	7 (7.2%)
Grade 1	9 (14.5%)	0	9 (7.5%)	2 (4.4%)	4 (7.7%)	6 (6.2%)
Grade 2	2 (3.2%)	1 (1.7%)	3 (2.5%)	0	1 (1.9%)	1 (1.0%)
Grade 3	0	1 (1.7%)	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Nausea and vomiting symptoms (cont)						
Vomiting	4 (16.7%)	1 (2.8%)	5 (8.3%)	1 (5.3%)	2 (6.3%)	3 (5.9%)
Grade 1	1 (4.2%)	1 (2.8%)	2 (3.3%)	1 (5.3%)	1 (3.1%)	2 (3.9%)
Grade 2	2 (8.3%)	0	2 (3.3%)	0	1 (3.1%)	1 (2.0%)
Grade 3	1 (4.2%)	0	1 (1.7%)	0	0	0
Retching	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Diarrhoea (excl infective)	5 (20.8%)	8 (22.2%)	13 (21.7%)	2 (10.5%)	6 (18.8%)	8 (15.7%)
Grade 1	1 (4.2%)	7 (19.4%)	8 (13.3%)	2 (10.5%)	4 (12.5%)	6 (11.8%)
Grade 2	3 (12.5%)	1 (2.8%)	4 (6.7%)	0	1 (3.1%)	1 (2.0%)
Grade 3	1 (4.2%)	0	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Diarrhoea	5 (20.8%)	8 (22.2%)	13 (21.7%)	2 (10.5%)	6 (18.8%)	8 (15.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Nausea and vomiting symptoms (cont)						
Vomiting	4 (6.5%)	4 (6.9%)	8 (6.7%)	3 (6.7%)	3 (5.8%)	6 (6.2%)
Grade 1	3 (4.8%)	2 (3.4%)	5 (4.2%)	2 (4.4%)	1 (1.9%)	3 (3.1%)
Grade 2	1 (1.6%)	2 (3.4%)	3 (2.5%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 3	0	0	0	0	1 (1.9%)	1 (1.0%)
Retching	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Diarrhoea (excl infective)	14 (22.6%)	11 (19.0%)	25 (20.8%)	6 (13.3%)	10 (19.2%)	16 (16.5%)
Grade 1	9 (14.5%)	7 (12.1%)	16 (13.3%)	5 (11.1%)	6 (11.5%)	11 (11.3%)
Grade 2	4 (6.5%)	3 (5.2%)	7 (5.8%)	1 (2.2%)	2 (3.8%)	3 (3.1%)
Grade 3	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	2 (3.8%)	2 (2.1%)
Diarrhoea	14 (22.6%)	11 (19.0%)	25 (20.8%)	6 (13.3%)	10 (19.2%)	16 (16.5%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Diarrhoea (excl infective) (cont)						
Diarrhoea (cont)						
Grade 1	1 (4.2%)	7 (19.4%)	8 (13.3%)	2 (10.5%)	4 (12.5%)	6 (11.8%)
Grade 2	3 (12.5%)	1 (2.8%)	4 (6.7%)	0	1 (3.1%)	1 (2.0%)
Grade 3	1 (4.2%)	0	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Gastrointestinal atonic and hypomotility disorders NEC	3 (12.5%)	2 (5.6%)	5 (8.3%)	1 (5.3%)	3 (9.4%)	4 (7.8%)
Grade 1	2 (8.3%)	2 (5.6%)	4 (6.7%)	1 (5.3%)	2 (6.3%)	3 (5.9%)
Grade 2	1 (4.2%)	0	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Grade 3	0	0	0	0	0	0
Constipation	2 (8.3%)	1 (2.8%)	3 (5.0%)	1 (5.3%)	2 (6.3%)	3 (5.9%)
Grade 1	2 (8.3%)	1 (2.8%)	3 (5.0%)	1 (5.3%)	1 (3.1%)	2 (3.9%)
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Diarrhoea (excl infective) (cont)						
Diarrhoea (cont)						
Grade 1	9 (14.5%)	7 (12.1%)	16 (13.3%)	5 (11.1%)	6 (11.5%)	11 (11.3%)
Grade 2	4 (6.5%)	3 (5.2%)	7 (5.8%)	1 (2.2%)	2 (3.8%)	3 (3.1%)
Grade 3	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	2 (3.8%)	2 (2.1%)
Gastrointestinal atonic and hypomotility disorders NEC	11 (17.7%)	5 (8.6%)	16 (13.3%)	0	7 (13.5%)	7 (7.2%)
Grade 1	10 (16.1%)	3 (5.2%)	13 (10.8%)	0	4 (7.7%)	4 (4.1%)
Grade 2	1 (1.6%)	2 (3.4%)	3 (2.5%)	0	2 (3.8%)	2 (2.1%)
Grade 3	0	0	0	0	1 (1.9%)	1 (1.0%)
Constipation	9 (14.5%)	5 (8.6%)	14 (11.7%)	0	3 (5.8%)	3 (3.1%)
Grade 1	9 (14.5%)	3 (5.2%)	12 (10.0%)	0	1 (1.9%)	1 (1.0%)
Grade 2	0	2 (3.4%)	2 (1.7%)	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal atonic and hypomotility disorders NEC (cont)						
Constipation (cont)						
Grade 3	0	0	0	0	0	0
Gastrooesophageal reflux disease	2 (8.3%)	1 (2.8%)	3 (5.0%)	0	1 (3.1%)	1 (2.0%)
Grade 1	1 (4.2%)	1 (2.8%)	2 (3.3%)	0	1 (3.1%)	1 (2.0%)
Grade 2	1 (4.2%)	0	1 (1.7%)	0	0	0
Gastrointestinal and abdominal pains (excl oral and throat)	6 (25.0%)	3 (8.3%)	9 (15.0%)	1 (5.3%)	3 (9.4%)	4 (7.8%)
Grade 1	4 (16.7%)	2 (5.6%)	6 (10.0%)	1 (5.3%)	3 (9.4%)	4 (7.8%)
Grade 2	1 (4.2%)	1 (2.8%)	2 (3.3%)	0	0	0
Grade 3	1 (4.2%)	0	1 (1.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal atonic and hypomotility disorders NEC (cont)						
Constipation (cont)						
Grade 3	0	0	0	0	1 (1.9%)	1 (1.0%)
Gastrooesophageal reflux disease	2 (3.2%)	0	2 (1.7%)	0	4 (7.7%)	4 (4.1%)
Grade 1	1 (1.6%)	0	1 (0.8%)	0	3 (5.8%)	3 (3.1%)
Grade 2	1 (1.6%)	0	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Gastrointestinal and abdominal pains (excl oral and throat)	7 (11.3%)	9 (15.5%)	16 (13.3%)	2 (4.4%)	6 (11.5%)	8 (8.2%)
Grade 1	4 (6.5%)	5 (8.6%)	9 (7.5%)	1 (2.2%)	2 (3.8%)	3 (3.1%)
Grade 2	2 (3.2%)	3 (5.2%)	5 (4.2%)	1 (2.2%)	4 (7.7%)	5 (5.2%)
Grade 3	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal and abdominal pains (excl oral and throat) (cont)						
Abdominal pain	6 (25.0%)	3 (8.3%)	9 (15.0%)	0	2 (6.3%)	2 (3.9%)
Grade 1	4 (16.7%)	2 (5.6%)	6 (10.0%)	0	2 (6.3%)	2 (3.9%)
Grade 2	1 (4.2%)	1 (2.8%)	2 (3.3%)	0	0	0
Grade 3	1 (4.2%)	0	1 (1.7%)	0	0	0
Abdominal pain upper	0	0	0	1 (5.3%)	1 (3.1%)	2 (3.9%)
Grade 1	0	0	0	1 (5.3%)	1 (3.1%)	2 (3.9%)
Grade 2	0	0	0	0	0	0
Abdominal rigidity	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	1 (3.1%)	1 (2.0%)
Oesophageal pain	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal and abdominal pains (excl oral and throat) (cont)						
Abdominal pain	5 (8.1%)	8 (13.8%)	13 (10.8%)	1 (2.2%)	4 (7.7%)	5 (5.2%)
Grade 1	2 (3.2%)	5 (8.6%)	7 (5.8%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 2	2 (3.2%)	2 (3.4%)	4 (3.3%)	0	3 (5.8%)	3 (3.1%)
Grade 3	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	0	0
Abdominal pain upper	3 (4.8%)	2 (3.4%)	5 (4.2%)	1 (2.2%)	2 (3.8%)	3 (3.1%)
Grade 1	3 (4.8%)	1 (1.7%)	4 (3.3%)	0	1 (1.9%)	1 (1.0%)
Grade 2	0	1 (1.7%)	1 (0.8%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Abdominal rigidity	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Oesophageal pain	0	1 (1.7%)	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal and abdominal pains (excl oral and throat) (cont)						
Oesophageal pain (cont)						
Grade 2	0	0	0	0	0	0
Flatulence, bloating and distension	1 (4.2%)	2 (5.6%)	3 (5.0%)	0	0	0
Grade 1	1 (4.2%)	2 (5.6%)	3 (5.0%)	0	0	0
Grade 2	0	0	0	0	0	0
Abdominal distension	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Flatulence	1 (4.2%)	2 (5.6%)	3 (5.0%)	0	0	0
Grade 1	1 (4.2%)	2 (5.6%)	3 (5.0%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal and abdominal pains (excl oral and throat) (cont)						
Oesophageal pain (cont)						
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0
Flatulence, bloating and distension	4 (6.5%)	4 (6.9%)	8 (6.7%)	0	2 (3.8%)	2 (2.1%)
Grade 1	2 (3.2%)	4 (6.9%)	6 (5.0%)	0	1 (1.9%)	1 (1.0%)
Grade 2	2 (3.2%)	0	2 (1.7%)	0	1 (1.9%)	1 (1.0%)
Abdominal distension	3 (4.8%)	2 (3.4%)	5 (4.2%)	0	1 (1.9%)	1 (1.0%)
Grade 1	1 (1.6%)	2 (3.4%)	3 (2.5%)	0	1 (1.9%)	1 (1.0%)
Grade 2	2 (3.2%)	0	2 (1.7%)	0	0	0
Flatulence	2 (3.2%)	3 (5.2%)	5 (4.2%)	0	1 (1.9%)	1 (1.0%)
Grade 1	2 (3.2%)	3 (5.2%)	5 (4.2%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Flatulence, bloating and distension (cont)						
Flatulence (cont)						
Grade 2	0	0	0	0	0	0
Gastrointestinal signs and symptoms NEC	0	1 (2.8%)	1 (1.7%)	0	2 (6.3%)	2 (3.9%)
Grade 1	0	0	0	0	2 (6.3%)	2 (3.9%)
Grade 2	0	1 (2.8%)	1 (1.7%)	0	0	0
Abdominal discomfort	0	1 (2.8%)	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 2	0	1 (2.8%)	1 (1.7%)	0	0	0
Dysphagia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Flatulence, bloating and distension (cont)						
Flatulence (cont)						
Grade 2	0	0	0	0	1 (1.9%)	1 (1.0%)
Gastrointestinal signs and symptoms NEC	4 (6.5%)	0	4 (3.3%)	0	2 (3.8%)	2 (2.1%)
Grade 1	4 (6.5%)	0	4 (3.3%)	0	1 (1.9%)	1 (1.0%)
Grade 2	0	0	0	0	1 (1.9%)	1 (1.0%)
Abdominal discomfort	3 (4.8%)	0	3 (2.5%)	0	1 (1.9%)	1 (1.0%)
Grade 1	3 (4.8%)	0	3 (2.5%)	0	1 (1.9%)	1 (1.0%)
Grade 2	0	0	0	0	0	0
Dysphagia	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal signs and symptoms NEC (cont)						
Anal incontinence	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 2	0	0	0	0	0	0
Haemorrhoids and gastrointestinal varices (excl oesophageal)	1 (4.2%)	0	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Grade 1	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)
Haemorrhoids	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal signs and symptoms NEC (cont)						
Anal incontinence	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (1.9%)	1 (1.0%)
Haemorrhoids and gastrointestinal varices (excl oesophageal)	2 (3.2%)	0	2 (1.7%)	0	1 (1.9%)	1 (1.0%)
Grade 1	1 (1.6%)	0	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Grade 2	1 (1.6%)	0	1 (0.8%)	0	0	0
Haemorrhoids	2 (3.2%)	0	2 (1.7%)	0	1 (1.9%)	1 (1.0%)
Grade 1	1 (1.6%)	0	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Grade 2	1 (1.6%)	0	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Haemorrhoids and gastrointestinal varices (excl oesophageal) (cont)						
Haemorrhoidal haemorrhage	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 1	1 (4.2%)	0	1 (1.7%)	0	0	0
Anal and rectal pains	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Proctalgia	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Intestinal haemorrhages	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	1 (3.1%)	1 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Haemorrhoids and gastrointestinal varices (excl oesophageal) (cont)						
Haemorrhoidal haemorrhage	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Anal and rectal pains	2 (3.2%)	0	2 (1.7%)	0	0	0
Grade 2	2 (3.2%)	0	2 (1.7%)	0	0	0
Proctalgia	2 (3.2%)	0	2 (1.7%)	0	0	0
Grade 2	2 (3.2%)	0	2 (1.7%)	0	0	0
Intestinal haemorrhages	2 (3.2%)	1 (1.7%)	3 (2.5%)	0	3 (5.8%)	3 (3.1%)
Grade 1	0	1 (1.7%)	1 (0.8%)	0	2 (3.8%)	2 (2.1%)
Grade 2	1 (1.6%)	0	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Grade 3	1 (1.6%)	0	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Intestinal haemorrhages (cont)						
Rectal haemorrhage	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Anal haemorrhage	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Lower gastrointestinal haemorrhage	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Small intestinal haemorrhage	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 3	0	0	0	0	1 (3.1%)	1 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Intestinal haemorrhages (cont)						
Rectal haemorrhage	2 (3.2%)	0	2 (1.7%)	0	2 (3.8%)	2 (2.1%)
Grade 1	0	0	0	0	2 (3.8%)	2 (2.1%)
Grade 2	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 3	1 (1.6%)	0	1 (0.8%)	0	0	0
Anal haemorrhage	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0
Lower gastrointestinal haemorrhage	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 2	0	0	0	0	1 (1.9%)	1 (1.0%)
Small intestinal haemorrhage	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Oral dryness and saliva altered	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Dry mouth	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Oral soft tissue pain and paraesthesia	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 3	0	0	0	0	0	0
Lip pain	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Oral dryness and saliva altered	2 (3.2%)	0	2 (1.7%)	2 (4.4%)	2 (3.8%)	4 (4.1%)
Grade 1	2 (3.2%)	0	2 (1.7%)	2 (4.4%)	0	2 (2.1%)
Grade 2	0	0	0	0	2 (3.8%)	2 (2.1%)
Dry mouth	2 (3.2%)	0	2 (1.7%)	2 (4.4%)	2 (3.8%)	4 (4.1%)
Grade 1	2 (3.2%)	0	2 (1.7%)	2 (4.4%)	0	2 (2.1%)
Grade 2	0	0	0	0	2 (3.8%)	2 (2.1%)
Oral soft tissue pain and paraesthesia	2 (3.2%)	0	2 (1.7%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	1 (1.6%)	0	1 (0.8%)	0	0	0
Lip pain	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Oral soft tissue pain and paraesthesia (cont)						
Odynophagia	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Oral pain	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)
Dental pain and sensation disorders	1 (4.2%)	0	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Grade 1	1 (4.2%)	0	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Toothache	1 (4.2%)	0	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Grade 1	1 (4.2%)	0	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Dyspeptic signs and symptoms	0	0	0	0	3 (9.4%)	3 (5.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Oral soft tissue pain and paraesthesia (cont)						
Odynophagia	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 3	1 (1.6%)	0	1 (0.8%)	0	0	0
Oral pain	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Dental pain and sensation disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Toothache	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dyspeptic signs and symptoms	1 (1.6%)	2 (3.4%)	3 (2.5%)	2 (4.4%)	0	2 (2.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Dyspeptic signs and symptoms (cont)						
(cont)						
Grade 1	0	0	0	0	3 (9.4%)	3 (5.9%)
Dyspepsia	0	0	0	0	3 (9.4%)	3 (5.9%)
Grade 1	0	0	0	0	3 (9.4%)	3 (5.9%)
Epigastric discomfort	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	1 (3.1%)	1 (2.0%)
Gastric ulcers and perforation	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 2	1 (4.2%)	0	1 (1.7%)	0	0	0
Gastric ulcer	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 2	1 (4.2%)	0	1 (1.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Dyspeptic signs and symptoms (cont)						
(cont)						
Grade 1	1 (1.6%)	2 (3.4%)	3 (2.5%)	2 (4.4%)	0	2 (2.1%)
Dyspepsia	1 (1.6%)	2 (3.4%)	3 (2.5%)	2 (4.4%)	0	2 (2.1%)
Grade 1	1 (1.6%)	2 (3.4%)	3 (2.5%)	2 (4.4%)	0	2 (2.1%)
Epigastric discomfort	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Gastric ulcers and perforation	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Gastric ulcer	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal vascular occlusion and infarction	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 5	1 (4.2%)	0	1 (1.7%)	0	0	0
Mesenteric vein thrombosis	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 5	1 (4.2%)	0	1 (1.7%)	0	0	0
Oral soft tissue disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Cheilitis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal vascular occlusion and infarction	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Mesenteric vein thrombosis	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Oral soft tissue disorders NEC	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	1 (1.9%)	1 (1.0%)
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	0	1 (1.7%)	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Cheilitis	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	1 (1.9%)	1 (1.0%)
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	0	1 (1.7%)	1 (0.8%)	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Peritoneal and retroperitoneal disorders	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	1 (4.2%)	0	1 (1.7%)	0	0	0
Ascites	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	1 (4.2%)	0	1 (1.7%)	0	0	0
Stomatitis and ulceration	0	2 (5.6%)	2 (3.3%)	0	0	0
Grade 1	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 2	0	1 (2.8%)	1 (1.7%)	0	0	0
Mouth ulceration	0	2 (5.6%)	2 (3.3%)	0	0	0
Grade 1	0	1 (2.8%)	1 (1.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Peritoneal and retroperitoneal disorders	0	1 (1.7%)	1 (0.8%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 2	0	0	0	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 3	0	1 (1.7%)	1 (0.8%)	0	0	0
Ascites	0	1 (1.7%)	1 (0.8%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 2	0	0	0	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 3	0	1 (1.7%)	1 (0.8%)	0	0	0
Stomatitis and ulceration	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	0	0
Grade 1	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	0	0
Grade 2	0	0	0	0	0	0
Mouth ulceration	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Stomatitis and ulceration (cont)						
Mouth ulceration (cont)						
Grade 2	0	1 (2.8%)	1 (1.7%)	0	0	0
Stomatitis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dental and periodontal infections and inflammations	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	1 (3.1%)	1 (2.0%)
Dental caries	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	1 (3.1%)	1 (2.0%)
Dental disorders NEC	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Stomatitis and ulceration (cont)						
Mouth ulceration (cont)						
Grade 2	0	0	0	0	0	0
Stomatitis	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0
Dental and periodontal infections and inflammations	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dental caries	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dental disorders NEC	0	0	0	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Dental disorders NEC (cont)						
(cont)						
Grade 1	0	0	0	0	0	0
Periodontal disease	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Gastric and oesophageal haemorrhages	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 3	0	0	0	0	1 (3.1%)	1 (2.0%)
Gastric haemorrhage	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 3	0	0	0	0	1 (3.1%)	1 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Dental disorders NEC (cont)						
(cont)						
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Periodontal disease	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Gastric and oesophageal haemorrhages	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Gastric haemorrhage	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal inflammatory disorders NEC	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (2.8%)	1 (1.7%)	0	0	0
Enteritis	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 2	0	1 (2.8%)	1 (1.7%)	0	0	0
Enterocolitis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Gastrointestinal spastic and hypermotility disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal inflammatory disorders NEC	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 2	0	0	0	0	0	0
Enteritis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Enterocolitis	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0
Gastrointestinal spastic and hypermotility disorders	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal spastic and hypermotility disorders (cont)						
Defaecation urgency	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Gastrointestinal stenosis and obstruction NEC	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Ileus	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Subileus	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal spastic and hypermotility disorders (cont)						
Defaecation urgency	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Gastrointestinal stenosis and obstruction NEC	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 4	0	1 (1.7%)	1 (0.8%)	0	0	0
Ileus	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 4	0	1 (1.7%)	1 (0.8%)	0	0	0
Subileus	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 4	0	1 (1.7%)	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
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Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
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SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gingival haemorrhages	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 1	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 2	0	0	0	0	0	0
Gingival bleeding	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 1	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 2	0	0	0	0	0	0
Non-site specific gastrointestinal haemorrhages	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Gastrointestinal haemorrhage	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gingival haemorrhages	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (1.9%)	1 (1.0%)
Gingival bleeding	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (1.9%)	1 (1.0%)
Non-site specific gastrointestinal haemorrhages	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 3	0	0	0	0	1 (1.9%)	1 (1.0%)
Gastrointestinal haemorrhage	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 3	0	0	0	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
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Data Extracted: CRF data: 01JUL2019
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Oesophageal varices	0	0	0	1 (5.3%)	1 (3.1%)	2 (3.9%)
Grade 1	0	0	0	1 (5.3%)	0	1 (2.0%)
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)
Varices oesophageal	0	0	0	1 (5.3%)	1 (3.1%)	2 (3.9%)
Grade 1	0	0	0	1 (5.3%)	0	1 (2.0%)
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)
Oral soft tissue haemorrhages	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)
Mouth haemorrhage	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Oesophageal varices	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Varices oesophageal	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Oral soft tissue haemorrhages	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 1	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 2	0	0	0	0	0	0
Mouth haemorrhage	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Oral soft tissue haemorrhages (cont)						
Oral mucosa haematoma	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Oral soft tissue infections	0	0	0	1 (5.3%)	0	1 (2.0%)
Grade 2	0	0	0	1 (5.3%)	0	1 (2.0%)
Angular cheilitis	0	0	0	1 (5.3%)	0	1 (2.0%)
Grade 2	0	0	0	1 (5.3%)	0	1 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Oral soft tissue haemorrhages (cont)						
Oral mucosa haematoma	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 1	0	0	0	1 (2.2%)	0	1 (1.0%)
Oral soft tissue infections	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 2	0	0	0	1 (2.2%)	0	1 (1.0%)
Angular cheilitis	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 2	0	0	0	1 (2.2%)	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions	10 (41.7%)	15 (41.7%)	25 (41.7%)	4 (21.1%)	8 (25.0%)	12 (23.5%)
Grade 1	4 (16.7%)	8 (22.2%)	12 (20.0%)	3 (15.8%)	6 (18.8%)	9 (17.6%)
Grade 2	5 (20.8%)	7 (19.4%)	12 (20.0%)	1 (5.3%)	2 (6.3%)	3 (5.9%)
Grade 3	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 5	0	0	0	0	0	0
Asthenic conditions	4 (16.7%)	11 (30.6%)	15 (25.0%)	0	3 (9.4%)	3 (5.9%)
Grade 1	2 (8.3%)	6 (16.7%)	8 (13.3%)	0	3 (9.4%)	3 (5.9%)
Grade 2	2 (8.3%)	5 (13.9%)	7 (11.7%)	0	0	0
Grade 3	0	0	0	0	0	0
Fatigue	2 (8.3%)	7 (19.4%)	9 (15.0%)	0	3 (9.4%)	3 (5.9%)
Grade 1	1 (4.2%)	5 (13.9%)	6 (10.0%)	0	3 (9.4%)	3 (5.9%)
Grade 2	1 (4.2%)	2 (5.6%)	3 (5.0%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions	28 (45.2%)	30 (51.7%)	58 (48.3%)	13 (28.9%)	13 (25.0%)	26 (26.8%)
Grade 1	22 (35.5%)	20 (34.5%)	42 (35.0%)	8 (17.8%)	3 (5.8%)	11 (11.3%)
Grade 2	4 (6.5%)	9 (15.5%)	13 (10.8%)	5 (11.1%)	8 (15.4%)	13 (13.4%)
Grade 3	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	2 (3.8%)	2 (2.1%)
Grade 5	1 (1.6%)	0	1 (0.8%)	0	0	0
Asthenic conditions	15 (24.2%)	12 (20.7%)	27 (22.5%)	5 (11.1%)	8 (15.4%)	13 (13.4%)
Grade 1	14 (22.6%)	6 (10.3%)	20 (16.7%)	2 (4.4%)	0	2 (2.1%)
Grade 2	1 (1.6%)	5 (8.6%)	6 (5.0%)	3 (6.7%)	6 (11.5%)	9 (9.3%)
Grade 3	0	1 (1.7%)	1 (0.8%)	0	2 (3.8%)	2 (2.1%)
Fatigue	11 (17.7%)	4 (6.9%)	15 (12.5%)	3 (6.7%)	4 (7.7%)	7 (7.2%)
Grade 1	10 (16.1%)	2 (3.4%)	12 (10.0%)	1 (2.2%)	0	1 (1.0%)
Grade 2	1 (1.6%)	2 (3.4%)	3 (2.5%)	2 (4.4%)	4 (7.7%)	6 (6.2%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Asthenic conditions (cont)						
Asthenia	2 (8.3%)	4 (11.1%)	6 (10.0%)	0	0	0
Grade 1	1 (4.2%)	1 (2.8%)	2 (3.3%)	0	0	0
Grade 2	1 (4.2%)	3 (8.3%)	4 (6.7%)	0	0	0
Grade 3	0	0	0	0	0	0
Malaise	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Febrile disorders	3 (12.5%)	2 (5.6%)	5 (8.3%)	2 (10.5%)	1 (3.1%)	3 (5.9%)
Grade 1	1 (4.2%)	2 (5.6%)	3 (5.0%)	1 (5.3%)	1 (3.1%)	2 (3.9%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (5.3%)	0	1 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Asthenic conditions (cont)						
Asthenia	2 (3.2%)	5 (8.6%)	7 (5.8%)	2 (4.4%)	3 (5.8%)	5 (5.2%)
Grade 1	2 (3.2%)	3 (5.2%)	5 (4.2%)	1 (2.2%)	0	1 (1.0%)
Grade 2	0	1 (1.7%)	1 (0.8%)	1 (2.2%)	2 (3.8%)	3 (3.1%)
Grade 3	0	1 (1.7%)	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Malaise	2 (3.2%)	3 (5.2%)	5 (4.2%)	0	2 (3.8%)	2 (2.1%)
Grade 1	2 (3.2%)	1 (1.7%)	3 (2.5%)	0	0	0
Grade 2	0	2 (3.4%)	2 (1.7%)	0	1 (1.9%)	1 (1.0%)
Grade 3	0	0	0	0	1 (1.9%)	1 (1.0%)
Febrile disorders	7 (11.3%)	8 (13.8%)	15 (12.5%)	2 (4.4%)	2 (3.8%)	4 (4.1%)
Grade 1	6 (9.7%)	7 (12.1%)	13 (10.8%)	1 (2.2%)	2 (3.8%)	3 (3.1%)
Grade 2	1 (1.6%)	1 (1.7%)	2 (1.7%)	1 (2.2%)	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Febrile disorders (cont)						
(cont)						
Grade 3	1 (4.2%)	0	1 (1.7%)	0	0	0
Pyrexia	3 (12.5%)	2 (5.6%)	5 (8.3%)	2 (10.5%)	1 (3.1%)	3 (5.9%)
Grade 1	1 (4.2%)	2 (5.6%)	3 (5.0%)	1 (5.3%)	1 (3.1%)	2 (3.9%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (5.3%)	0	1 (2.0%)
Grade 3	1 (4.2%)	0	1 (1.7%)	0	0	0
Oedema NEC	2 (8.3%)	3 (8.3%)	5 (8.3%)	0	2 (6.3%)	2 (3.9%)
Grade 1	1 (4.2%)	2 (5.6%)	3 (5.0%)	0	2 (6.3%)	2 (3.9%)
Grade 2	1 (4.2%)	1 (2.8%)	2 (3.3%)	0	0	0
Oedema peripheral	1 (4.2%)	3 (8.3%)	4 (6.7%)	0	1 (3.1%)	1 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Febrile disorders (cont)						
(cont)						
Grade 3	0	0	0	0	0	0
Pyrexia	7 (11.3%)	8 (13.8%)	15 (12.5%)	2 (4.4%)	2 (3.8%)	4 (4.1%)
Grade 1	6 (9.7%)	7 (12.1%)	13 (10.8%)	1 (2.2%)	2 (3.8%)	3 (3.1%)
Grade 2	1 (1.6%)	1 (1.7%)	2 (1.7%)	1 (2.2%)	0	1 (1.0%)
Grade 3	0	0	0	0	0	0
Oedema NEC	5 (8.1%)	7 (12.1%)	12 (10.0%)	4 (8.9%)	0	4 (4.1%)
Grade 1	3 (4.8%)	6 (10.3%)	9 (7.5%)	3 (6.7%)	0	3 (3.1%)
Grade 2	2 (3.2%)	1 (1.7%)	3 (2.5%)	1 (2.2%)	0	1 (1.0%)
Oedema peripheral	5 (8.1%)	5 (8.6%)	10 (8.3%)	4 (8.9%)	0	4 (4.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Oedema NEC (cont)						
Oedema peripheral (cont)						
Grade 1	0	2 (5.6%)	2 (3.3%)	0	1 (3.1%)	1 (2.0%)
Grade 2	1 (4.2%)	1 (2.8%)	2 (3.3%)	0	0	0
Generalised oedema	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Oedema	1 (4.2%)	0	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Grade 1	1 (4.2%)	0	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Grade 2	0	0	0	0	0	0
Pain and discomfort NEC	3 (12.5%)	2 (5.6%)	5 (8.3%)	0	0	0
Grade 1	2 (8.3%)	2 (5.6%)	4 (6.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Oedema NEC (cont)						
Oedema peripheral (cont)						
Grade 1	4 (6.5%)	5 (8.6%)	9 (7.5%)	3 (6.7%)	0	3 (3.1%)
Grade 2	1 (1.6%)	0	1 (0.8%)	1 (2.2%)	0	1 (1.0%)
Generalised oedema	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	1 (1.6%)	0	1 (0.8%)	0	0	0
Oedema	0	2 (3.4%)	2 (1.7%)	0	0	0
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0
Pain and discomfort NEC	4 (6.5%)	3 (5.2%)	7 (5.8%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 1	3 (4.8%)	3 (5.2%)	6 (5.0%)	1 (2.2%)	1 (1.9%)	2 (2.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Pain and discomfort NEC (cont)						
(cont)						
Grade 2	1 (4.2%)	0	1 (1.7%)	0	0	0
Chest pain	2 (8.3%)	1 (2.8%)	3 (5.0%)	0	0	0
Grade 1	2 (8.3%)	1 (2.8%)	3 (5.0%)	0	0	0
Pain	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Facial pain	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	1 (4.2%)	0	1 (1.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Pain and discomfort NEC (cont)						
(cont)						
Grade 2	1 (1.6%)	0	1 (0.8%)	0	0	0
Chest pain	2 (3.2%)	2 (3.4%)	4 (3.3%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 1	2 (3.2%)	2 (3.4%)	4 (3.3%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Pain	2 (3.2%)	0	2 (1.7%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	1 (1.6%)	0	1 (0.8%)	0	0	0
Facial pain	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Pain and discomfort NEC (cont)						
Chest discomfort	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 1	0	1 (2.8%)	1 (1.7%)	0	0	0
General signs and symptoms NEC	1 (4.2%)	1 (2.8%)	2 (3.3%)	2 (10.5%)	2 (6.3%)	4 (7.8%)
Grade 1	1 (4.2%)	1 (2.8%)	2 (3.3%)	2 (10.5%)	1 (3.1%)	3 (5.9%)
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)
Peripheral swelling	0	0	0	1 (5.3%)	0	1 (2.0%)
Grade 1	0	0	0	1 (5.3%)	0	1 (2.0%)
Grade 2	0	0	0	0	0	0
Influenza like illness	1 (4.2%)	1 (2.8%)	2 (3.3%)	1 (5.3%)	2 (6.3%)	3 (5.9%)
Grade 1	1 (4.2%)	1 (2.8%)	2 (3.3%)	1 (5.3%)	1 (3.1%)	2 (3.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Pain and discomfort NEC (cont)						
Chest discomfort	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
General signs and symptoms NEC	4 (6.5%)	4 (6.9%)	8 (6.7%)	2 (4.4%)	1 (1.9%)	3 (3.1%)
Grade 1	3 (4.8%)	4 (6.9%)	7 (5.8%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 2	1 (1.6%)	0	1 (0.8%)	1 (2.2%)	0	1 (1.0%)
Peripheral swelling	3 (4.8%)	0	3 (2.5%)	0	0	0
Grade 1	2 (3.2%)	0	2 (1.7%)	0	0	0
Grade 2	1 (1.6%)	0	1 (0.8%)	0	0	0
Influenza like illness	1 (1.6%)	1 (1.7%)	2 (1.7%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 1	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
General signs and symptoms NEC (cont)						
Influenza like illness (cont)						
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)
Crepitations	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
General physical health deterioration	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Swelling	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
General signs and symptoms NEC (cont)						
Influenza like illness (cont)						
Grade 2	0	0	0	1 (2.2%)	0	1 (1.0%)
Crepitations	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
General physical health deterioration	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0
Swelling	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
General signs and symptoms NEC (cont)						
Xerosis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Mucosal findings abnormal	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Mucosal inflammation	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Mucosal haemorrhage	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
General signs and symptoms NEC (cont)						
Xerosis	0	1 (1.7%)	1 (0.8%)	1 (2.2%)	0	1 (1.0%)
Grade 1	0	1 (1.7%)	1 (0.8%)	1 (2.2%)	0	1 (1.0%)
Mucosal findings abnormal	2 (3.2%)	1 (1.7%)	3 (2.5%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 3	1 (1.6%)	0	1 (0.8%)	0	0	0
Mucosal inflammation	2 (3.2%)	0	2 (1.7%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 3	1 (1.6%)	0	1 (0.8%)	0	0	0
Mucosal haemorrhage	0	1 (1.7%)	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Mucosal findings abnormal (cont)						
Mucosal haemorrhage (cont)						
Grade 2	0	0	0	0	0	0
Death and sudden death	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Sudden death	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Feelings and sensations NEC	0	2 (5.6%)	2 (3.3%)	0	1 (3.1%)	1 (2.0%)
Grade 1	0	1 (2.8%)	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Grade 2	0	1 (2.8%)	1 (1.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Mucosal findings abnormal (cont)						
Mucosal haemorrhage (cont)						
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0
Death and sudden death	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 5	1 (1.6%)	0	1 (0.8%)	0	0	0
Sudden death	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 5	1 (1.6%)	0	1 (0.8%)	0	0	0
Feelings and sensations NEC	1 (1.6%)	4 (6.9%)	5 (4.2%)	1 (2.2%)	0	1 (1.0%)
Grade 1	1 (1.6%)	4 (6.9%)	5 (4.2%)	1 (2.2%)	0	1 (1.0%)
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Feelings and sensations NEC (cont)						
Chills	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (2.8%)	1 (1.7%)	0	0	0
Early satiety	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Feeling cold	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 1	0	1 (2.8%)	1 (1.7%)	0	0	0
Feeling hot	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	1 (3.1%)	1 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Feelings and sensations NEC (cont)						
Chills	1 (1.6%)	2 (3.4%)	3 (2.5%)	0	0	0
Grade 1	1 (1.6%)	2 (3.4%)	3 (2.5%)	0	0	0
Grade 2	0	0	0	0	0	0
Early satiety	0	2 (3.4%)	2 (1.7%)	1 (2.2%)	0	1 (1.0%)
Grade 1	0	2 (3.4%)	2 (1.7%)	1 (2.2%)	0	1 (1.0%)
Feeling cold	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Feeling hot	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Gait disturbances	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Gait disturbance	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Healing abnormal NEC	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Impaired healing	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Implant and catheter site reactions	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Gait disturbances	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Gait disturbance	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Healing abnormal NEC	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 2	0	0	0	0	1 (1.9%)	1 (1.0%)
Impaired healing	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 2	0	0	0	0	1 (1.9%)	1 (1.0%)
Implant and catheter site reactions	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Implant and catheter site reactions (cont)						
Catheter site haemorrhage	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Catheter site pain	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)
Withdrawal and rebound effects	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Drug withdrawal syndrome	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Implant and catheter site reactions (cont)						
Catheter site haemorrhage	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0
Catheter site pain	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Withdrawal and rebound effects	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 2	0	0	0	0	1 (1.9%)	1 (1.0%)
Drug withdrawal syndrome	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 2	0	0	0	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations	7 (29.2%)	18 (50.0%)	25 (41.7%)	6 (31.6%)	14 (43.8%)	20 (39.2%)
Grade 1	4 (16.7%)	10 (27.8%)	14 (23.3%)	2 (10.5%)	4 (12.5%)	6 (11.8%)
Grade 2	2 (8.3%)	6 (16.7%)	8 (13.3%)	3 (15.8%)	9 (28.1%)	12 (23.5%)
Grade 3	1 (4.2%)	2 (5.6%)	3 (5.0%)	1 (5.3%)	1 (3.1%)	2 (3.9%)
Grade 4	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Urinary tract infections	0	0	0	1 (5.3%)	0	1 (2.0%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	1 (5.3%)	0	1 (2.0%)
Grade 3	0	0	0	0	0	0
Urinary tract infection	0	0	0	1 (5.3%)	0	1 (2.0%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	1 (5.3%)	0	1 (2.0%)
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations	30 (48.4%)	26 (44.8%)	56 (46.7%)	16 (35.6%)	19 (36.5%)	35 (36.1%)
Grade 1	12 (19.4%)	5 (8.6%)	17 (14.2%)	5 (11.1%)	4 (7.7%)	9 (9.3%)
Grade 2	8 (12.9%)	17 (29.3%)	25 (20.8%)	5 (11.1%)	11 (21.2%)	16 (16.5%)
Grade 3	8 (12.9%)	2 (3.4%)	10 (8.3%)	5 (11.1%)	4 (7.7%)	9 (9.3%)
Grade 4	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	0	0
Grade 5	1 (1.6%)	1 (1.7%)	2 (1.7%)	1 (2.2%)	0	1 (1.0%)
Urinary tract infections	10 (16.1%)	4 (6.9%)	14 (11.7%)	4 (8.9%)	4 (7.7%)	8 (8.2%)
Grade 1	3 (4.8%)	0	3 (2.5%)	0	0	0
Grade 2	6 (9.7%)	4 (6.9%)	10 (8.3%)	3 (6.7%)	4 (7.7%)	7 (7.2%)
Grade 3	1 (1.6%)	0	1 (0.8%)	1 (2.2%)	0	1 (1.0%)
Urinary tract infection	6 (9.7%)	4 (6.9%)	10 (8.3%)	3 (6.7%)	3 (5.8%)	6 (6.2%)
Grade 1	2 (3.2%)	0	2 (1.7%)	0	0	0
Grade 2	4 (6.5%)	4 (6.9%)	8 (6.7%)	2 (4.4%)	3 (5.8%)	5 (5.2%)
Grade 3	0	0	0	1 (2.2%)	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Urinary tract infections (cont)						
Cystitis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Pyelocystitis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Lower respiratory tract and lung infections	0	4 (11.1%)	4 (6.7%)	2 (10.5%)	3 (9.4%)	5 (9.8%)
Grade 1	0	2 (5.6%)	2 (3.3%)	0	0	0
Grade 2	0	2 (5.6%)	2 (3.3%)	1 (5.3%)	2 (6.3%)	3 (5.9%)
Grade 3	0	0	0	1 (5.3%)	1 (3.1%)	2 (3.9%)
Grade 4	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Urinary tract infections (cont)						
Cystitis	4 (6.5%)	0	4 (3.3%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	2 (3.2%)	0	2 (1.7%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 3	1 (1.6%)	0	1 (0.8%)	0	0	0
Pyelocystitis	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	1 (1.6%)	0	1 (0.8%)	0	0	0
Lower respiratory tract and lung infections	8 (12.9%)	6 (10.3%)	14 (11.7%)	4 (8.9%)	6 (11.5%)	10 (10.3%)
Grade 1	2 (3.2%)	0	2 (1.7%)	0	1 (1.9%)	1 (1.0%)
Grade 2	1 (1.6%)	3 (5.2%)	4 (3.3%)	1 (2.2%)	2 (3.8%)	3 (3.1%)
Grade 3	5 (8.1%)	1 (1.7%)	6 (5.0%)	2 (4.4%)	3 (5.8%)	5 (5.2%)
Grade 4	0	1 (1.7%)	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Lower respiratory tract and lung infections (cont)						
(cont)						
Grade 5	0	0	0	0	0	0
Pneumonia	0	1 (2.8%)	1 (1.7%)	2 (10.5%)	1 (3.1%)	3 (5.9%)
Grade 2	0	1 (2.8%)	1 (1.7%)	1 (5.3%)	0	1 (2.0%)
Grade 3	0	0	0	1 (5.3%)	1 (3.1%)	2 (3.9%)
Grade 4	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Lower respiratory tract infection	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Lower respiratory tract and lung infections (cont)						
(cont)						
Grade 5	0	1 (1.7%)	1 (0.8%)	1 (2.2%)	0	1 (1.0%)
Pneumonia	4 (6.5%)	4 (6.9%)	8 (6.7%)	2 (4.4%)	2 (3.8%)	4 (4.1%)
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 3	4 (6.5%)	1 (1.7%)	5 (4.2%)	1 (2.2%)	2 (3.8%)	3 (3.1%)
Grade 4	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 5	0	1 (1.7%)	1 (0.8%)	1 (2.2%)	0	1 (1.0%)
Lower respiratory tract infection	3 (4.8%)	0	3 (2.5%)	0	1 (1.9%)	1 (1.0%)
Grade 1	2 (3.2%)	0	2 (1.7%)	0	0	0
Grade 2	1 (1.6%)	0	1 (0.8%)	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Lower respiratory tract and lung infections (cont)						
Lung infection	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Bronchitis	0	1 (2.8%)	1 (1.7%)	0	2 (6.3%)	2 (3.9%)
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (2.8%)	1 (1.7%)	0	2 (6.3%)	2 (3.9%)
Grade 3	0	0	0	0	0	0
Tracheobronchitis	0	2 (5.6%)	2 (3.3%)	0	0	0
Grade 1	0	2 (5.6%)	2 (3.3%)	0	0	0
Upper respiratory tract infections	4 (16.7%)	7 (19.4%)	11 (18.3%)	3 (15.8%)	7 (21.9%)	10 (19.6%)
Grade 1	3 (12.5%)	3 (8.3%)	6 (10.0%)	1 (5.3%)	2 (6.3%)	3 (5.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Lower respiratory tract and lung infections (cont)						
Lung infection	1 (1.6%)	0	1 (0.8%)	1 (2.2%)	0	1 (1.0%)
Grade 3	1 (1.6%)	0	1 (0.8%)	1 (2.2%)	0	1 (1.0%)
Bronchitis	0	2 (3.4%)	2 (1.7%)	1 (2.2%)	3 (5.8%)	4 (4.1%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 2	0	2 (3.4%)	2 (1.7%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 3	0	0	0	0	1 (1.9%)	1 (1.0%)
Tracheobronchitis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Upper respiratory tract infections	4 (6.5%)	8 (13.8%)	12 (10.0%)	2 (4.4%)	5 (9.6%)	7 (7.2%)
Grade 1	4 (6.5%)	4 (6.9%)	8 (6.7%)	2 (4.4%)	3 (5.8%)	5 (5.2%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Upper respiratory tract infections (cont) (cont)						
Grade 2	1 (4.2%)	4 (11.1%)	5 (8.3%)	2 (10.5%)	5 (15.6%)	7 (13.7%)
Upper respiratory tract infection	2 (8.3%)	3 (8.3%)	5 (8.3%)	0	4 (12.5%)	4 (7.8%)
Grade 1	2 (8.3%)	0	2 (3.3%)	0	1 (3.1%)	1 (2.0%)
Grade 2	0	3 (8.3%)	3 (5.0%)	0	3 (9.4%)	3 (5.9%)
Nasopharyngitis	1 (4.2%)	3 (8.3%)	4 (6.7%)	2 (10.5%)	2 (6.3%)	4 (7.8%)
Grade 1	1 (4.2%)	2 (5.6%)	3 (5.0%)	1 (5.3%)	1 (3.1%)	2 (3.9%)
Grade 2	0	1 (2.8%)	1 (1.7%)	1 (5.3%)	1 (3.1%)	2 (3.9%)
Laryngitis	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 2	1 (4.2%)	0	1 (1.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Upper respiratory tract infections (cont) (cont) (cont)						
Grade 2	0	4 (6.9%)	4 (3.3%)	0	2 (3.8%)	2 (2.1%)
Upper respiratory tract infection	3 (4.8%)	3 (5.2%)	6 (5.0%)	1 (2.2%)	3 (5.8%)	4 (4.1%)
Grade 1	3 (4.8%)	0	3 (2.5%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 2	0	3 (5.2%)	3 (2.5%)	0	2 (3.8%)	2 (2.1%)
Nasopharyngitis	1 (1.6%)	2 (3.4%)	3 (2.5%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 1	1 (1.6%)	2 (3.4%)	3 (2.5%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 2	0	0	0	0	0	0
Laryngitis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Upper respiratory tract infections (cont)						
Rhinitis	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 1	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 2	0	0	0	0	0	0
Sinusitis	0	0	0	0	2 (6.3%)	2 (3.9%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	2 (6.3%)	2 (3.9%)
Tonsillitis	0	0	0	1 (5.3%)	1 (3.1%)	2 (3.9%)
Grade 1	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 2	0	0	0	1 (5.3%)	0	1 (2.0%)
Tracheitis	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Upper respiratory tract infections (cont)						
Rhinitis	0	2 (3.4%)	2 (1.7%)	0	0	0
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0
Sinusitis	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 2	0	0	0	0	0	0
Tonsillitis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Tracheitis	0	1 (1.7%)	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Upper respiratory tract infections (cont)						
Tracheitis (cont)						
Grade 1	0	0	0	0	0	0
Herpes viral infections	1 (4.2%)	3 (8.3%)	4 (6.7%)	1 (5.3%)	2 (6.3%)	3 (5.9%)
Grade 1	1 (4.2%)	1 (2.8%)	2 (3.3%)	0	0	0
Grade 2	0	1 (2.8%)	1 (1.7%)	1 (5.3%)	2 (6.3%)	3 (5.9%)
Grade 3	0	1 (2.8%)	1 (1.7%)	0	0	0
Herpes zoster	1 (4.2%)	1 (2.8%)	2 (3.3%)	1 (5.3%)	0	1 (2.0%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (5.3%)	0	1 (2.0%)
Grade 2	0	0	0	0	0	0
Grade 3	0	1 (2.8%)	1 (1.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Upper respiratory tract infections (cont)						
Tracheitis (cont)						
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0
Herpes viral infections	3 (4.8%)	5 (8.6%)	8 (6.7%)	2 (4.4%)	1 (1.9%)	3 (3.1%)
Grade 1	0	0	0	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 2	3 (4.8%)	5 (8.6%)	8 (6.7%)	1 (2.2%)	0	1 (1.0%)
Grade 3	0	0	0	0	0	0
Herpes zoster	2 (3.2%)	2 (3.4%)	4 (3.3%)	1 (2.2%)	0	1 (1.0%)
Grade 1	0	0	0	0	0	0
Grade 2	2 (3.2%)	2 (3.4%)	4 (3.3%)	1 (2.2%)	0	1 (1.0%)
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Herpes viral infections (cont)						
Oral herpes	0	2 (5.6%)	2 (3.3%)	0	0	0
Grade 1	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 2	0	1 (2.8%)	1 (1.7%)	0	0	0
Genital herpes	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Herpes simplex	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)
Nasal herpes	0	0	0	1 (5.3%)	0	1 (2.0%)
Grade 2	0	0	0	1 (5.3%)	0	1 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Herpes viral infections (cont)						
Oral herpes	1 (1.6%)	3 (5.2%)	4 (3.3%)	1 (2.2%)	0	1 (1.0%)
Grade 1	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 2	1 (1.6%)	3 (5.2%)	4 (3.3%)	0	0	0
Genital herpes	0	0	0	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 2	0	0	0	1 (2.2%)	0	1 (1.0%)
Herpes simplex	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Nasal herpes	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Herpes viral infections (cont)						
Varicella zoster virus infection	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)
Dental and oral soft tissue infections	2 (8.3%)	0	2 (3.3%)	0	1 (3.1%)	1 (2.0%)
Grade 1	2 (8.3%)	0	2 (3.3%)	0	1 (3.1%)	1 (2.0%)
Gingivitis	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 1	1 (4.2%)	0	1 (1.7%)	0	0	0
Lip infection	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 1	1 (4.2%)	0	1 (1.7%)	0	0	0
Periodontitis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Herpes viral infections (cont)						
Varicella zoster virus infection	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Dental and oral soft tissue infections	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	0	0
Grade 1	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	0	0
Gingivitis	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0
Lip infection	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Periodontitis	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Dental and oral soft tissue infections (cont)						
Tooth abscess	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	1 (3.1%)	1 (2.0%)
Infections NEC	1 (4.2%)	4 (11.1%)	5 (8.3%)	0	0	0
Grade 1	0	3 (8.3%)	3 (5.0%)	0	0	0
Grade 2	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 3	1 (4.2%)	0	1 (1.7%)	0	0	0
Infection	1 (4.2%)	1 (2.8%)	2 (3.3%)	0	0	0
Grade 1	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 3	1 (4.2%)	0	1 (1.7%)	0	0	0
Localised infection	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Dental and oral soft tissue infections (cont)						
Tooth abscess	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Infections NEC	2 (3.2%)	6 (10.3%)	8 (6.7%)	0	1 (1.9%)	1 (1.0%)
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	1 (1.6%)	6 (10.3%)	7 (5.8%)	0	1 (1.9%)	1 (1.0%)
Grade 3	0	0	0	0	0	0
Infection	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Localised infection	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Infections NEC (cont)						
Localised infection (cont)						
Grade 2	0	0	0	0	0	0
Respiratory tract infection	0	2 (5.6%)	2 (3.3%)	0	0	0
Grade 1	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 2	0	1 (2.8%)	1 (1.7%)	0	0	0
Postoperative wound infection	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 1	0	1 (2.8%)	1 (1.7%)	0	0	0
Wound infection	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Infections NEC (cont)						
Localised infection (cont)						
Grade 2	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	0	0
Respiratory tract infection	1 (1.6%)	4 (6.9%)	5 (4.2%)	0	1 (1.9%)	1 (1.0%)
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	0	4 (6.9%)	4 (3.3%)	0	1 (1.9%)	1 (1.0%)
Postoperative wound infection	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Wound infection	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Sepsis, bacteraemia, viraemia and fungaemia NEC	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Sepsis	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Pulmonary sepsis	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Sepsis, bacteraemia, viraemia and fungaemia NEC	3 (4.8%)	1 (1.7%)	4 (3.3%)	1 (2.2%)	0	1 (1.0%)
Grade 3	2 (3.2%)	1 (1.7%)	3 (2.5%)	1 (2.2%)	0	1 (1.0%)
Grade 5	1 (1.6%)	0	1 (0.8%)	0	0	0
Sepsis	3 (4.8%)	0	3 (2.5%)	1 (2.2%)	0	1 (1.0%)
Grade 3	2 (3.2%)	0	2 (1.7%)	1 (2.2%)	0	1 (1.0%)
Grade 5	1 (1.6%)	0	1 (0.8%)	0	0	0
Pulmonary sepsis	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 3	0	1 (1.7%)	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Skin structures and soft tissue infections	0	3 (8.3%)	3 (5.0%)	0	0	0
Grade 1	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 2	0	2 (5.6%)	2 (3.3%)	0	0	0
Grade 3	0	0	0	0	0	0
Skin infection	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 2	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 3	0	0	0	0	0	0
Folliculitis	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 2	0	1 (2.8%)	1 (1.7%)	0	0	0
Infected skin ulcer	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Skin structures and soft tissue infections	3 (4.8%)	0	3 (2.5%)	1 (2.2%)	0	1 (1.0%)
Grade 1	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 2	2 (3.2%)	0	2 (1.7%)	0	0	0
Grade 3	1 (1.6%)	0	1 (0.8%)	0	0	0
Skin infection	3 (4.8%)	0	3 (2.5%)	0	0	0
Grade 2	2 (3.2%)	0	2 (1.7%)	0	0	0
Grade 3	1 (1.6%)	0	1 (0.8%)	0	0	0
Folliculitis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Infected skin ulcer	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 1	0	0	0	1 (2.2%)	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Skin structures and soft tissue infections (cont)						
Paronychia	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 1	0	1 (2.8%)	1 (1.7%)	0	0	0
Abdominal and gastrointestinal infections	0	1 (2.8%)	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 3	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 4	0	0	0	0	0	0
Anal abscess	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Skin structures and soft tissue infections (cont)						
Paronychia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Abdominal and gastrointestinal infections	2 (3.2%)	2 (3.4%)	4 (3.3%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 3	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 4	0	1 (1.7%)	1 (0.8%)	0	0	0
Anal abscess	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 3	1 (1.6%)	0	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Abdominal and gastrointestinal infections (cont)						
Gastroenteritis	0	1 (2.8%)	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 3	0	1 (2.8%)	1 (1.7%)	0	0	0
Peritonitis	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Bacterial infections NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Cellulitis	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Abdominal and gastrointestinal infections (cont)						
Gastroenteritis	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 3	0	0	0	0	0	0
Peritonitis	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 4	0	1 (1.7%)	1 (0.8%)	0	0	0
Bacterial infections NEC	2 (3.2%)	0	2 (1.7%)	1 (2.2%)	0	1 (1.0%)
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 3	1 (1.6%)	0	1 (0.8%)	1 (2.2%)	0	1 (1.0%)
Cellulitis	1 (1.6%)	0	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Bacterial infections NEC (cont)						
Cellulitis (cont)						
Grade 1	0	0	0	0	0	0
Pneumonia bacterial	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Gangrene	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Fungal infections NEC	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 1	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 2	0	0	0	0	0	0
Fungal infection	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Bacterial infections NEC (cont)						
Cellulitis (cont)						
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Pneumonia bacterial	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 3	1 (1.6%)	0	1 (0.8%)	0	0	0
Gangrene	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 3	0	0	0	1 (2.2%)	0	1 (1.0%)
Fungal infections NEC	1 (1.6%)	1 (1.7%)	2 (1.7%)	1 (2.2%)	0	1 (1.0%)
Grade 1	1 (1.6%)	0	1 (0.8%)	1 (2.2%)	0	1 (1.0%)
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0
Fungal infection	1 (1.6%)	0	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Fungal infections NEC (cont)						
Fungal infection (cont)						
Grade 1	0	0	0	0	0	0
Fungal skin infection	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 1	1 (4.2%)	0	1 (1.7%)	0	0	0
Fungal oesophagitis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Borrelial infections	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Lyme disease	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Fungal infections NEC (cont)						
Fungal infection (cont)						
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Fungal skin infection	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 1	0	0	0	1 (2.2%)	0	1 (1.0%)
Fungal oesophagitis	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0
Borrelial infections	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Lyme disease	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Candida infections	0	1 (2.8%)	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Grade 1	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)
Oral candidiasis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Gastrointestinal candidiasis	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)
Vulvovaginal candidiasis	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 1	0	1 (2.8%)	1 (1.7%)	0	0	0
Escherichia infections	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Candida infections	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	0	0	0	0	0	0
Oral candidiasis	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Gastrointestinal candidiasis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Escherichia infections	1 (1.6%)	0	1 (0.8%)	1 (2.2%)	0	1 (1.0%)
Grade 1	0	0	0	1 (2.2%)	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Escherichia infections (cont)						
(cont)						
Grade 4	0	0	0	0	0	0
Escherichia sepsis	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Escherichia urinary tract infection	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Influenza viral infections	0	2 (5.6%)	2 (3.3%)	0	0	0
Grade 1	0	2 (5.6%)	2 (3.3%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Escherichia infections (cont)						
(cont)						
Grade 4	1 (1.6%)	0	1 (0.8%)	0	0	0
Escherichia sepsis	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 4	1 (1.6%)	0	1 (0.8%)	0	0	0
Escherichia urinary tract infection	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 1	0	0	0	1 (2.2%)	0	1 (1.0%)
Influenza viral infections	1 (1.6%)	2 (3.4%)	3 (2.5%)	0	1 (1.9%)	1 (1.0%)
Grade 1	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	0	0
Grade 2	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 3	0	1 (1.7%)	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase	DB Phase	DB Phase	OL Phase (Week 24 - 48) Continuing	OL Phase (Week 24 - 48) Switch	OL Phase (Week 24 - 48)
	MMB (N=24)	RUX (N=36)	Total (N=60)	(MMB->MMB) (N=19)	(RUX->MMB) (N=32)	Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Influenza viral infections (cont)						
Influenza	0	2 (5.6%)	2 (3.3%)	0	0	0
Grade 1	0	2 (5.6%)	2 (3.3%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Male reproductive tract infections	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 2	1 (4.2%)	0	1 (1.7%)	0	0	0
Scrotal abscess	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 2	1 (4.2%)	0	1 (1.7%)	0	0	0
Tinea infections	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 1	1 (4.2%)	0	1 (1.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Influenza viral infections (cont)						
Influenza	1 (1.6%)	2 (3.4%)	3 (2.5%)	0	1 (1.9%)	1 (1.0%)
Grade 1	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	0	0
Grade 2	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 3	0	1 (1.7%)	1 (0.8%)	0	0	0
Male reproductive tract infections	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Scrotal abscess	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Tinea infections	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Tinea infections (cont)						
Tinea versicolour	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 1	1 (4.2%)	0	1 (1.7%)	0	0	0
Bordetella infections	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	1 (3.1%)	1 (2.0%)
Pertussis	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	1 (3.1%)	1 (2.0%)
Clostridia infections	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Tinea infections (cont)						
Tinea versicolour	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Bordetella infections	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Pertussis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Clostridia infections	0	1 (1.7%)	1 (0.8%)	0	2 (3.8%)	2 (2.1%)
Grade 2	0	1 (1.7%)	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Grade 3	0	0	0	0	1 (1.9%)	1 (1.0%)
Clostridium difficile colitis	0	1 (1.7%)	1 (0.8%)	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Clostridia infections (cont)						
Clostridium difficile colitis (cont)						
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Ear infections	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Ear infection	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Clostridia infections (cont)						
Clostridium difficile colitis (cont)						
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 3	0	0	0	0	1 (1.9%)	1 (1.0%)
Clostridium difficile infection	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 2	0	0	0	0	1 (1.9%)	1 (1.0%)
Ear infections	0	0	0	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 1	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 2	0	0	0	0	1 (1.9%)	1 (1.0%)
Ear infection	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 1	0	0	0	1 (2.2%)	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Ear infections (cont)						
Labyrinthitis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Otitis externa	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Eye and eyelid infections	0	3 (8.3%)	3 (5.0%)	0	0	0
Grade 1	0	3 (8.3%)	3 (5.0%)	0	0	0
Conjunctivitis	0	2 (5.6%)	2 (3.3%)	0	0	0
Grade 1	0	2 (5.6%)	2 (3.3%)	0	0	0
Hordeolum	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 1	0	1 (2.8%)	1 (1.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Ear infections (cont)						
Labyrinthitis	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 1	0	0	0	1 (2.2%)	0	1 (1.0%)
Otitis externa	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 2	0	0	0	0	1 (1.9%)	1 (1.0%)
Eye and eyelid infections	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Conjunctivitis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hordeolum	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Streptococcal infections	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)
Erysipelas	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)
Viral infections NEC	0	0	0	1 (5.3%)	1 (3.1%)	2 (3.9%)
Grade 1	0	0	0	1 (5.3%)	0	1 (2.0%)
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)
Viral infection	0	0	0	1 (5.3%)	1 (3.1%)	2 (3.9%)
Grade 1	0	0	0	1 (5.3%)	0	1 (2.0%)
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)
Viral uveitis	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Streptococcal infections	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Erysipelas	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Viral infections NEC	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (1.9%)	1 (1.0%)
Viral infection	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Viral uveitis	0	0	0	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Viral infections NEC (cont)						
Viral uveitis (cont)						
Grade 2	0	0	0	0	0	0
Nervous system disorders	13 (54.2%)	10 (27.8%)	23 (38.3%)	2 (10.5%)	9 (28.1%)	11 (21.6%)
Grade 1	9 (37.5%)	6 (16.7%)	15 (25.0%)	1 (5.3%)	6 (18.8%)	7 (13.7%)
Grade 2	3 (12.5%)	4 (11.1%)	7 (11.7%)	1 (5.3%)	2 (6.3%)	3 (5.9%)
Grade 3	1 (4.2%)	0	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Grade 4	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Neurological signs and symptoms NEC	5 (20.8%)	3 (8.3%)	8 (13.3%)	1 (5.3%)	2 (6.3%)	3 (5.9%)
Grade 1	4 (16.7%)	3 (8.3%)	7 (11.7%)	1 (5.3%)	2 (6.3%)	3 (5.9%)
Grade 2	0	0	0	0	0	0
Grade 3	1 (4.2%)	0	1 (1.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Viral infections NEC (cont)						
Viral uveitis (cont)						
Grade 2	0	0	0	0	1 (1.9%)	1 (1.0%)
Nervous system disorders	23 (37.1%)	20 (34.5%)	43 (35.8%)	11 (24.4%)	14 (26.9%)	25 (25.8%)
Grade 1	14 (22.6%)	15 (25.9%)	29 (24.2%)	8 (17.8%)	8 (15.4%)	16 (16.5%)
Grade 2	7 (11.3%)	3 (5.2%)	10 (8.3%)	1 (2.2%)	2 (3.8%)	3 (3.1%)
Grade 3	2 (3.2%)	1 (1.7%)	3 (2.5%)	1 (2.2%)	4 (7.7%)	5 (5.2%)
Grade 4	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 5	0	1 (1.7%)	1 (0.8%)	0	0	0
Neurological signs and symptoms NEC	11 (17.7%)	7 (12.1%)	18 (15.0%)	4 (8.9%)	5 (9.6%)	9 (9.3%)
Grade 1	8 (12.9%)	5 (8.6%)	13 (10.8%)	4 (8.9%)	3 (5.8%)	7 (7.2%)
Grade 2	3 (4.8%)	1 (1.7%)	4 (3.3%)	0	1 (1.9%)	1 (1.0%)
Grade 3	0	1 (1.7%)	1 (0.8%)	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Neurological signs and symptoms NEC (cont)						
Dizziness	5 (20.8%)	3 (8.3%)	8 (13.3%)	1 (5.3%)	2 (6.3%)	3 (5.9%)
Grade 1	5 (20.8%)	3 (8.3%)	8 (13.3%)	1 (5.3%)	2 (6.3%)	3 (5.9%)
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Presyncope	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	1 (4.2%)	0	1 (1.7%)	0	0	0
Headaches NEC	6 (25.0%)	7 (19.4%)	13 (21.7%)	0	1 (3.1%)	1 (2.0%)
Grade 1	4 (16.7%)	5 (13.9%)	9 (15.0%)	0	0	0
Grade 2	2 (8.3%)	2 (5.6%)	4 (6.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Neurological signs and symptoms NEC (cont)						
Dizziness	10 (16.1%)	7 (12.1%)	17 (14.2%)	4 (8.9%)	5 (9.6%)	9 (9.3%)
Grade 1	8 (12.9%)	5 (8.6%)	13 (10.8%)	4 (8.9%)	3 (5.8%)	7 (7.2%)
Grade 2	2 (3.2%)	1 (1.7%)	3 (2.5%)	0	1 (1.9%)	1 (1.0%)
Grade 3	0	1 (1.7%)	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Presyncope	2 (3.2%)	0	2 (1.7%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 3	0	0	0	0	0	0
Headaches NEC	4 (6.5%)	8 (13.8%)	12 (10.0%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 1	3 (4.8%)	7 (12.1%)	10 (8.3%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 2	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Headaches NEC (cont)						
(cont)						
Grade 3	0	0	0	0	1 (3.1%)	1 (2.0%)
Headache	6 (25.0%)	7 (19.4%)	13 (21.7%)	0	1 (3.1%)	1 (2.0%)
Grade 1	4 (16.7%)	5 (13.9%)	9 (15.0%)	0	0	0
Grade 2	2 (8.3%)	2 (5.6%)	4 (6.7%)	0	0	0
Grade 3	0	0	0	0	1 (3.1%)	1 (2.0%)
Sinus headache	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Peripheral neuropathies NEC	5 (20.8%)	1 (2.8%)	6 (10.0%)	0	3 (9.4%)	3 (5.9%)
Grade 1	3 (12.5%)	1 (2.8%)	4 (6.7%)	0	2 (6.3%)	2 (3.9%)
Grade 2	2 (8.3%)	0	2 (3.3%)	0	1 (3.1%)	1 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Headaches NEC (cont)						
(cont)						
Grade 3	0	0	0	0	0	0
Headache	4 (6.5%)	8 (13.8%)	12 (10.0%)	1 (2.2%)	0	1 (1.0%)
Grade 1	3 (4.8%)	7 (12.1%)	10 (8.3%)	1 (2.2%)	0	1 (1.0%)
Grade 2	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	0	0
Grade 3	0	0	0	0	0	0
Sinus headache	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Peripheral neuropathies NEC	5 (8.1%)	4 (6.9%)	9 (7.5%)	2 (4.4%)	6 (11.5%)	8 (8.2%)
Grade 1	4 (6.5%)	3 (5.2%)	7 (5.8%)	1 (2.2%)	3 (5.8%)	4 (4.1%)
Grade 2	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Peripheral neuropathies NEC (cont)						
(cont)						
Grade 3	0	0	0	0	0	0
Peripheral sensory neuropathy	5 (20.8%)	1 (2.8%)	6 (10.0%)	0	3 (9.4%)	3 (5.9%)
Grade 1	3 (12.5%)	1 (2.8%)	4 (6.7%)	0	2 (6.3%)	2 (3.9%)
Grade 2	2 (8.3%)	0	2 (3.3%)	0	1 (3.1%)	1 (2.0%)
Grade 3	0	0	0	0	0	0
Peripheral sensorimotor neuropathy	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Paraesthesias and dysaesthesias	3 (12.5%)	1 (2.8%)	4 (6.7%)	1 (5.3%)	2 (6.3%)	3 (5.9%)
Grade 1	3 (12.5%)	1 (2.8%)	4 (6.7%)	0	2 (6.3%)	2 (3.9%)
Grade 2	0	0	0	1 (5.3%)	0	1 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Peripheral neuropathies NEC (cont)						
(cont)						
Grade 3	0	0	0	1 (2.2%)	2 (3.8%)	3 (3.1%)
Peripheral sensory neuropathy	5 (8.1%)	4 (6.9%)	9 (7.5%)	1 (2.2%)	6 (11.5%)	7 (7.2%)
Grade 1	4 (6.5%)	3 (5.2%)	7 (5.8%)	1 (2.2%)	3 (5.8%)	4 (4.1%)
Grade 2	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	1 (1.9%)	1 (1.0%)
Grade 3	0	0	0	0	2 (3.8%)	2 (2.1%)
Peripheral sensorimotor neuropathy	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 3	0	0	0	1 (2.2%)	0	1 (1.0%)
Paraesthesias and dysaesthesias	4 (6.5%)	2 (3.4%)	6 (5.0%)	3 (6.7%)	2 (3.8%)	5 (5.2%)
Grade 1	4 (6.5%)	2 (3.4%)	6 (5.0%)	3 (6.7%)	1 (1.9%)	4 (4.1%)
Grade 2	0	0	0	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Paraesthesias and dysaesthesias (cont)						
Paraesthesia	3 (12.5%)	1 (2.8%)	4 (6.7%)	0	2 (6.3%)	2 (3.9%)
Grade 1	3 (12.5%)	1 (2.8%)	4 (6.7%)	0	2 (6.3%)	2 (3.9%)
Grade 2	0	0	0	0	0	0
Dysaesthesia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hypoaesthesia	0	0	0	1 (5.3%)	1 (3.1%)	2 (3.9%)
Grade 1	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 2	0	0	0	1 (5.3%)	0	1 (2.0%)
Disturbances in consciousness NEC	0	1 (2.8%)	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 2	0	1 (2.8%)	1 (1.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Paraesthesias and dysaesthesias (cont)						
Paraesthesia	4 (6.5%)	2 (3.4%)	6 (5.0%)	2 (4.4%)	1 (1.9%)	3 (3.1%)
Grade 1	4 (6.5%)	2 (3.4%)	6 (5.0%)	2 (4.4%)	0	2 (2.1%)
Grade 2	0	0	0	0	1 (1.9%)	1 (1.0%)
Dysaesthesia	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Hypoaesthesia	0	0	0	2 (4.4%)	0	2 (2.1%)
Grade 1	0	0	0	2 (4.4%)	0	2 (2.1%)
Grade 2	0	0	0	0	0	0
Disturbances in consciousness NEC	4 (6.5%)	0	4 (3.3%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	1 (1.6%)	0	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Disturbances in consciousness NEC (cont)						
(cont)						
Grade 3	0	0	0	0	0	0
Syncope	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Lethargy	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 2	0	1 (2.8%)	1 (1.7%)	0	0	0
Somnolence	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	1 (3.1%)	1 (2.0%)
Coordination and balance disturbances	1 (4.2%)	0	1 (1.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Disturbances in consciousness NEC (cont)						
(cont)						
Grade 3	2 (3.2%)	0	2 (1.7%)	0	0	0
Syncope	2 (3.2%)	0	2 (1.7%)	0	0	0
Grade 3	2 (3.2%)	0	2 (1.7%)	0	0	0
Lethargy	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	1 (1.6%)	0	1 (0.8%)	0	0	0
Somnolence	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Coordination and balance disturbances	1 (1.6%)	0	1 (0.8%)	1 (2.2%)	2 (3.8%)	3 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Coordination and balance disturbances (cont)						
(cont)						
Grade 1	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 2	0	0	0	0	0	0
Balance disorder	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 1	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 2	0	0	0	0	0	0
Ataxia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Memory loss (excl dementia)	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 1	0	1 (2.8%)	1 (1.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Coordination and balance disturbances (cont)						
(cont)						
Grade 1	1 (1.6%)	0	1 (0.8%)	0	2 (3.8%)	2 (2.1%)
Grade 2	0	0	0	1 (2.2%)	0	1 (1.0%)
Balance disorder	1 (1.6%)	0	1 (0.8%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 1	1 (1.6%)	0	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Grade 2	0	0	0	1 (2.2%)	0	1 (1.0%)
Ataxia	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Memory loss (excl dementia)	2 (3.2%)	0	2 (1.7%)	0	1 (1.9%)	1 (1.0%)
Grade 1	2 (3.2%)	0	2 (1.7%)	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Memory loss (excl dementia) (cont)						
Amnesia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Memory impairment	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 1	0	1 (2.8%)	1 (1.7%)	0	0	0
Sensory abnormalities NEC	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 2	0	0	0	0	0	0
Taste disorder	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Ageusia	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Memory loss (excl dementia) (cont)						
Amnesia	1 (1.6%)	0	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Grade 1	1 (1.6%)	0	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Memory impairment	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Sensory abnormalities NEC	2 (3.2%)	1 (1.7%)	3 (2.5%)	0	1 (1.9%)	1 (1.0%)
Grade 1	2 (3.2%)	0	2 (1.7%)	0	1 (1.9%)	1 (1.0%)
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0
Taste disorder	2 (3.2%)	0	2 (1.7%)	0	0	0
Grade 1	2 (3.2%)	0	2 (1.7%)	0	0	0
Ageusia	0	0	0	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Sensory abnormalities NEC (cont)						
Ageusia (cont)						
Grade 1	0	0	0	0	0	0
Dysgeusia	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	1 (3.1%)	1 (2.0%)
Post herpetic neuralgia	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Central nervous system haemorrhages and cerebrovascular accidents	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Sensory abnormalities NEC (cont)						
Ageusia (cont)						
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Dysgeusia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Post herpetic neuralgia	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0
Central nervous system haemorrhages and cerebrovascular accidents	1 (1.6%)	0	1 (0.8%)	1 (2.2%)	0	1 (1.0%)
Grade 2	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 4	0	0	0	1 (2.2%)	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Central nervous system haemorrhages and cerebrovascular accidents (cont)						
Cerebral ischaemia	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Cerebrovascular accident	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Tremor (excl congenital)	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Tremor	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Central nervous system haemorrhages and cerebrovascular accidents (cont)						
Cerebral ischaemia	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	1 (1.6%)	0	1 (0.8%)	0	0	0
Cerebrovascular accident	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 4	0	0	0	1 (2.2%)	0	1 (1.0%)
Tremor (excl congenital)	1 (1.6%)	1 (1.7%)	2 (1.7%)	1 (2.2%)	0	1 (1.0%)
Grade 1	1 (1.6%)	1 (1.7%)	2 (1.7%)	1 (2.2%)	0	1 (1.0%)
Tremor	1 (1.6%)	1 (1.7%)	2 (1.7%)	1 (2.2%)	0	1 (1.0%)
Grade 1	1 (1.6%)	1 (1.7%)	2 (1.7%)	1 (2.2%)	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Central nervous system vascular disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Cerebral microangiopathy	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Coma states	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Coma	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Demyelinating disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Central nervous system vascular disorders NEC	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 1	0	0	0	1 (2.2%)	0	1 (1.0%)
Cerebral microangiopathy	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 1	0	0	0	1 (2.2%)	0	1 (1.0%)
Coma states	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 5	0	1 (1.7%)	1 (0.8%)	0	0	0
Coma	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 5	0	1 (1.7%)	1 (0.8%)	0	0	0
Demyelinating disorders NEC	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Demyelinating disorders NEC (cont)						
Demyelination	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Encephalopathies NEC	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Encephalopathy	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Lumbar spinal cord and nerve root disorders	0	1 (2.8%)	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Grade 2	0	1 (2.8%)	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Sciatica	0	1 (2.8%)	1 (1.7%)	0	1 (3.1%)	1 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Demyelinating disorders NEC (cont)						
Demyelination	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Encephalopathies NEC	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 4	0	1 (1.7%)	1 (0.8%)	0	0	0
Encephalopathy	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 4	0	1 (1.7%)	1 (0.8%)	0	0	0
Lumbar spinal cord and nerve root disorders	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Sciatica	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Lumbar spinal cord and nerve root disorders (cont)						
Sciatica (cont)						
Grade 2	0	1 (2.8%)	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Transient cerebrovascular events	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Transient ischaemic attack	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Lumbar spinal cord and nerve root disorders (cont)						
Sciatica (cont)						
Grade 2	0	0	0	0	0	0
Transient cerebrovascular events	0	1 (1.7%)	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 3	0	0	0	0	1 (1.9%)	1 (1.0%)
Transient ischaemic attack	0	1 (1.7%)	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 3	0	0	0	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders	11 (45.8%)	23 (63.9%)	34 (56.7%)	3 (15.8%)	9 (28.1%)	12 (23.5%)
Grade 1	1 (4.2%)	4 (11.1%)	5 (8.3%)	0	0	0
Grade 2	4 (16.7%)	2 (5.6%)	6 (10.0%)	0	3 (9.4%)	3 (5.9%)
Grade 3	5 (20.8%)	12 (33.3%)	17 (28.3%)	3 (15.8%)	4 (12.5%)	7 (13.7%)
Grade 4	1 (4.2%)	5 (13.9%)	6 (10.0%)	0	2 (6.3%)	2 (3.9%)
Grade 5	0	0	0	0	0	0
Thrombocytopenias	5 (20.8%)	12 (33.3%)	17 (28.3%)	0	5 (15.6%)	5 (9.8%)
Grade 1	1 (4.2%)	5 (13.9%)	6 (10.0%)	0	0	0
Grade 2	3 (12.5%)	1 (2.8%)	4 (6.7%)	0	2 (6.3%)	2 (3.9%)
Grade 3	0	4 (11.1%)	4 (6.7%)	0	1 (3.1%)	1 (2.0%)
Grade 4	1 (4.2%)	2 (5.6%)	3 (5.0%)	0	2 (6.3%)	2 (3.9%)
Thrombocytopenia	5 (20.8%)	12 (33.3%)	17 (28.3%)	0	5 (15.6%)	5 (9.8%)
Grade 1	1 (4.2%)	5 (13.9%)	6 (10.0%)	0	0	0
Grade 2	3 (12.5%)	1 (2.8%)	4 (6.7%)	0	2 (6.3%)	2 (3.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders	24 (38.7%)	35 (60.3%)	59 (49.2%)	7 (15.6%)	14 (26.9%)	21 (21.6%)
Grade 1	6 (9.7%)	4 (6.9%)	10 (8.3%)	3 (6.7%)	3 (5.8%)	6 (6.2%)
Grade 2	5 (8.1%)	15 (25.9%)	20 (16.7%)	0	4 (7.7%)	4 (4.1%)
Grade 3	11 (17.7%)	12 (20.7%)	23 (19.2%)	3 (6.7%)	6 (11.5%)	9 (9.3%)
Grade 4	2 (3.2%)	4 (6.9%)	6 (5.0%)	1 (2.2%)	0	1 (1.0%)
Grade 5	0	0	0	0	1 (1.9%)	1 (1.0%)
Thrombocytopenias	14 (22.6%)	20 (34.5%)	34 (28.3%)	7 (15.6%)	6 (11.5%)	13 (13.4%)
Grade 1	3 (4.8%)	8 (13.8%)	11 (9.2%)	3 (6.7%)	1 (1.9%)	4 (4.1%)
Grade 2	3 (4.8%)	12 (20.7%)	15 (12.5%)	0	3 (5.8%)	3 (3.1%)
Grade 3	6 (9.7%)	0	6 (5.0%)	4 (8.9%)	2 (3.8%)	6 (6.2%)
Grade 4	2 (3.2%)	0	2 (1.7%)	0	0	0
Thrombocytopenia	14 (22.6%)	20 (34.5%)	34 (28.3%)	7 (15.6%)	6 (11.5%)	13 (13.4%)
Grade 1	3 (4.8%)	8 (13.8%)	11 (9.2%)	3 (6.7%)	1 (1.9%)	4 (4.1%)
Grade 2	3 (4.8%)	12 (20.7%)	15 (12.5%)	0	3 (5.8%)	3 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Thrombocytopenias (cont)						
Thrombocytopenia (cont)						
Grade 3	0	4 (11.1%)	4 (6.7%)	0	1 (3.1%)	1 (2.0%)
Grade 4	1 (4.2%)	2 (5.6%)	3 (5.0%)	0	2 (6.3%)	2 (3.9%)
Anaemias NEC	4 (16.7%)	15 (41.7%)	19 (31.7%)	1 (5.3%)	4 (12.5%)	5 (9.8%)
Grade 1	0	2 (5.6%)	2 (3.3%)	0	0	0
Grade 2	1 (4.2%)	1 (2.8%)	2 (3.3%)	0	2 (6.3%)	2 (3.9%)
Grade 3	3 (12.5%)	10 (27.8%)	13 (21.7%)	1 (5.3%)	2 (6.3%)	3 (5.9%)
Grade 4	0	2 (5.6%)	2 (3.3%)	0	0	0
Anaemia	4 (16.7%)	15 (41.7%)	19 (31.7%)	1 (5.3%)	4 (12.5%)	5 (9.8%)
Grade 1	0	2 (5.6%)	2 (3.3%)	0	0	0
Grade 2	1 (4.2%)	1 (2.8%)	2 (3.3%)	0	2 (6.3%)	2 (3.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Thrombocytopenias (cont)						
Thrombocytopenia (cont)						
Grade 3	6 (9.7%)	0	6 (5.0%)	4 (8.9%)	2 (3.8%)	6 (6.2%)
Grade 4	2 (3.2%)	0	2 (1.7%)	0	0	0
Anaemias NEC	10 (16.1%)	21 (36.2%)	31 (25.8%)	1 (2.2%)	4 (7.7%)	5 (5.2%)
Grade 1	0	1 (1.7%)	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Grade 2	3 (4.8%)	6 (10.3%)	9 (7.5%)	0	1 (1.9%)	1 (1.0%)
Grade 3	7 (11.3%)	11 (19.0%)	18 (15.0%)	0	2 (3.8%)	2 (2.1%)
Grade 4	0	3 (5.2%)	3 (2.5%)	1 (2.2%)	0	1 (1.0%)
Anaemia	10 (16.1%)	21 (36.2%)	31 (25.8%)	1 (2.2%)	4 (7.7%)	5 (5.2%)
Grade 1	0	1 (1.7%)	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Grade 2	3 (4.8%)	6 (10.3%)	9 (7.5%)	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Anaemias NEC (cont)						
Anaemia (cont)						
Grade 3	3 (12.5%)	10 (27.8%)	13 (21.7%)	1 (5.3%)	2 (6.3%)	3 (5.9%)
Grade 4	0	2 (5.6%)	2 (3.3%)	0	0	0
Neutropenias	3 (12.5%)	5 (13.9%)	8 (13.3%)	1 (5.3%)	1 (3.1%)	2 (3.9%)
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 3	3 (12.5%)	2 (5.6%)	5 (8.3%)	1 (5.3%)	1 (3.1%)	2 (3.9%)
Grade 4	0	2 (5.6%)	2 (3.3%)	0	0	0
Neutropenia	2 (8.3%)	5 (13.9%)	7 (11.7%)	1 (5.3%)	1 (3.1%)	2 (3.9%)
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (2.8%)	1 (1.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Anaemias NEC (cont)						
Anaemia (cont)						
Grade 3	7 (11.3%)	11 (19.0%)	18 (15.0%)	0	2 (3.8%)	2 (2.1%)
Grade 4	0	3 (5.2%)	3 (2.5%)	1 (2.2%)	0	1 (1.0%)
Neutropenias	2 (3.2%)	4 (6.9%)	6 (5.0%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 1	1 (1.6%)	0	1 (0.8%)	1 (2.2%)	0	1 (1.0%)
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 3	0	2 (3.4%)	2 (1.7%)	0	1 (1.9%)	1 (1.0%)
Grade 4	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	0	0
Neutropenia	2 (3.2%)	4 (6.9%)	6 (5.0%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 1	1 (1.6%)	0	1 (0.8%)	1 (2.2%)	0	1 (1.0%)
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Neutropenias (cont)						
Neutropenia (cont)						
Grade 3	2 (8.3%)	2 (5.6%)	4 (6.7%)	1 (5.3%)	1 (3.1%)	2 (3.9%)
Grade 4	0	2 (5.6%)	2 (3.3%)	0	0	0
Febrile neutropenia	1 (4.2%)	0	1 (1.7%)	1 (5.3%)	0	1 (2.0%)
Grade 3	1 (4.2%)	0	1 (1.7%)	1 (5.3%)	0	1 (2.0%)
Leukopenias NEC	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	1 (4.2%)	0	1 (1.7%)	0	0	0
Leukopenia	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Neutropenias (cont)						
Neutropenia (cont)						
Grade 3	0	2 (3.4%)	2 (1.7%)	0	1 (1.9%)	1 (1.0%)
Grade 4	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	0	0
Febrile neutropenia	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Leukopenias NEC	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	0	0
Grade 1	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	0	0
Grade 3	0	0	0	0	0	0
Leukopenia	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	0	0
Grade 1	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Leukopenias NEC (cont)						
Leukopenia (cont)						
Grade 3	1 (4.2%)	0	1 (1.7%)	0	0	0
Bleeding tendencies	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	1 (3.1%)	1 (2.0%)
Increased tendency to bruise	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	1 (3.1%)	1 (2.0%)
Coagulation factor deficiencies	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 2	1 (4.2%)	0	1 (1.7%)	0	0	0
Hypoprothrombinaemia	1 (4.2%)	0	1 (1.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Leukopenias NEC (cont)						
Leukopenia (cont)						
Grade 3	0	0	0	0	0	0
Bleeding tendencies	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Increased tendency to bruise	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Coagulation factor deficiencies	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Hypoprothrombinaemia	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Coagulation factor deficiencies (cont)						
Hypoprothrombinaemia (cont)						
Grade 2	1 (4.2%)	0	1 (1.7%)	0	0	0
Leukocytoses NEC	0	0	0	1 (5.3%)	0	1 (2.0%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	1 (5.3%)	0	1 (2.0%)
Leukocytosis	0	0	0	1 (5.3%)	0	1 (2.0%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	1 (5.3%)	0	1 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Coagulation factor deficiencies (cont)						
Hypoprothrombinaemia (cont)						
Grade 2	0	0	0	0	0	0
Leukocytoses NEC	1 (1.6%)	0	1 (0.8%)	0	2 (3.8%)	2 (2.1%)
Grade 1	1 (1.6%)	0	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Grade 2	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 3	0	0	0	0	0	0
Leukocytosis	1 (1.6%)	0	1 (0.8%)	0	2 (3.8%)	2 (2.1%)
Grade 1	1 (1.6%)	0	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Grade 2	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Leukocytoses NEC (cont)						
Neutrophilia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Spleen disorders	0	0	0	1 (5.3%)	0	1 (2.0%)
Grade 3	0	0	0	1 (5.3%)	0	1 (2.0%)
Grade 5	0	0	0	0	0	0
Splenomegaly	0	0	0	1 (5.3%)	0	1 (2.0%)
Grade 3	0	0	0	1 (5.3%)	0	1 (2.0%)
Splenic haematoma	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Leukocytoses NEC (cont)						
Neutrophilia	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Spleen disorders	1 (1.6%)	0	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Grade 3	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 5	0	0	0	0	1 (1.9%)	1 (1.0%)
Splenomegaly	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 3	1 (1.6%)	0	1 (0.8%)	0	0	0
Splenic haematoma	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 5	0	0	0	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Thrombocytoses	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Thrombocytosis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Thrombocytoses	0	1 (1.7%)	1 (0.8%)	0	2 (3.8%)	2 (2.1%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 3	0	0	0	0	1 (1.9%)	1 (1.0%)
Thrombocytosis	0	1 (1.7%)	1 (0.8%)	0	2 (3.8%)	2 (2.1%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 3	0	0	0	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders	6 (25.0%)	12 (33.3%)	18 (30.0%)	4 (21.1%)	9 (28.1%)	13 (25.5%)
Grade 1	5 (20.8%)	8 (22.2%)	13 (21.7%)	2 (10.5%)	5 (15.6%)	7 (13.7%)
Grade 2	1 (4.2%)	4 (11.1%)	5 (8.3%)	2 (10.5%)	3 (9.4%)	5 (9.8%)
Grade 3	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 4	0	0	0	0	0	0
Breathing abnormalities	2 (8.3%)	4 (11.1%)	6 (10.0%)	0	2 (6.3%)	2 (3.9%)
Grade 1	2 (8.3%)	1 (2.8%)	3 (5.0%)	0	1 (3.1%)	1 (2.0%)
Grade 2	0	3 (8.3%)	3 (5.0%)	0	0	0
Grade 3	0	0	0	0	1 (3.1%)	1 (2.0%)
Dyspnoea	1 (4.2%)	2 (5.6%)	3 (5.0%)	0	2 (6.3%)	2 (3.9%)
Grade 1	1 (4.2%)	0	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Grade 2	0	2 (5.6%)	2 (3.3%)	0	0	0
Grade 3	0	0	0	0	1 (3.1%)	1 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders	26 (41.9%)	15 (25.9%)	41 (34.2%)	10 (22.2%)	10 (19.2%)	20 (20.6%)
Grade 1	18 (29.0%)	9 (15.5%)	27 (22.5%)	6 (13.3%)	5 (9.6%)	11 (11.3%)
Grade 2	4 (6.5%)	4 (6.9%)	8 (6.7%)	4 (8.9%)	4 (7.7%)	8 (8.2%)
Grade 3	2 (3.2%)	1 (1.7%)	3 (2.5%)	0	1 (1.9%)	1 (1.0%)
Grade 4	2 (3.2%)	1 (1.7%)	3 (2.5%)	0	0	0
Breathing abnormalities	14 (22.6%)	7 (12.1%)	21 (17.5%)	0	2 (3.8%)	2 (2.1%)
Grade 1	12 (19.4%)	3 (5.2%)	15 (12.5%)	0	0	0
Grade 2	2 (3.2%)	3 (5.2%)	5 (4.2%)	0	1 (1.9%)	1 (1.0%)
Grade 3	0	1 (1.7%)	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Dyspnoea	10 (16.1%)	6 (10.3%)	16 (13.3%)	0	2 (3.8%)	2 (2.1%)
Grade 1	8 (12.9%)	2 (3.4%)	10 (8.3%)	0	0	0
Grade 2	2 (3.2%)	3 (5.2%)	5 (4.2%)	0	1 (1.9%)	1 (1.0%)
Grade 3	0	1 (1.7%)	1 (0.8%)	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Breathing abnormalities (cont)						
Dyspnoea exertional	1 (4.2%)	2 (5.6%)	3 (5.0%)	0	0	0
Grade 1	1 (4.2%)	1 (2.8%)	2 (3.3%)	0	0	0
Grade 2	0	1 (2.8%)	1 (1.7%)	0	0	0
Coughing and associated symptoms	5 (20.8%)	4 (11.1%)	9 (15.0%)	1 (5.3%)	5 (15.6%)	6 (11.8%)
Grade 1	4 (16.7%)	4 (11.1%)	8 (13.3%)	1 (5.3%)	3 (9.4%)	4 (7.8%)
Grade 2	1 (4.2%)	0	1 (1.7%)	0	2 (6.3%)	2 (3.9%)
Cough	5 (20.8%)	4 (11.1%)	9 (15.0%)	1 (5.3%)	5 (15.6%)	6 (11.8%)
Grade 1	4 (16.7%)	4 (11.1%)	8 (13.3%)	1 (5.3%)	3 (9.4%)	4 (7.8%)
Grade 2	1 (4.2%)	0	1 (1.7%)	0	2 (6.3%)	2 (3.9%)
Haemoptysis	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Breathing abnormalities (cont)						
Dyspnoea exertional	4 (6.5%)	2 (3.4%)	6 (5.0%)	0	0	0
Grade 1	4 (6.5%)	2 (3.4%)	6 (5.0%)	0	0	0
Grade 2	0	0	0	0	0	0
Coughing and associated symptoms	8 (12.9%)	6 (10.3%)	14 (11.7%)	7 (15.6%)	5 (9.6%)	12 (12.4%)
Grade 1	6 (9.7%)	5 (8.6%)	11 (9.2%)	5 (11.1%)	4 (7.7%)	9 (9.3%)
Grade 2	2 (3.2%)	1 (1.7%)	3 (2.5%)	2 (4.4%)	1 (1.9%)	3 (3.1%)
Cough	7 (11.3%)	5 (8.6%)	12 (10.0%)	6 (13.3%)	5 (9.6%)	11 (11.3%)
Grade 1	6 (9.7%)	4 (6.9%)	10 (8.3%)	5 (11.1%)	4 (7.7%)	9 (9.3%)
Grade 2	1 (1.6%)	1 (1.7%)	2 (1.7%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Haemoptysis	1 (1.6%)	0	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Coughing and associated symptoms (cont)						
Haemoptysis (cont)						
Grade 2	0	0	0	0	0	0
Productive cough	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Nasal disorders NEC	1 (4.2%)	4 (11.1%)	5 (8.3%)	2 (10.5%)	1 (3.1%)	3 (5.9%)
Grade 1	1 (4.2%)	2 (5.6%)	3 (5.0%)	1 (5.3%)	0	1 (2.0%)
Grade 2	0	2 (5.6%)	2 (3.3%)	1 (5.3%)	1 (3.1%)	2 (3.9%)
Epistaxis	1 (4.2%)	4 (11.1%)	5 (8.3%)	2 (10.5%)	1 (3.1%)	3 (5.9%)
Grade 1	1 (4.2%)	2 (5.6%)	3 (5.0%)	1 (5.3%)	0	1 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Coughing and associated symptoms (cont)						
Haemoptysis (cont)						
Grade 2	1 (1.6%)	0	1 (0.8%)	0	0	0
Productive cough	1 (1.6%)	1 (1.7%)	2 (1.7%)	1 (2.2%)	0	1 (1.0%)
Grade 1	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	0	0
Grade 2	0	0	0	1 (2.2%)	0	1 (1.0%)
Nasal disorders NEC	3 (4.8%)	1 (1.7%)	4 (3.3%)	2 (4.4%)	1 (1.9%)	3 (3.1%)
Grade 1	1 (1.6%)	1 (1.7%)	2 (1.7%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 2	2 (3.2%)	0	2 (1.7%)	1 (2.2%)	0	1 (1.0%)
Epistaxis	3 (4.8%)	1 (1.7%)	4 (3.3%)	2 (4.4%)	1 (1.9%)	3 (3.1%)
Grade 1	1 (1.6%)	1 (1.7%)	2 (1.7%)	1 (2.2%)	1 (1.9%)	2 (2.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Nasal disorders NEC (cont)						
Epistaxis (cont)						
Grade 2	0	2 (5.6%)	2 (3.3%)	1 (5.3%)	1 (3.1%)	2 (3.9%)
Upper respiratory tract signs and symptoms	0	2 (5.6%)	2 (3.3%)	0	1 (3.1%)	1 (2.0%)
Grade 1	0	2 (5.6%)	2 (3.3%)	0	1 (3.1%)	1 (2.0%)
Grade 2	0	0	0	0	0	0
Dysphonia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Rhinorrhoea	0	1 (2.8%)	1 (1.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Nasal disorders NEC (cont)						
Epistaxis (cont)						
Grade 2	2 (3.2%)	0	2 (1.7%)	1 (2.2%)	0	1 (1.0%)
Upper respiratory tract signs and symptoms	4 (6.5%)	1 (1.7%)	5 (4.2%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 1	4 (6.5%)	1 (1.7%)	5 (4.2%)	1 (2.2%)	0	1 (1.0%)
Grade 2	0	0	0	0	1 (1.9%)	1 (1.0%)
Dysphonia	2 (3.2%)	0	2 (1.7%)	0	1 (1.9%)	1 (1.0%)
Grade 1	2 (3.2%)	0	2 (1.7%)	0	0	0
Grade 2	0	0	0	0	1 (1.9%)	1 (1.0%)
Rhinorrhoea	1 (1.6%)	0	1 (0.8%)	1 (2.2%)	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Upper respiratory tract signs and symptoms (cont)						
Rhinorrhoea (cont)						
Grade 1	0	1 (2.8%)	1 (1.7%)	0	0	0
Throat tightness	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Catarrh	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 1	0	1 (2.8%)	1 (1.7%)	0	0	0
Oropharyngeal pain	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	1 (3.1%)	1 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Upper respiratory tract signs and symptoms (cont)						
Rhinorrhoea (cont)						
Grade 1	1 (1.6%)	0	1 (0.8%)	1 (2.2%)	0	1 (1.0%)
Throat tightness	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Catarrh	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Oropharyngeal pain	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Lower respiratory tract signs and symptoms	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 1	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 2	0	0	0	0	0	0
Rales	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Hiccups	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 1	0	1 (2.8%)	1 (1.7%)	0	0	0
Bronchospasm and obstruction	0	0	0	1 (5.3%)	0	1 (2.0%)
Grade 1	0	0	0	1 (5.3%)	0	1 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Lower respiratory tract signs and symptoms	2 (3.2%)	0	2 (1.7%)	1 (2.2%)	0	1 (1.0%)
Grade 1	1 (1.6%)	0	1 (0.8%)	1 (2.2%)	0	1 (1.0%)
Grade 2	1 (1.6%)	0	1 (0.8%)	0	0	0
Rales	2 (3.2%)	0	2 (1.7%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	1 (1.6%)	0	1 (0.8%)	0	0	0
Hiccups	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 1	0	0	0	1 (2.2%)	0	1 (1.0%)
Bronchospasm and obstruction	1 (1.6%)	0	1 (0.8%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 1	0	0	0	1 (2.2%)	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
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Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Bronchospasm and obstruction (cont) (cont)						
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Chronic obstructive pulmonary disease	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Bronchitis chronic	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Wheezing	0	0	0	1 (5.3%)	0	1 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Bronchospasm and obstruction (cont) (cont)						
Grade 2	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 3	1 (1.6%)	0	1 (0.8%)	0	0	0
Chronic obstructive pulmonary disease	1 (1.6%)	0	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Grade 2	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 3	1 (1.6%)	0	1 (0.8%)	0	0	0
Bronchitis chronic	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 1	0	0	0	1 (2.2%)	0	1 (1.0%)
Wheezing	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Bronchospasm and obstruction (cont)						
Wheezing (cont)						
Grade 1	0	0	0	1 (5.3%)	0	1 (2.0%)
Conditions associated with abnormal gas exchange	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Hypoxia	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Bronchospasm and obstruction (cont)						
Wheezing (cont)						
Grade 1	0	0	0	0	0	0
Conditions associated with abnormal gas exchange	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 4	1 (1.6%)	0	1 (0.8%)	0	0	0
Hypoxia	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 4	1 (1.6%)	0	1 (0.8%)	0	0	0
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	1 (1.6%)	0	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms) (cont)						
Reflux laryngitis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Laryngeal inflammation	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)
Lower respiratory tract inflammatory and immunologic conditions	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Pneumonia aspiration	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms) (cont)						
Reflux laryngitis	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	1 (1.6%)	0	1 (0.8%)	0	0	0
Laryngeal inflammation	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Lower respiratory tract inflammatory and immunologic conditions	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 3	1 (1.6%)	0	1 (0.8%)	0	0	0
Pneumonia aspiration	1 (1.6%)	0	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Lower respiratory tract inflammatory and immunologic conditions (cont)						
Pneumonia aspiration (cont)						
Grade 3	0	0	0	0	0	0
Pharyngeal disorders (excl infections and neoplasms)	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Pharyngeal ulceration	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Respiratory failures (excl neonatal)	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 3	0	0	0	0	1 (3.1%)	1 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Lower respiratory tract inflammatory and immunologic conditions (cont)						
Pneumonia aspiration (cont)						
Grade 3	1 (1.6%)	0	1 (0.8%)	0	0	0
Pharyngeal disorders (excl infections and neoplasms)	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 3	1 (1.6%)	0	1 (0.8%)	0	0	0
Pharyngeal ulceration	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 3	1 (1.6%)	0	1 (0.8%)	0	0	0
Respiratory failures (excl neonatal)	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Respiratory failures (excl neonatal) (cont)						
(cont)						
Grade 4	0	0	0	0	0	0
Respiratory failure	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 3	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 4	0	0	0	0	0	0
Acute respiratory failure	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Parenchymal lung disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Respiratory failures (excl neonatal) (cont) (cont)						
Grade 4	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	0	0
Respiratory failure	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 3	0	0	0	0	0	0
Grade 4	1 (1.6%)	0	1 (0.8%)	0	0	0
Acute respiratory failure	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 4	0	1 (1.7%)	1 (0.8%)	0	0	0
Parenchymal lung disorders NEC	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 1	0	0	0	1 (2.2%)	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Parenchymal lung disorders NEC (cont)						
Emphysema	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Pleural infections and inflammations	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Pleurisy	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Pneumothorax and pleural effusions NEC	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 3	0	0	0	0	1 (3.1%)	1 (2.0%)
Pleural effusion	0	0	0	0	1 (3.1%)	1 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Parenchymal lung disorders NEC (cont)						
Emphysema	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 1	0	0	0	1 (2.2%)	0	1 (1.0%)
Pleural infections and inflammations	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Pleurisy	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Pneumothorax and pleural effusions NEC	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Pleural effusion	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Pneumothorax and pleural effusions NEC (cont)						
Pleural effusion (cont)						
Grade 3	0	0	0	0	1 (3.1%)	1 (2.0%)
Pulmonary oedemas	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Pulmonary oedema	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Pulmonary thrombotic and embolic conditions	0	0	0	1 (5.3%)	0	1 (2.0%)
Grade 2	0	0	0	1 (5.3%)	0	1 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
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Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Pneumothorax and pleural effusions NEC (cont)						
Pleural effusion (cont)						
Grade 3	0	0	0	0	0	0
Pulmonary oedemas	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 2	0	0	0	1 (2.2%)	0	1 (1.0%)
Pulmonary oedema	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 2	0	0	0	1 (2.2%)	0	1 (1.0%)
Pulmonary thrombotic and embolic conditions	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
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Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Pulmonary thrombotic and embolic conditions (cont)						
Pulmonary embolism	0	0	0	1 (5.3%)	0	1 (2.0%)
Grade 2	0	0	0	1 (5.3%)	0	1 (2.0%)
Respiratory tract disorders NEC	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Lung disorder	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Pulmonary thrombotic and embolic conditions (cont)						
Pulmonary embolism	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Respiratory tract disorders NEC	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 2	0	0	0	0	1 (1.9%)	1 (1.0%)
Lung disorder	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 2	0	0	0	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders	7 (29.2%)	5 (13.9%)	12 (20.0%)	1 (5.3%)	8 (25.0%)	9 (17.6%)
Grade 1	4 (16.7%)	2 (5.6%)	6 (10.0%)	1 (5.3%)	5 (15.6%)	6 (11.8%)
Grade 2	2 (8.3%)	1 (2.8%)	3 (5.0%)	0	3 (9.4%)	3 (5.9%)
Grade 3	1 (4.2%)	2 (5.6%)	3 (5.0%)	0	0	0
Grade 4	0	0	0	0	0	0
Potassium imbalance	3 (12.5%)	1 (2.8%)	4 (6.7%)	0	0	0
Grade 1	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 2	2 (8.3%)	0	2 (3.3%)	0	0	0
Grade 3	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 4	0	0	0	0	0	0
Hyperkalaemia	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	1 (2.8%)	1 (1.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders	20 (32.3%)	15 (25.9%)	35 (29.2%)	9 (20.0%)	15 (28.8%)	24 (24.7%)
Grade 1	7 (11.3%)	5 (8.6%)	12 (10.0%)	2 (4.4%)	7 (13.5%)	9 (9.3%)
Grade 2	6 (9.7%)	8 (13.8%)	14 (11.7%)	5 (11.1%)	5 (9.6%)	10 (10.3%)
Grade 3	5 (8.1%)	1 (1.7%)	6 (5.0%)	2 (4.4%)	1 (1.9%)	3 (3.1%)
Grade 4	2 (3.2%)	1 (1.7%)	3 (2.5%)	0	2 (3.8%)	2 (2.1%)
Potassium imbalance	4 (6.5%)	3 (5.2%)	7 (5.8%)	1 (2.2%)	3 (5.8%)	4 (4.1%)
Grade 1	0	0	0	0	2 (3.8%)	2 (2.1%)
Grade 2	2 (3.2%)	1 (1.7%)	3 (2.5%)	0	1 (1.9%)	1 (1.0%)
Grade 3	2 (3.2%)	1 (1.7%)	3 (2.5%)	1 (2.2%)	0	1 (1.0%)
Grade 4	0	1 (1.7%)	1 (0.8%)	0	0	0
Hyperkalaemia	4 (6.5%)	1 (1.7%)	5 (4.2%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 2	2 (3.2%)	0	2 (1.7%)	0	0	0
Grade 3	2 (3.2%)	1 (1.7%)	3 (2.5%)	1 (2.2%)	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Potassium imbalance (cont)						
Hypokalaemia	3 (12.5%)	0	3 (5.0%)	0	0	0
Grade 1	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 2	2 (8.3%)	0	2 (3.3%)	0	0	0
Grade 4	0	0	0	0	0	0
Disorders of purine metabolism	1 (4.2%)	1 (2.8%)	2 (3.3%)	0	3 (9.4%)	3 (5.9%)
Grade 1	1 (4.2%)	0	1 (1.7%)	0	3 (9.4%)	3 (5.9%)
Grade 2	0	0	0	0	0	0
Grade 3	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 4	0	0	0	0	0	0
Hyperuricaemia	1 (4.2%)	1 (2.8%)	2 (3.3%)	0	3 (9.4%)	3 (5.9%)
Grade 1	1 (4.2%)	0	1 (1.7%)	0	3 (9.4%)	3 (5.9%)
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Potassium imbalance (cont)						
Hypokalaemia	0	2 (3.4%)	2 (1.7%)	0	2 (3.8%)	2 (2.1%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 2	0	1 (1.7%)	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Grade 4	0	1 (1.7%)	1 (0.8%)	0	0	0
Disorders of purine metabolism	5 (8.1%)	2 (3.4%)	7 (5.8%)	1 (2.2%)	2 (3.8%)	3 (3.1%)
Grade 1	2 (3.2%)	1 (1.7%)	3 (2.5%)	0	0	0
Grade 2	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	0	0
Grade 3	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 4	2 (3.2%)	0	2 (1.7%)	0	2 (3.8%)	2 (2.1%)
Hyperuricaemia	4 (6.5%)	2 (3.4%)	6 (5.0%)	0	2 (3.8%)	2 (2.1%)
Grade 1	2 (3.2%)	1 (1.7%)	3 (2.5%)	0	0	0
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Disorders of purine metabolism (cont)						
Hyperuricaemia (cont)						
Grade 3	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 4	0	0	0	0	0	0
Gout	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Water soluble vitamin deficiencies	2 (8.3%)	2 (5.6%)	4 (6.7%)	1 (5.3%)	1 (3.1%)	2 (3.9%)
Grade 1	1 (4.2%)	1 (2.8%)	2 (3.3%)	1 (5.3%)	1 (3.1%)	2 (3.9%)
Grade 2	1 (4.2%)	1 (2.8%)	2 (3.3%)	0	0	0
Vitamin B1 deficiency	1 (4.2%)	2 (5.6%)	3 (5.0%)	1 (5.3%)	1 (3.1%)	2 (3.9%)
Grade 1	0	1 (2.8%)	1 (1.7%)	1 (5.3%)	1 (3.1%)	2 (3.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Disorders of purine metabolism (cont)						
Hyperuricaemia (cont)						
Grade 3	0	0	0	0	0	0
Grade 4	2 (3.2%)	0	2 (1.7%)	0	2 (3.8%)	2 (2.1%)
Gout	1 (1.6%)	0	1 (0.8%)	1 (2.2%)	0	1 (1.0%)
Grade 2	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 3	0	0	0	1 (2.2%)	0	1 (1.0%)
Water soluble vitamin deficiencies	4 (6.5%)	5 (8.6%)	9 (7.5%)	3 (6.7%)	4 (7.7%)	7 (7.2%)
Grade 1	2 (3.2%)	4 (6.9%)	6 (5.0%)	0	3 (5.8%)	3 (3.1%)
Grade 2	2 (3.2%)	1 (1.7%)	3 (2.5%)	3 (6.7%)	1 (1.9%)	4 (4.1%)
Vitamin B1 deficiency	4 (6.5%)	4 (6.9%)	8 (6.7%)	3 (6.7%)	4 (7.7%)	7 (7.2%)
Grade 1	2 (3.2%)	3 (5.2%)	5 (4.2%)	0	3 (5.8%)	3 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Water soluble vitamin deficiencies (cont)						
Vitamin B1 deficiency (cont)						
Grade 2	1 (4.2%)	1 (2.8%)	2 (3.3%)	0	0	0
Vitamin B complex deficiency	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 1	1 (4.2%)	0	1 (1.7%)	0	0	0
Magnesium metabolism disorders	3 (12.5%)	0	3 (5.0%)	0	0	0
Grade 1	2 (8.3%)	0	2 (3.3%)	0	0	0
Grade 2	1 (4.2%)	0	1 (1.7%)	0	0	0
Hypomagnesaemia	3 (12.5%)	0	3 (5.0%)	0	0	0
Grade 1	2 (8.3%)	0	2 (3.3%)	0	0	0
Grade 2	1 (4.2%)	0	1 (1.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Water soluble vitamin deficiencies (cont)						
Vitamin B1 deficiency (cont)						
Grade 2	2 (3.2%)	1 (1.7%)	3 (2.5%)	3 (6.7%)	1 (1.9%)	4 (4.1%)
Vitamin B complex deficiency	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0
Magnesium metabolism disorders	2 (3.2%)	0	2 (1.7%)	0	0	0
Grade 1	2 (3.2%)	0	2 (1.7%)	0	0	0
Grade 2	0	0	0	0	0	0
Hypomagnesaemia	2 (3.2%)	0	2 (1.7%)	0	0	0
Grade 1	2 (3.2%)	0	2 (1.7%)	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Appetite disorders	1 (4.2%)	3 (8.3%)	4 (6.7%)	0	2 (6.3%)	2 (3.9%)
Grade 1	1 (4.2%)	2 (5.6%)	3 (5.0%)	0	1 (3.1%)	1 (2.0%)
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 3	0	1 (2.8%)	1 (1.7%)	0	0	0
Decreased appetite	1 (4.2%)	3 (8.3%)	4 (6.7%)	0	2 (6.3%)	2 (3.9%)
Grade 1	1 (4.2%)	2 (5.6%)	3 (5.0%)	0	1 (3.1%)	1 (2.0%)
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 3	0	1 (2.8%)	1 (1.7%)	0	0	0
Calcium metabolism disorders	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 2	1 (4.2%)	0	1 (1.7%)	0	0	0
Hypocalcaemia	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 2	1 (4.2%)	0	1 (1.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Appetite disorders	3 (4.8%)	3 (5.2%)	6 (5.0%)	3 (6.7%)	3 (5.8%)	6 (6.2%)
Grade 1	2 (3.2%)	1 (1.7%)	3 (2.5%)	2 (4.4%)	2 (3.8%)	4 (4.1%)
Grade 2	1 (1.6%)	2 (3.4%)	3 (2.5%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 3	0	0	0	0	0	0
Decreased appetite	3 (4.8%)	3 (5.2%)	6 (5.0%)	3 (6.7%)	3 (5.8%)	6 (6.2%)
Grade 1	2 (3.2%)	1 (1.7%)	3 (2.5%)	2 (4.4%)	2 (3.8%)	4 (4.1%)
Grade 2	1 (1.6%)	2 (3.4%)	3 (2.5%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 3	0	0	0	0	0	0
Calcium metabolism disorders	2 (3.2%)	0	2 (1.7%)	0	1 (1.9%)	1 (1.0%)
Grade 2	2 (3.2%)	0	2 (1.7%)	0	1 (1.9%)	1 (1.0%)
Hypocalcaemia	2 (3.2%)	0	2 (1.7%)	0	1 (1.9%)	1 (1.0%)
Grade 2	2 (3.2%)	0	2 (1.7%)	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Fat soluble vitamin deficiencies and disorders	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 1	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 2	0	0	0	0	0	0
Vitamin D deficiency	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 1	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 2	0	0	0	0	0	0
Vitamin K deficiency	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 1	1 (4.2%)	0	1 (1.7%)	0	0	0
Iron excess	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Fat soluble vitamin deficiencies and disorders	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	1 (1.9%)	1 (1.0%)
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	0	1 (1.7%)	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Vitamin D deficiency	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	1 (1.9%)	1 (1.0%)
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	0	1 (1.7%)	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Vitamin K deficiency	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Iron excess	2 (3.2%)	1 (1.7%)	3 (2.5%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Iron excess (cont)						
(cont)						
Grade 3	0	0	0	0	0	0
Haemosiderosis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Iron overload	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Hyperglycaemic conditions NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Iron excess (cont)						
(cont)						
Grade 3	1 (1.6%)	0	1 (0.8%)	0	0	0
Haemosiderosis	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Iron overload	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	0	0
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 3	1 (1.6%)	0	1 (0.8%)	0	0	0
Hyperglycaemic conditions NEC	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Hyperglycaemic conditions NEC (cont)						
Hyperglycaemia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Hypoglycaemic conditions NEC	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Hypoglycaemia	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Phosphorus metabolism disorders	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 3	1 (4.2%)	0	1 (1.7%)	0	0	0
Hypophosphataemia	1 (4.2%)	0	1 (1.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Hyperglycaemic conditions NEC (cont)						
Hyperglycaemia	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0
Hypoglycaemic conditions NEC	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 3	1 (1.6%)	0	1 (0.8%)	0	0	0
Hypoglycaemia	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 3	1 (1.6%)	0	1 (0.8%)	0	0	0
Phosphorus metabolism disorders	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Hypophosphataemia	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Phosphorus metabolism disorders (cont)						
Hypophosphataemia (cont)						
Grade 3	1 (4.2%)	0	1 (1.7%)	0	0	0
Protein metabolism disorders NEC	1 (4.2%)	0	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 2	1 (4.2%)	0	1 (1.7%)	0	0	0
Hypoalbuminaemia	1 (4.2%)	0	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 2	1 (4.2%)	0	1 (1.7%)	0	0	0
Sodium imbalance	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 3	1 (4.2%)	0	1 (1.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Phosphorus metabolism disorders (cont)						
Hypophosphataemia (cont)						
Grade 3	0	0	0	0	0	0
Protein metabolism disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Hypoalbuminaemia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Sodium imbalance	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 3	0	0	0	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Sodium imbalance (cont)						
Hyponatraemia	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 3	1 (4.2%)	0	1 (1.7%)	0	0	0
Total fluid volume decreased	0	1 (2.8%)	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Grade 2	0	1 (2.8%)	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Grade 3	0	0	0	0	0	0
Dehydration	0	1 (2.8%)	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Grade 2	0	1 (2.8%)	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Grade 3	0	0	0	0	0	0
Diabetes mellitus (incl subtypes)	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Sodium imbalance (cont)						
Hyponatraemia	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 3	0	0	0	0	1 (1.9%)	1 (1.0%)
Total fluid volume decreased	1 (1.6%)	0	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Grade 2	0	0	0	0	0	0
Grade 3	1 (1.6%)	0	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Dehydration	1 (1.6%)	0	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Grade 2	0	0	0	0	0	0
Grade 3	1 (1.6%)	0	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Diabetes mellitus (incl subtypes)	0	0	0	0	2 (3.8%)	2 (2.1%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 2	0	0	0	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Diabetes mellitus (incl subtypes) (cont)						
Diabetes mellitus	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)
Electrolyte imbalance NEC	0	1 (2.8%)	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 3	0	1 (2.8%)	1 (1.7%)	0	0	0
Electrolyte imbalance	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	1 (3.1%)	1 (2.0%)
Tumour lysis syndrome	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 3	0	1 (2.8%)	1 (1.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Diabetes mellitus (incl subtypes) (cont)						
Diabetes mellitus	0	0	0	0	2 (3.8%)	2 (2.1%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 2	0	0	0	0	1 (1.9%)	1 (1.0%)
Electrolyte imbalance NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Electrolyte imbalance	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
General nutritional disorders NEC	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)
Abnormal loss of weight	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)
Total fluid volume increased	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Fluid retention	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Hypervolaemia	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
General nutritional disorders NEC	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Abnormal loss of weight	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Total fluid volume increased	0	1 (1.7%)	1 (0.8%)	1 (2.2%)	0	1 (1.0%)
Grade 2	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 3	0	1 (1.7%)	1 (0.8%)	0	0	0
Fluid retention	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 2	0	0	0	1 (2.2%)	0	1 (1.0%)
Hypervolaemia	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 3	0	1 (1.7%)	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders	7 (29.2%)	10 (27.8%)	17 (28.3%)	3 (15.8%)	8 (25.0%)	11 (21.6%)
Grade 1	3 (12.5%)	7 (19.4%)	10 (16.7%)	1 (5.3%)	5 (15.6%)	6 (11.8%)
Grade 2	4 (16.7%)	3 (8.3%)	7 (11.7%)	2 (10.5%)	3 (9.4%)	5 (9.8%)
Grade 3	0	0	0	0	0	0
Musculoskeletal and connective tissue pain and discomfort	6 (25.0%)	5 (13.9%)	11 (18.3%)	2 (10.5%)	7 (21.9%)	9 (17.6%)
Grade 1	4 (16.7%)	5 (13.9%)	9 (15.0%)	1 (5.3%)	5 (15.6%)	6 (11.8%)
Grade 2	2 (8.3%)	0	2 (3.3%)	1 (5.3%)	2 (6.3%)	3 (5.9%)
Grade 3	0	0	0	0	0	0
Pain in extremity	6 (25.0%)	4 (11.1%)	10 (16.7%)	1 (5.3%)	2 (6.3%)	3 (5.9%)
Grade 1	4 (16.7%)	4 (11.1%)	8 (13.3%)	0	2 (6.3%)	2 (3.9%)
Grade 2	2 (8.3%)	0	2 (3.3%)	1 (5.3%)	0	1 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders	15 (24.2%)	13 (22.4%)	28 (23.3%)	5 (11.1%)	10 (19.2%)	15 (15.5%)
Grade 1	10 (16.1%)	9 (15.5%)	19 (15.8%)	3 (6.7%)	3 (5.8%)	6 (6.2%)
Grade 2	4 (6.5%)	4 (6.9%)	8 (6.7%)	2 (4.4%)	7 (13.5%)	9 (9.3%)
Grade 3	1 (1.6%)	0	1 (0.8%)	0	0	0
Musculoskeletal and connective tissue pain and discomfort	8 (12.9%)	2 (3.4%)	10 (8.3%)	3 (6.7%)	6 (11.5%)	9 (9.3%)
Grade 1	5 (8.1%)	1 (1.7%)	6 (5.0%)	2 (4.4%)	2 (3.8%)	4 (4.1%)
Grade 2	2 (3.2%)	1 (1.7%)	3 (2.5%)	1 (2.2%)	4 (7.7%)	5 (5.2%)
Grade 3	1 (1.6%)	0	1 (0.8%)	0	0	0
Pain in extremity	3 (4.8%)	1 (1.7%)	4 (3.3%)	2 (4.4%)	2 (3.8%)	4 (4.1%)
Grade 1	2 (3.2%)	0	2 (1.7%)	1 (2.2%)	0	1 (1.0%)
Grade 2	1 (1.6%)	1 (1.7%)	2 (1.7%)	1 (2.2%)	2 (3.8%)	3 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Musculoskeletal and connective tissue pain and discomfort (cont)						
Back pain	1 (4.2%)	0	1 (1.7%)	1 (5.3%)	4 (12.5%)	5 (9.8%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (5.3%)	2 (6.3%)	3 (5.9%)
Grade 2	0	0	0	0	2 (6.3%)	2 (3.9%)
Grade 3	0	0	0	0	0	0
Musculoskeletal pain	0	1 (2.8%)	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Grade 1	0	1 (2.8%)	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Flank pain	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Musculoskeletal chest pain	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Musculoskeletal and connective tissue pain and discomfort (cont)						
Back pain	5 (8.1%)	2 (3.4%)	7 (5.8%)	1 (2.2%)	3 (5.8%)	4 (4.1%)
Grade 1	3 (4.8%)	1 (1.7%)	4 (3.3%)	1 (2.2%)	2 (3.8%)	3 (3.1%)
Grade 2	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	1 (1.9%)	1 (1.0%)
Grade 3	1 (1.6%)	0	1 (0.8%)	0	0	0
Musculoskeletal pain	2 (3.2%)	0	2 (1.7%)	0	0	0
Grade 1	2 (3.2%)	0	2 (1.7%)	0	0	0
Flank pain	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Musculoskeletal chest pain	1 (1.6%)	0	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Musculoskeletal and connective tissue pain and discomfort (cont)						
Musculoskeletal chest pain (cont)						
Grade 1	0	0	0	0	0	0
Neck pain	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Bone related signs and symptoms	0	5 (13.9%)	5 (8.3%)	1 (5.3%)	1 (3.1%)	2 (3.9%)
Grade 1	0	2 (5.6%)	2 (3.3%)	0	1 (3.1%)	1 (2.0%)
Grade 2	0	3 (8.3%)	3 (5.0%)	1 (5.3%)	0	1 (2.0%)
Bone pain	0	5 (13.9%)	5 (8.3%)	1 (5.3%)	1 (3.1%)	2 (3.9%)
Grade 1	0	2 (5.6%)	2 (3.3%)	0	1 (3.1%)	1 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Musculoskeletal and connective tissue pain and discomfort (cont)						
Musculoskeletal chest pain (cont)						
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Neck pain	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 2	0	0	0	0	1 (1.9%)	1 (1.0%)
Bone related signs and symptoms	4 (6.5%)	4 (6.9%)	8 (6.7%)	2 (4.4%)	2 (3.8%)	4 (4.1%)
Grade 1	3 (4.8%)	2 (3.4%)	5 (4.2%)	2 (4.4%)	0	2 (2.1%)
Grade 2	1 (1.6%)	2 (3.4%)	3 (2.5%)	0	2 (3.8%)	2 (2.1%)
Bone pain	2 (3.2%)	4 (6.9%)	6 (5.0%)	1 (2.2%)	2 (3.8%)	3 (3.1%)
Grade 1	2 (3.2%)	2 (3.4%)	4 (3.3%)	1 (2.2%)	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Bone related signs and symptoms (cont)						
Bone pain (cont)						
Grade 2	0	3 (8.3%)	3 (5.0%)	1 (5.3%)	0	1 (2.0%)
Pain in jaw	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Spinal pain	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Joint related signs and symptoms	2 (8.3%)	0	2 (3.3%)	0	1 (3.1%)	1 (2.0%)
Grade 1	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 2	1 (4.2%)	0	1 (1.7%)	0	1 (3.1%)	1 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Bone related signs and symptoms (cont)						
Bone pain (cont)						
Grade 2	0	2 (3.4%)	2 (1.7%)	0	2 (3.8%)	2 (2.1%)
Pain in jaw	1 (1.6%)	0	1 (0.8%)	1 (2.2%)	0	1 (1.0%)
Grade 1	1 (1.6%)	0	1 (0.8%)	1 (2.2%)	0	1 (1.0%)
Spinal pain	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	1 (1.6%)	0	1 (0.8%)	0	0	0
Joint related signs and symptoms	2 (3.2%)	2 (3.4%)	4 (3.3%)	1 (2.2%)	0	1 (1.0%)
Grade 1	1 (1.6%)	2 (3.4%)	3 (2.5%)	0	0	0
Grade 2	1 (1.6%)	0	1 (0.8%)	1 (2.2%)	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Joint related signs and symptoms (cont)						
Arthralgia	2 (8.3%)	0	2 (3.3%)	0	0	0
Grade 1	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 2	1 (4.2%)	0	1 (1.7%)	0	0	0
Joint effusion	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)
Muscle related signs and symptoms NEC	0	2 (5.6%)	2 (3.3%)	0	0	0
Grade 1	0	2 (5.6%)	2 (3.3%)	0	0	0
Grade 2	0	0	0	0	0	0
Muscle spasms	0	2 (5.6%)	2 (3.3%)	0	0	0
Grade 1	0	2 (5.6%)	2 (3.3%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Joint related signs and symptoms (cont)						
Arthralgia	2 (3.2%)	2 (3.4%)	4 (3.3%)	1 (2.2%)	0	1 (1.0%)
Grade 1	1 (1.6%)	2 (3.4%)	3 (2.5%)	0	0	0
Grade 2	1 (1.6%)	0	1 (0.8%)	1 (2.2%)	0	1 (1.0%)
Joint effusion	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Muscle related signs and symptoms NEC	2 (3.2%)	4 (6.9%)	6 (5.0%)	0	2 (3.8%)	2 (2.1%)
Grade 1	2 (3.2%)	3 (5.2%)	5 (4.2%)	0	1 (1.9%)	1 (1.0%)
Grade 2	0	1 (1.7%)	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Muscle spasms	2 (3.2%)	4 (6.9%)	6 (5.0%)	0	2 (3.8%)	2 (2.1%)
Grade 1	2 (3.2%)	3 (5.2%)	5 (4.2%)	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Muscle related signs and symptoms NEC (cont)						
Muscle spasms (cont)						
Grade 2	0	0	0	0	0	0
Soft tissue disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Groin pain	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Bursal disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Muscle related signs and symptoms NEC (cont)						
Muscle spasms (cont)						
Grade 2	0	1 (1.7%)	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Soft tissue disorders NEC	2 (3.2%)	0	2 (1.7%)	0	0	0
Grade 1	2 (3.2%)	0	2 (1.7%)	0	0	0
Groin pain	2 (3.2%)	0	2 (1.7%)	0	0	0
Grade 1	2 (3.2%)	0	2 (1.7%)	0	0	0
Bursal disorders	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Bursal disorders (cont)						
Bursal fluid accumulation	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Crystal arthropathic disorders	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Gouty arthritis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Muscle pains	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	1 (4.2%)	0	1 (1.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Bursal disorders (cont)						
Bursal fluid accumulation	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Crystal arthropathic disorders	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	1 (1.6%)	0	1 (0.8%)	0	0	0
Gouty arthritis	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	1 (1.6%)	0	1 (0.8%)	0	0	0
Muscle pains	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase	DB Phase	DB Phase	OL Phase (Week 24 - 48) Continuing	OL Phase (Week 24 - 48) Switch	OL Phase (Week 24 - 48)
	MMB (N=24)	RUX (N=36)	Total (N=60)	(MMB->MMB) (N=19)	(RUX->MMB) (N=32)	Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Muscle pains (cont)						
Myalgia	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	1 (4.2%)	0	1 (1.7%)	0	0	0
Tendon disorders	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 2	1 (4.2%)	0	1 (1.7%)	0	0	0
Tendonitis	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 2	1 (4.2%)	0	1 (1.7%)	0	0	0
Arthropathies NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Muscle pains (cont)						
Myalgia	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 2	0	0	0	0	0	0
Tendon disorders	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Tendonitis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Arthropathies NEC	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Arthropathies NEC (cont)						
Arthritis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Bone disorders NEC	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	1 (3.1%)	1 (2.0%)
Bone lesion	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	1 (3.1%)	1 (2.0%)
Osteosclerosis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Muscle weakness conditions	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Arthropathies NEC (cont)						
Arthritis	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0
Bone disorders NEC	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Bone lesion	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Osteosclerosis	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Muscle weakness conditions	0	3 (5.2%)	3 (2.5%)	1 (2.2%)	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Muscle weakness conditions (cont) (cont)						
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Muscular weakness	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Musculoskeletal and connective tissue infections and inflammations NEC	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	1 (3.1%)	1 (2.0%)
Fasciitis	0	0	0	0	1 (3.1%)	1 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Muscle weakness conditions (cont) (cont)						
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 2	0	2 (3.4%)	2 (1.7%)	1 (2.2%)	0	1 (1.0%)
Muscular weakness	0	3 (5.2%)	3 (2.5%)	1 (2.2%)	0	1 (1.0%)
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 2	0	2 (3.4%)	2 (1.7%)	1 (2.2%)	0	1 (1.0%)
Musculoskeletal and connective tissue infections and inflammations NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Fasciitis	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Musculoskeletal and connective tissue infections and inflammations NEC (cont)						
Fasciitis (cont)						
Grade 1	0	0	0	0	1 (3.1%)	1 (2.0%)
Investigations	6 (25.0%)	5 (13.9%)	11 (18.3%)	4 (21.1%)	2 (6.3%)	6 (11.8%)
Grade 1	5 (20.8%)	1 (2.8%)	6 (10.0%)	2 (10.5%)	0	2 (3.9%)
Grade 2	1 (4.2%)	4 (11.1%)	5 (8.3%)	1 (5.3%)	2 (6.3%)	3 (5.9%)
Grade 3	0	0	0	1 (5.3%)	0	1 (2.0%)
Grade 4	0	0	0	0	0	0
Liver function analyses	4 (16.7%)	3 (8.3%)	7 (11.7%)	1 (5.3%)	1 (3.1%)	2 (3.9%)
Grade 1	3 (12.5%)	1 (2.8%)	4 (6.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Musculoskeletal and connective tissue infections and inflammations NEC (cont)						
Fasciitis (cont)						
Grade 1	0	0	0	0	0	0
Investigations	15 (24.2%)	14 (24.1%)	29 (24.2%)	7 (15.6%)	13 (25.0%)	20 (20.6%)
Grade 1	4 (6.5%)	8 (13.8%)	12 (10.0%)	2 (4.4%)	9 (17.3%)	11 (11.3%)
Grade 2	6 (9.7%)	3 (5.2%)	9 (7.5%)	5 (11.1%)	4 (7.7%)	9 (9.3%)
Grade 3	4 (6.5%)	3 (5.2%)	7 (5.8%)	0	0	0
Grade 4	1 (1.6%)	0	1 (0.8%)	0	0	0
Liver function analyses	7 (11.3%)	8 (13.8%)	15 (12.5%)	2 (4.4%)	4 (7.7%)	6 (6.2%)
Grade 1	2 (3.2%)	4 (6.9%)	6 (5.0%)	2 (4.4%)	1 (1.9%)	3 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Liver function analyses (cont)						
(cont)						
Grade 2	1 (4.2%)	2 (5.6%)	3 (5.0%)	0	1 (3.1%)	1 (2.0%)
Grade 3	0	0	0	1 (5.3%)	0	1 (2.0%)
Alanine aminotransferase increased	1 (4.2%)	2 (5.6%)	3 (5.0%)	0	1 (3.1%)	1 (2.0%)
Grade 1	1 (4.2%)	2 (5.6%)	3 (5.0%)	0	0	0
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 3	0	0	0	0	0	0
Gamma-glutamyltransferase increased	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Liver function analyses (cont)						
(cont)						
Grade 2	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	3 (5.8%)	3 (3.1%)
Grade 3	4 (6.5%)	3 (5.2%)	7 (5.8%)	0	0	0
Alanine aminotransferase increased	6 (9.7%)	4 (6.9%)	10 (8.3%)	1 (2.2%)	2 (3.8%)	3 (3.1%)
Grade 1	2 (3.2%)	3 (5.2%)	5 (4.2%)	1 (2.2%)	2 (3.8%)	3 (3.1%)
Grade 2	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	0	0
Grade 3	3 (4.8%)	0	3 (2.5%)	0	0	0
Gamma-glutamyltransferase increased	4 (6.5%)	3 (5.2%)	7 (5.8%)	1 (2.2%)	2 (3.8%)	3 (3.1%)
Grade 1	2 (3.2%)	0	2 (1.7%)	1 (2.2%)	0	1 (1.0%)
Grade 2	1 (1.6%)	0	1 (0.8%)	0	2 (3.8%)	2 (2.1%)
Grade 3	1 (1.6%)	3 (5.2%)	4 (3.3%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Liver function analyses (cont)						
Aspartate aminotransferase increased	1 (4.2%)	2 (5.6%)	3 (5.0%)	0	0	0
Grade 1	1 (4.2%)	1 (2.8%)	2 (3.3%)	0	0	0
Grade 2	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 3	0	0	0	0	0	0
Blood bilirubin increased	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	1 (4.2%)	0	1 (1.7%)	0	0	0
Transaminases increased	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 1	1 (4.2%)	0	1 (1.7%)	0	0	0
Liver function test abnormal	0	0	0	1 (5.3%)	0	1 (2.0%)
Grade 3	0	0	0	1 (5.3%)	0	1 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Liver function analyses (cont)						
Aspartate aminotransferase increased	2 (3.2%)	1 (1.7%)	3 (2.5%)	0	1 (1.9%)	1 (1.0%)
Grade 1	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	1 (1.9%)	1 (1.0%)
Grade 2	0	0	0	0	0	0
Grade 3	1 (1.6%)	0	1 (0.8%)	0	0	0
Blood bilirubin increased	0	2 (3.4%)	2 (1.7%)	0	1 (1.9%)	1 (1.0%)
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 2	0	1 (1.7%)	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Transaminases increased	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0
Liver function test abnormal	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Physical examination procedures and organ system status	3 (12.5%)	1 (2.8%)	4 (6.7%)	1 (5.3%)	0	1 (2.0%)
Grade 1	3 (12.5%)	0	3 (5.0%)	0	0	0
Grade 2	0	1 (2.8%)	1 (1.7%)	1 (5.3%)	0	1 (2.0%)
Weight decreased	1 (4.2%)	1 (2.8%)	2 (3.3%)	1 (5.3%)	0	1 (2.0%)
Grade 1	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 2	0	1 (2.8%)	1 (1.7%)	1 (5.3%)	0	1 (2.0%)
Weight increased	2 (8.3%)	0	2 (3.3%)	0	0	0
Grade 1	2 (8.3%)	0	2 (3.3%)	0	0	0
Grade 2	0	0	0	0	0	0
Lymph node palpable	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Physical examination procedures and organ system status	3 (4.8%)	3 (5.2%)	6 (5.0%)	2 (4.4%)	2 (3.8%)	4 (4.1%)
Grade 1	3 (4.8%)	2 (3.4%)	5 (4.2%)	0	2 (3.8%)	2 (2.1%)
Grade 2	0	1 (1.7%)	1 (0.8%)	2 (4.4%)	0	2 (2.1%)
Weight decreased	2 (3.2%)	0	2 (1.7%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 1	2 (3.2%)	0	2 (1.7%)	0	1 (1.9%)	1 (1.0%)
Grade 2	0	0	0	1 (2.2%)	0	1 (1.0%)
Weight increased	0	2 (3.4%)	2 (1.7%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 1	0	1 (1.7%)	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Grade 2	0	1 (1.7%)	1 (0.8%)	1 (2.2%)	0	1 (1.0%)
Lymph node palpable	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Physical examination procedures and organ system status (cont)						
Body temperature increased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Renal function analyses	1 (4.2%)	0	1 (1.7%)	1 (5.3%)	0	1 (2.0%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (5.3%)	0	1 (2.0%)
Grade 2	0	0	0	0	0	0
Blood creatinine increased	1 (4.2%)	0	1 (1.7%)	1 (5.3%)	0	1 (2.0%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (5.3%)	0	1 (2.0%)
Grade 2	0	0	0	0	0	0
Creatinine renal clearance decreased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Physical examination procedures and organ system status (cont)						
Body temperature increased	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0
Renal function analyses	5 (8.1%)	1 (1.7%)	6 (5.0%)	3 (6.7%)	4 (7.7%)	7 (7.2%)
Grade 1	2 (3.2%)	1 (1.7%)	3 (2.5%)	1 (2.2%)	3 (5.8%)	4 (4.1%)
Grade 2	3 (4.8%)	0	3 (2.5%)	2 (4.4%)	1 (1.9%)	3 (3.1%)
Blood creatinine increased	3 (4.8%)	1 (1.7%)	4 (3.3%)	2 (4.4%)	3 (5.8%)	5 (5.2%)
Grade 1	2 (3.2%)	1 (1.7%)	3 (2.5%)	1 (2.2%)	2 (3.8%)	3 (3.1%)
Grade 2	1 (1.6%)	0	1 (0.8%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Creatinine renal clearance decreased	2 (3.2%)	0	2 (1.7%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Renal function analyses (cont)						
Creatinine renal clearance decreased (cont)						
Grade 2	0	0	0	0	0	0
ECG investigations	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 4	0	0	0	0	0	0
Electrocardiogram QT prolonged	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 2	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 4	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Renal function analyses (cont)						
Creatinine renal clearance decreased (cont)						
Grade 2	2 (3.2%)	0	2 (1.7%)	1 (2.2%)	0	1 (1.0%)
ECG investigations	2 (3.2%)	1 (1.7%)	3 (2.5%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 4	1 (1.6%)	0	1 (0.8%)	0	0	0
Electrocardiogram QT prolonged	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	0	0
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 4	1 (1.6%)	0	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
ECG investigations (cont)						
Electrocardiogram ST segment depression	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Protein analyses NEC	1 (4.2%)	0	1 (1.7%)	1 (5.3%)	0	1 (2.0%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (5.3%)	0	1 (2.0%)
Protein total increased	1 (4.2%)	0	1 (1.7%)	1 (5.3%)	0	1 (2.0%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (5.3%)	0	1 (2.0%)
Tissue enzyme analyses NEC	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 1	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
ECG investigations (cont)						
Electrocardiogram ST segment depression	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Protein analyses NEC	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Protein total increased	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Tissue enzyme analyses NEC	2 (3.2%)	3 (5.2%)	5 (4.2%)	0	1 (1.9%)	1 (1.0%)
Grade 1	1 (1.6%)	2 (3.4%)	3 (2.5%)	0	1 (1.9%)	1 (1.0%)
Grade 2	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Tissue enzyme analyses NEC (cont)						
Blood alkaline phosphatase increased	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 1	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 2	0	0	0	0	0	0
Blood lactate dehydrogenase increased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Blood gas and acid base analyses	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 1	1 (4.2%)	0	1 (1.7%)	0	0	0
Blood lactic acid increased	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 1	1 (4.2%)	0	1 (1.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Tissue enzyme analyses NEC (cont)						
Blood alkaline phosphatase increased	2 (3.2%)	3 (5.2%)	5 (4.2%)	0	0	0
Grade 1	1 (1.6%)	2 (3.4%)	3 (2.5%)	0	0	0
Grade 2	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	0	0
Blood lactate dehydrogenase increased	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Blood gas and acid base analyses	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Blood lactic acid increased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Mineral and electrolyte analyses	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)
Blood bicarbonate decreased	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Serum ferritin increased	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)
Autoimmunity analyses	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Antiphospholipid antibodies positive	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Mineral and electrolyte analyses	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	1 (1.6%)	0	1 (0.8%)	0	0	0
Blood bicarbonate decreased	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	1 (1.6%)	0	1 (0.8%)	0	0	0
Serum ferritin increased	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Autoimmunity analyses	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 2	0	0	0	1 (2.2%)	0	1 (1.0%)
Antiphospholipid antibodies positive	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 2	0	0	0	1 (2.2%)	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Cardiac auscultatory investigations	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Cardiac murmur	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Coagulation and bleeding analyses	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Activated partial thromboplastin time prolonged	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
International normalised ratio increased	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Cardiac auscultatory investigations	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0
Cardiac murmur	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0
Coagulation and bleeding analyses	0	0	0	0	3 (5.8%)	3 (3.1%)
Grade 1	0	0	0	0	3 (5.8%)	3 (3.1%)
Activated partial thromboplastin time prolonged	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
International normalised ratio increased	0	0	0	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Coagulation and bleeding analyses (cont)						
International normalised ratio increased (cont)						
Grade 1	0	0	0	0	0	0
Prothrombin time prolonged	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Digestive enzymes	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Lipase increased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Coagulation and bleeding analyses (cont)						
International normalised ratio increased (cont)						
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Prothrombin time prolonged	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Digestive enzymes	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0
Lipase increased	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Reproductive organ and breast imaging procedures	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Computerised tomogram pelvis abnormal	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Respiratory tract and thoracic imaging procedures	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Chest X-ray abnormal	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Reproductive organ and breast imaging procedures	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Computerised tomogram pelvis abnormal	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Respiratory tract and thoracic imaging procedures	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Chest X-ray abnormal	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Skeletal and cardiac muscle analyses	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Blood creatine phosphokinase increased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Vitamin analyses	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Blood folate decreased	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Skeletal and cardiac muscle analyses	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0
Blood creatine phosphokinase increased	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0
Vitamin analyses	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 2	0	0	0	1 (2.2%)	0	1 (1.0%)
Blood folate decreased	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 2	0	0	0	1 (2.2%)	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders	6 (25.0%)	5 (13.9%)	11 (18.3%)	4 (21.1%)	6 (18.8%)	10 (19.6%)
Grade 1	6 (25.0%)	2 (5.6%)	8 (13.3%)	4 (21.1%)	6 (18.8%)	10 (19.6%)
Grade 2	0	3 (8.3%)	3 (5.0%)	0	0	0
Grade 3	0	0	0	0	0	0
Rashes, eruptions and exanthems NEC	3 (12.5%)	1 (2.8%)	4 (6.7%)	2 (10.5%)	4 (12.5%)	6 (11.8%)
Grade 1	3 (12.5%)	0	3 (5.0%)	2 (10.5%)	4 (12.5%)	6 (11.8%)
Grade 2	0	1 (2.8%)	1 (1.7%)	0	0	0
Rash	2 (8.3%)	1 (2.8%)	3 (5.0%)	2 (10.5%)	3 (9.4%)	5 (9.8%)
Grade 1	2 (8.3%)	0	2 (3.3%)	2 (10.5%)	3 (9.4%)	5 (9.8%)
Grade 2	0	1 (2.8%)	1 (1.7%)	0	0	0
Rash maculo-papular	2 (8.3%)	0	2 (3.3%)	0	0	0
Grade 1	2 (8.3%)	0	2 (3.3%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders	14 (22.6%)	10 (17.2%)	24 (20.0%)	9 (20.0%)	11 (21.2%)	20 (20.6%)
Grade 1	10 (16.1%)	8 (13.8%)	18 (15.0%)	5 (11.1%)	8 (15.4%)	13 (13.4%)
Grade 2	4 (6.5%)	1 (1.7%)	5 (4.2%)	3 (6.7%)	2 (3.8%)	5 (5.2%)
Grade 3	0	1 (1.7%)	1 (0.8%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Rashes, eruptions and exanthems NEC	4 (6.5%)	1 (1.7%)	5 (4.2%)	1 (2.2%)	4 (7.7%)	5 (5.2%)
Grade 1	3 (4.8%)	1 (1.7%)	4 (3.3%)	1 (2.2%)	4 (7.7%)	5 (5.2%)
Grade 2	1 (1.6%)	0	1 (0.8%)	0	0	0
Rash	3 (4.8%)	1 (1.7%)	4 (3.3%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 1	2 (3.2%)	1 (1.7%)	3 (2.5%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 2	1 (1.6%)	0	1 (0.8%)	0	0	0
Rash maculo-papular	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Rashes, eruptions and exanthems NEC (cont)						
Rash macular	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Rash generalised	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	1 (3.1%)	1 (2.0%)
Rash papular	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Apocrine and eccrine gland disorders	1 (4.2%)	2 (5.6%)	3 (5.0%)	1 (5.3%)	1 (3.1%)	2 (3.9%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (5.3%)	1 (3.1%)	2 (3.9%)
Grade 2	0	2 (5.6%)	2 (3.3%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Rashes, eruptions and exanthems NEC (cont)						
Rash macular	1 (1.6%)	0	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Grade 1	1 (1.6%)	0	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Rash generalised	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Rash papular	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Apocrine and eccrine gland disorders	3 (4.8%)	2 (3.4%)	5 (4.2%)	4 (8.9%)	4 (7.7%)	8 (8.2%)
Grade 1	3 (4.8%)	2 (3.4%)	5 (4.2%)	4 (8.9%)	3 (5.8%)	7 (7.2%)
Grade 2	0	0	0	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Apocrine and eccrine gland disorders (cont)						
Night sweats	1 (4.2%)	1 (2.8%)	2 (3.3%)	1 (5.3%)	1 (3.1%)	2 (3.9%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (5.3%)	1 (3.1%)	2 (3.9%)
Grade 2	0	1 (2.8%)	1 (1.7%)	0	0	0
Hyperhidrosis	0	1 (2.8%)	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 2	0	1 (2.8%)	1 (1.7%)	0	0	0
Purpura and related conditions	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 1	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Apocrine and eccrine gland disorders (cont)						
Night sweats	3 (4.8%)	0	3 (2.5%)	4 (8.9%)	2 (3.8%)	6 (6.2%)
Grade 1	3 (4.8%)	0	3 (2.5%)	4 (8.9%)	1 (1.9%)	5 (5.2%)
Grade 2	0	0	0	0	1 (1.9%)	1 (1.0%)
Hyperhidrosis	0	2 (3.4%)	2 (1.7%)	0	2 (3.8%)	2 (2.1%)
Grade 1	0	2 (3.4%)	2 (1.7%)	0	2 (3.8%)	2 (2.1%)
Grade 2	0	0	0	0	0	0
Purpura and related conditions	3 (4.8%)	1 (1.7%)	4 (3.3%)	2 (4.4%)	0	2 (2.1%)
Grade 1	3 (4.8%)	1 (1.7%)	4 (3.3%)	1 (2.2%)	0	1 (1.0%)
Grade 2	0	0	0	1 (2.2%)	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase	DB Phase	DB Phase	OL Phase (Week 24 - 48) Continuing	OL Phase (Week 24 - 48) Switch	OL Phase (Week 24 - 48)
	MMB (N=24)	RUX (N=36)	Total (N=60)	(MMB->MMB) (N=19)	(RUX->MMB) (N=32)	Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Purpura and related conditions (cont)						
Ecchymosis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Petechiae	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 1	1 (4.2%)	0	1 (1.7%)	0	0	0
Purpura	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dermatitis and eczema	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 1	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Purpura and related conditions (cont)						
Ecchymosis	2 (3.2%)	0	2 (1.7%)	1 (2.2%)	0	1 (1.0%)
Grade 1	2 (3.2%)	0	2 (1.7%)	0	0	0
Grade 2	0	0	0	1 (2.2%)	0	1 (1.0%)
Petechiae	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	0	0
Grade 1	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	0	0
Purpura	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 1	0	0	0	1 (2.2%)	0	1 (1.0%)
Dermatitis and eczema	1 (1.6%)	0	1 (0.8%)	1 (2.2%)	0	1 (1.0%)
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 3	0	0	0	1 (2.2%)	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Dermatitis and eczema (cont)						
Dermatitis contact	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 1	1 (4.2%)	0	1 (1.7%)	0	0	0
Dermatitis allergic	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Pruritus NEC	0	2 (5.6%)	2 (3.3%)	0	2 (6.3%)	2 (3.9%)
Grade 1	0	1 (2.8%)	1 (1.7%)	0	2 (6.3%)	2 (3.9%)
Grade 2	0	1 (2.8%)	1 (1.7%)	0	0	0
Pruritus	0	1 (2.8%)	1 (1.7%)	0	2 (6.3%)	2 (3.9%)
Grade 1	0	1 (2.8%)	1 (1.7%)	0	2 (6.3%)	2 (3.9%)
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Dermatitis and eczema (cont)						
Dermatitis contact	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Dermatitis allergic	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 3	0	0	0	1 (2.2%)	0	1 (1.0%)
Pruritus NEC	2 (3.2%)	5 (8.6%)	7 (5.8%)	1 (2.2%)	5 (9.6%)	6 (6.2%)
Grade 1	2 (3.2%)	4 (6.9%)	6 (5.0%)	0	4 (7.7%)	4 (4.1%)
Grade 2	0	1 (1.7%)	1 (0.8%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Pruritus	1 (1.6%)	5 (8.6%)	6 (5.0%)	1 (2.2%)	5 (9.6%)	6 (6.2%)
Grade 1	1 (1.6%)	4 (6.9%)	5 (4.2%)	0	4 (7.7%)	4 (4.1%)
Grade 2	0	1 (1.7%)	1 (0.8%)	1 (2.2%)	1 (1.9%)	2 (2.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Pruritus NEC (cont)						
Pruritus generalised	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Aquagenic pruritus	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 1	0	1 (2.8%)	1 (1.7%)	0	0	0
Rash pruritic	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 2	0	1 (2.8%)	1 (1.7%)	0	0	0
Alopecias	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Alopecia	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Pruritus NEC (cont)						
Pruritus generalised	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Aquagenic pruritus	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Rash pruritic	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Alopecias	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Alopecia	1 (1.6%)	0	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Alopecias (cont)						
Alopecia (cont)						
Grade 1	0	0	0	0	0	0
Bullous conditions	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Blister	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Blood blister	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dermal and epidermal conditions NEC	0	2 (5.6%)	2 (3.3%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Alopecias (cont)						
Alopecia (cont)						
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Bullous conditions	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Blister	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Blood blister	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Dermal and epidermal conditions NEC	1 (1.6%)	1 (1.7%)	2 (1.7%)	2 (4.4%)	0	2 (2.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Dermal and epidermal conditions NEC (cont)						
(cont)						
Grade 1	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 2	0	1 (2.8%)	1 (1.7%)	0	0	0
Skin lesion	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 2	0	1 (2.8%)	1 (1.7%)	0	0	0
Dermatosis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Dry skin	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 1	0	1 (2.8%)	1 (1.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Dermal and epidermal conditions NEC (cont)						
(cont)						
Grade 1	0	1 (1.7%)	1 (0.8%)	1 (2.2%)	0	1 (1.0%)
Grade 2	1 (1.6%)	0	1 (0.8%)	1 (2.2%)	0	1 (1.0%)
Skin lesion	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	1 (1.6%)	0	1 (0.8%)	0	0	0
Dermatosis	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 2	0	0	0	1 (2.2%)	0	1 (1.0%)
Dry skin	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Dermal and epidermal conditions NEC (cont)						
Pain of skin	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Skin fragility	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Erythemas	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Erythema	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Dermal and epidermal conditions NEC (cont)						
Pain of skin	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0
Skin fragility	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 1	0	0	0	1 (2.2%)	0	1 (1.0%)
Erythemas	1 (1.6%)	0	1 (0.8%)	1 (2.2%)	0	1 (1.0%)
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	0	0	0	1 (2.2%)	0	1 (1.0%)
Erythema	1 (1.6%)	0	1 (0.8%)	1 (2.2%)	0	1 (1.0%)
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Erythemas (cont)						
Erythema (cont)						
Grade 2	0	0	0	0	0	0
Hyperkeratoses	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Hyperkeratosis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Nail and nail bed conditions (excl infections and infestations)	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Erythemas (cont)						
Erythema (cont)						
Grade 2	0	0	0	1 (2.2%)	0	1 (1.0%)
Hyperkeratoses	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	1 (1.6%)	0	1 (0.8%)	0	0	0
Hyperkeratosis	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	1 (1.6%)	0	1 (0.8%)	0	0	0
Nail and nail bed conditions (excl infections and infestations)	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	1 (1.6%)	0	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Nail and nail bed conditions (excl infections and infestations) (cont)						
Ingrowing nail	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Skin haemorrhages	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Skin haemorrhage	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Telangiectasia and related conditions	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Nail and nail bed conditions (excl infections and infestations) (cont)						
Ingrowing nail	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	1 (1.6%)	0	1 (0.8%)	0	0	0
Skin haemorrhages	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Skin haemorrhage	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Telangiectasia and related conditions	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Telangiectasia and related conditions (cont)						
Telangiectasia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dermatitis ascribed to specific agent	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Drug eruption	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Toxic skin eruption	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Telangiectasia and related conditions (cont)						
Telangiectasia	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Dermatitis ascribed to specific agent	0	0	0	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 3	0	0	0	1 (2.2%)	1 (1.9%)	2 (2.1%)
Drug eruption	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 3	0	0	0	0	1 (1.9%)	1 (1.0%)
Toxic skin eruption	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 3	0	0	0	1 (2.2%)	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Exfoliative conditions	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Skin exfoliation	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Skin and subcutaneous tissue ulcerations	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Skin ulcer	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Skin preneoplastic conditions NEC	0	0	0	1 (5.3%)	0	1 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Exfoliative conditions	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 1	0	0	0	1 (2.2%)	0	1 (1.0%)
Skin exfoliation	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 1	0	0	0	1 (2.2%)	0	1 (1.0%)
Skin and subcutaneous tissue ulcerations	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 3	0	1 (1.7%)	1 (0.8%)	0	0	0
Skin ulcer	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 3	0	1 (1.7%)	1 (0.8%)	0	0	0
Skin preneoplastic conditions NEC	0	0	0	1 (2.2%)	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Skin preneoplastic conditions NEC (cont)						
(cont)						
Grade 1	0	0	0	1 (5.3%)	0	1 (2.0%)
Grade 2	0	0	0	0	0	0
Actinic keratosis	0	0	0	1 (5.3%)	0	1 (2.0%)
Grade 1	0	0	0	1 (5.3%)	0	1 (2.0%)
Grade 2	0	0	0	0	0	0
Vascular disorders	6 (25.0%)	3 (8.3%)	9 (15.0%)	2 (10.5%)	2 (6.3%)	4 (7.8%)
Grade 1	4 (16.7%)	0	4 (6.7%)	1 (5.3%)	1 (3.1%)	2 (3.9%)
Grade 2	2 (8.3%)	2 (5.6%)	4 (6.7%)	1 (5.3%)	0	1 (2.0%)
Grade 3	0	1 (2.8%)	1 (1.7%)	0	1 (3.1%)	1 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Skin preneoplastic conditions NEC (cont)						
(cont)						
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	1 (2.2%)	0	1 (1.0%)
Actinic keratosis	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	1 (2.2%)	0	1 (1.0%)
Vascular disorders	12 (19.4%)	7 (12.1%)	19 (15.8%)	6 (13.3%)	10 (19.2%)	16 (16.5%)
Grade 1	6 (9.7%)	3 (5.2%)	9 (7.5%)	2 (4.4%)	4 (7.7%)	6 (6.2%)
Grade 2	3 (4.8%)	0	3 (2.5%)	2 (4.4%)	4 (7.7%)	6 (6.2%)
Grade 3	3 (4.8%)	3 (5.2%)	6 (5.0%)	2 (4.4%)	2 (3.8%)	4 (4.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont) (cont) (cont)						
Grade 4	0	0	0	0	0	0
Vascular hypotensive disorders	3 (12.5%)	0	3 (5.0%)	0	1 (3.1%)	1 (2.0%)
Grade 1	1 (4.2%)	0	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Grade 2	2 (8.3%)	0	2 (3.3%)	0	0	0
Grade 3	0	0	0	0	0	0
Hypotension	3 (12.5%)	0	3 (5.0%)	0	1 (3.1%)	1 (2.0%)
Grade 1	1 (4.2%)	0	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Grade 2	2 (8.3%)	0	2 (3.3%)	0	0	0
Grade 3	0	0	0	0	0	0
Peripheral vascular disorders NEC	2 (8.3%)	0	2 (3.3%)	1 (5.3%)	1 (3.1%)	2 (3.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont) (cont) (cont) Grade 4	0	1 (1.7%)	1 (0.8%)	0	0	0
Vascular hypotensive disorders	9 (14.5%)	0	9 (7.5%)	1 (2.2%)	2 (3.8%)	3 (3.1%)
Grade 1	5 (8.1%)	0	5 (4.2%)	0	0	0
Grade 2	2 (3.2%)	0	2 (1.7%)	0	2 (3.8%)	2 (2.1%)
Grade 3	2 (3.2%)	0	2 (1.7%)	1 (2.2%)	0	1 (1.0%)
Hypotension	9 (14.5%)	0	9 (7.5%)	1 (2.2%)	2 (3.8%)	3 (3.1%)
Grade 1	5 (8.1%)	0	5 (4.2%)	0	0	0
Grade 2	2 (3.2%)	0	2 (1.7%)	0	2 (3.8%)	2 (2.1%)
Grade 3	2 (3.2%)	0	2 (1.7%)	1 (2.2%)	0	1 (1.0%)
Peripheral vascular disorders NEC	3 (4.8%)	0	3 (2.5%)	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Peripheral vascular disorders NEC (cont) (cont)						
Grade 1	2 (8.3%)	0	2 (3.3%)	1 (5.3%)	1 (3.1%)	2 (3.9%)
Grade 2	0	0	0	0	0	0
Flushing	2 (8.3%)	0	2 (3.3%)	0	0	0
Grade 1	2 (8.3%)	0	2 (3.3%)	0	0	0
Grade 2	0	0	0	0	0	0
Hot flush	0	0	0	1 (5.3%)	1 (3.1%)	2 (3.9%)
Grade 1	0	0	0	1 (5.3%)	1 (3.1%)	2 (3.9%)
Haemorrhages NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Peripheral vascular disorders NEC (cont) (cont)						
Grade 1	2 (3.2%)	0	2 (1.7%)	0	1 (1.9%)	1 (1.0%)
Grade 2	1 (1.6%)	0	1 (0.8%)	0	0	0
Flushing	2 (3.2%)	0	2 (1.7%)	0	1 (1.9%)	1 (1.0%)
Grade 1	1 (1.6%)	0	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Grade 2	1 (1.6%)	0	1 (0.8%)	0	0	0
Hot flush	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Haemorrhages NEC	1 (1.6%)	2 (3.4%)	3 (2.5%)	2 (4.4%)	1 (1.9%)	3 (3.1%)
Grade 1	1 (1.6%)	2 (3.4%)	3 (2.5%)	2 (4.4%)	1 (1.9%)	3 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Haemorrhages NEC (cont)						
Haematoma	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Non-site specific vascular disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Poor venous access	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Peripheral vasoconstriction, necrosis and vascular insufficiency	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 1	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Haemorrhages NEC (cont)						
Haematoma	1 (1.6%)	2 (3.4%)	3 (2.5%)	2 (4.4%)	1 (1.9%)	3 (3.1%)
Grade 1	1 (1.6%)	2 (3.4%)	3 (2.5%)	2 (4.4%)	1 (1.9%)	3 (3.1%)
Non-site specific vascular disorders NEC	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Poor venous access	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Peripheral vasoconstriction, necrosis and vascular insufficiency	0	1 (1.7%)	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Peripheral vasoconstriction, necrosis and vascular insufficiency (cont) (cont)						
Grade 4	0	0	0	0	0	0
Peripheral arterial occlusive disease	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 1	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 2	0	0	0	0	0	0
Peripheral ischaemia	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Vascular hypertensive disorders NEC	0	3 (8.3%)	3 (5.0%)	1 (5.3%)	1 (3.1%)	2 (3.9%)
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Peripheral vasoconstriction, necrosis and vascular insufficiency (cont) (cont)						
Grade 4	0	1 (1.7%)	1 (0.8%)	0	0	0
Peripheral arterial occlusive disease	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (1.9%)	1 (1.0%)
Peripheral ischaemia	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 4	0	1 (1.7%)	1 (0.8%)	0	0	0
Vascular hypertensive disorders NEC	1 (1.6%)	4 (6.9%)	5 (4.2%)	2 (4.4%)	3 (5.8%)	5 (5.2%)
Grade 1	0	1 (1.7%)	1 (0.8%)	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Vascular hypertensive disorders NEC (cont) (cont) (cont)						
Grade 2	0	2 (5.6%)	2 (3.3%)	1 (5.3%)	0	1 (2.0%)
Grade 3	0	1 (2.8%)	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Hypertension	0	3 (8.3%)	3 (5.0%)	1 (5.3%)	1 (3.1%)	2 (3.9%)
Grade 1	0	0	0	0	0	0
Grade 2	0	2 (5.6%)	2 (3.3%)	1 (5.3%)	0	1 (2.0%)
Grade 3	0	1 (2.8%)	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Accelerated and malignant hypertension	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Hypertensive crisis	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Vascular hypertensive disorders NEC (cont) (cont)						
Grade 2	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 3	1 (1.6%)	3 (5.2%)	4 (3.3%)	1 (2.2%)	2 (3.8%)	3 (3.1%)
Hypertension	1 (1.6%)	4 (6.9%)	5 (4.2%)	2 (4.4%)	3 (5.8%)	5 (5.2%)
Grade 1	0	1 (1.7%)	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Grade 2	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 3	1 (1.6%)	3 (5.2%)	4 (3.3%)	1 (2.2%)	2 (3.8%)	3 (3.1%)
Accelerated and malignant hypertension	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 3	0	1 (1.7%)	1 (0.8%)	0	0	0
Hypertensive crisis	0	1 (1.7%)	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Accelerated and malignant hypertension (cont)						
Hypertensive crisis (cont)						
Grade 3	0	0	0	0	0	0
Aortic necrosis and vascular insufficiency	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Aortic stenosis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Non-site specific necrosis and vascular insufficiency NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Accelerated and malignant hypertension (cont)						
Hypertensive crisis (cont)						
Grade 3	0	1 (1.7%)	1 (0.8%)	0	0	0
Aortic necrosis and vascular insufficiency	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 2	0	0	0	0	1 (1.9%)	1 (1.0%)
Aortic stenosis	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 2	0	0	0	0	1 (1.9%)	1 (1.0%)
Non-site specific necrosis and vascular insufficiency NEC	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Non-site specific necrosis and vascular insufficiency NEC (cont)						
Arteriosclerosis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Peripheral embolism and thrombosis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Thrombophlebitis superficial	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Non-site specific necrosis and vascular insufficiency NEC (cont)						
Arteriosclerosis	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Peripheral embolism and thrombosis	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 2	0	0	0	1 (2.2%)	0	1 (1.0%)
Thrombophlebitis superficial	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 2	0	0	0	1 (2.2%)	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders	2 (8.3%)	1 (2.8%)	3 (5.0%)	0	2 (6.3%)	2 (3.9%)
Grade 1	1 (4.2%)	0	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 3	0	0	0	0	0	0
Grade 4	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 5	1 (4.2%)	0	1 (1.7%)	0	0	0
Renal failure and impairment	1 (4.2%)	1 (2.8%)	2 (3.3%)	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 3	0	0	0	0	0	0
Grade 4	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 5	1 (4.2%)	0	1 (1.7%)	0	0	0
Acute kidney injury	0	1 (2.8%)	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders	11 (17.7%)	8 (13.8%)	19 (15.8%)	3 (6.7%)	6 (11.5%)	9 (9.3%)
Grade 1	7 (11.3%)	2 (3.4%)	9 (7.5%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 2	1 (1.6%)	4 (6.9%)	5 (4.2%)	1 (2.2%)	2 (3.8%)	3 (3.1%)
Grade 3	2 (3.2%)	2 (3.4%)	4 (3.3%)	1 (2.2%)	3 (5.8%)	4 (4.1%)
Grade 4	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 5	0	0	0	0	0	0
Renal failure and impairment	6 (9.7%)	1 (1.7%)	7 (5.8%)	3 (6.7%)	3 (5.8%)	6 (6.2%)
Grade 1	4 (6.5%)	1 (1.7%)	5 (4.2%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 2	0	0	0	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 3	1 (1.6%)	0	1 (0.8%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 4	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 5	0	0	0	0	0	0
Acute kidney injury	2 (3.2%)	0	2 (1.7%)	2 (4.4%)	0	2 (2.1%)
Grade 1	2 (3.2%)	0	2 (1.7%)	1 (2.2%)	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Renal failure and impairment (cont)						
Acute kidney injury (cont)						
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 3	0	0	0	0	0	0
Grade 4	0	1 (2.8%)	1 (1.7%)	0	0	0
Renal failure	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 5	1 (4.2%)	0	1 (1.7%)	0	0	0
Renal impairment	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Renal failure and impairment (cont)						
Acute kidney injury (cont)						
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 4	0	0	0	0	0	0
Renal failure	1 (1.6%)	1 (1.7%)	2 (1.7%)	1 (2.2%)	2 (3.8%)	3 (3.1%)
Grade 1	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	1 (1.9%)	1 (1.0%)
Grade 2	0	0	0	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 5	0	0	0	0	0	0
Renal impairment	2 (3.2%)	0	2 (1.7%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 3	1 (1.6%)	0	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Renal failure and impairment (cont)						
Chronic kidney disease	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Bladder and urethral symptoms	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 1	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Dysuria	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Pollakiuria	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 1	1 (4.2%)	0	1 (1.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Renal failure and impairment (cont)						
Chronic kidney disease	1 (1.6%)	0	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Grade 3	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 4	1 (1.6%)	0	1 (0.8%)	0	0	0
Bladder and urethral symptoms	4 (6.5%)	2 (3.4%)	6 (5.0%)	0	0	0
Grade 1	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	0	0
Grade 2	2 (3.2%)	0	2 (1.7%)	0	0	0
Grade 3	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	0	0
Dysuria	2 (3.2%)	1 (1.7%)	3 (2.5%)	0	0	0
Grade 1	2 (3.2%)	1 (1.7%)	3 (2.5%)	0	0	0
Pollakiuria	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Bladder and urethral symptoms (cont)						
Pollakiuria (cont)						
Grade 3	0	0	0	0	0	0
Urinary incontinence	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Urinary retention	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Urinary tract signs and symptoms NEC	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Bladder and urethral symptoms (cont)						
Pollakiuria (cont)						
Grade 3	1 (1.6%)	0	1 (0.8%)	0	0	0
Urinary incontinence	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	0	0
Grade 2	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 3	0	1 (1.7%)	1 (0.8%)	0	0	0
Urinary retention	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	1 (1.6%)	0	1 (0.8%)	0	0	0
Urinary tract signs and symptoms NEC	2 (3.2%)	3 (5.2%)	5 (4.2%)	0	1 (1.9%)	1 (1.0%)
Grade 1	2 (3.2%)	0	2 (1.7%)	0	0	0
Grade 2	0	3 (5.2%)	3 (2.5%)	0	0	0
Grade 3	0	0	0	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Urinary tract signs and symptoms NEC (cont)						
Nocturia	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	1 (3.1%)	1 (2.0%)
Renal colic	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Renal lithiasis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Nephrolithiasis	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Urinary tract signs and symptoms NEC (cont)						
Nocturia	2 (3.2%)	0	2 (1.7%)	0	0	0
Grade 1	2 (3.2%)	0	2 (1.7%)	0	0	0
Renal colic	0	3 (5.2%)	3 (2.5%)	0	1 (1.9%)	1 (1.0%)
Grade 2	0	3 (5.2%)	3 (2.5%)	0	0	0
Grade 3	0	0	0	0	1 (1.9%)	1 (1.0%)
Renal lithiasis	1 (1.6%)	2 (3.4%)	3 (2.5%)	0	1 (1.9%)	1 (1.0%)
Grade 1	1 (1.6%)	0	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 3	0	1 (1.7%)	1 (0.8%)	0	0	0
Nephrolithiasis	1 (1.6%)	2 (3.4%)	3 (2.5%)	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Renal lithiasis (cont)						
Nephrolithiasis (cont)						
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Urinary abnormalities	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	1 (2.8%)	1 (1.7%)	0	0	0
Chromaturia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Haematuria	0	1 (2.8%)	1 (1.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Renal lithiasis (cont)						
Nephrolithiasis (cont)						
Grade 1	1 (1.6%)	0	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 3	0	1 (1.7%)	1 (0.8%)	0	0	0
Urinary abnormalities	1 (1.6%)	0	1 (0.8%)	0	2 (3.8%)	2 (2.1%)
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 3	0	0	0	0	1 (1.9%)	1 (1.0%)
Chromaturia	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Haematuria	1 (1.6%)	0	1 (0.8%)	0	2 (3.8%)	2 (2.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Urinary abnormalities (cont)						
Haematuria (cont)						
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	1 (2.8%)	1 (1.7%)	0	0	0
Renal vascular and ischaemic conditions	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Renal artery stenosis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Urinary abnormalities (cont)						
Haematuria (cont)						
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 3	0	0	0	0	1 (1.9%)	1 (1.0%)
Renal vascular and ischaemic conditions	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0
Renal artery stenosis	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders	1 (4.2%)	1 (2.8%)	2 (3.3%)	0	3 (9.4%)	3 (5.9%)
Grade 1	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 2	1 (4.2%)	0	1 (1.7%)	0	2 (6.3%)	2 (3.9%)
Grade 3	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 4	0	0	0	0	0	0
Supraventricular arrhythmias	1 (4.2%)	0	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	0	0
Grade 2	1 (4.2%)	0	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Grade 3	0	0	0	0	0	0
Atrial fibrillation	1 (4.2%)	0	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	0	0
Grade 2	1 (4.2%)	0	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders	11 (17.7%)	7 (12.1%)	18 (15.0%)	3 (6.7%)	3 (5.8%)	6 (6.2%)
Grade 1	3 (4.8%)	2 (3.4%)	5 (4.2%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 2	2 (3.2%)	2 (3.4%)	4 (3.3%)	1 (2.2%)	0	1 (1.0%)
Grade 3	5 (8.1%)	3 (5.2%)	8 (6.7%)	1 (2.2%)	2 (3.8%)	3 (3.1%)
Grade 4	1 (1.6%)	0	1 (0.8%)	0	0	0
Supraventricular arrhythmias	5 (8.1%)	2 (3.4%)	7 (5.8%)	2 (4.4%)	1 (1.9%)	3 (3.1%)
Grade 1	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	0	0
Grade 2	2 (3.2%)	0	2 (1.7%)	1 (2.2%)	0	1 (1.0%)
Grade 3	2 (3.2%)	1 (1.7%)	3 (2.5%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Atrial fibrillation	4 (6.5%)	1 (1.7%)	5 (4.2%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	1 (1.6%)	0	1 (0.8%)	1 (2.2%)	0	1 (1.0%)
Grade 3	2 (3.2%)	1 (1.7%)	3 (2.5%)	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Supraventricular arrhythmias (cont)						
Supraventricular tachycardia	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Atrial flutter	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)
Sinus bradycardia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Heart failures NEC	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Supraventricular arrhythmias (cont)						
Supraventricular tachycardia	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	1 (1.6%)	0	1 (0.8%)	0	0	0
Atrial flutter	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Sinus bradycardia	0	1 (1.7%)	1 (0.8%)	1 (2.2%)	0	1 (1.0%)
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 3	0	0	0	1 (2.2%)	0	1 (1.0%)
Heart failures NEC	3 (4.8%)	4 (6.9%)	7 (5.8%)	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 2	0	2 (3.4%)	2 (1.7%)	0	0	0
Grade 3	3 (4.8%)	2 (3.4%)	5 (4.2%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Heart failures NEC (cont)						
Cardiac failure	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 3	0	0	0	0	0	0
Cardiac failure congestive	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Cardiac failure acute	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Rate and rhythm disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Heart failures NEC (cont)						
Cardiac failure	2 (3.2%)	2 (3.4%)	4 (3.3%)	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 2	0	2 (3.4%)	2 (1.7%)	0	0	0
Grade 3	2 (3.2%)	0	2 (1.7%)	0	0	0
Cardiac failure congestive	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	0	0
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 3	1 (1.6%)	0	1 (0.8%)	0	0	0
Cardiac failure acute	0	2 (3.4%)	2 (1.7%)	0	0	0
Grade 3	0	2 (3.4%)	2 (1.7%)	0	0	0
Rate and rhythm disorders NEC	2 (3.2%)	0	2 (1.7%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Rate and rhythm disorders NEC (cont)						
(cont)						
Grade 2	0	0	0	0	0	0
Extrasystoles	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Tachycardia	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Cardiac conduction disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Atrioventricular block complete	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Rate and rhythm disorders NEC (cont)						
(cont)						
Grade 2	1 (1.6%)	0	1 (0.8%)	0	0	0
Extrasystoles	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Tachycardia	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	1 (1.6%)	0	1 (0.8%)	0	0	0
Cardiac conduction disorders	1 (1.6%)	0	1 (0.8%)	1 (2.2%)	0	1 (1.0%)
Grade 1	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 3	1 (1.6%)	0	1 (0.8%)	0	0	0
Atrioventricular block complete	1 (1.6%)	0	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Cardiac conduction disorders (cont)						
Atrioventricular block complete (cont)						
Grade 3	0	0	0	0	0	0
Atrioventricular block first degree	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Cardiac signs and symptoms NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Palpitations	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Cardiac conduction disorders (cont)						
Atrioventricular block complete (cont)						
Grade 3	1 (1.6%)	0	1 (0.8%)	0	0	0
Atrioventricular block first degree	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 1	0	0	0	1 (2.2%)	0	1 (1.0%)
Cardiac signs and symptoms NEC	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Palpitations	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Ischaemic coronary artery disorders	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Acute myocardial infarction	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Angina pectoris	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Myocardial disorders NEC	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Ischaemic coronary artery disorders	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 3	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 4	1 (1.6%)	0	1 (0.8%)	0	0	0
Acute myocardial infarction	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 4	1 (1.6%)	0	1 (0.8%)	0	0	0
Angina pectoris	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 3	1 (1.6%)	0	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Myocardial disorders NEC	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Myocardial disorders NEC (cont)						
(cont)						
Grade 2	0	0	0	0	0	0
Cardiomegaly	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Left ventricular dysfunction	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Pericardial disorders NEC	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Pericardial effusion	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Myocardial disorders NEC (cont)						
(cont)						
Grade 2	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	0	0
Cardiomegaly	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	1 (1.6%)	0	1 (0.8%)	0	0	0
Left ventricular dysfunction	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0
Pericardial disorders NEC	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 3	1 (1.6%)	0	1 (0.8%)	0	0	0
Pericardial effusion	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 3	1 (1.6%)	0	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Cardiac hypertensive complications	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 3	0	1 (2.8%)	1 (1.7%)	0	0	0
Hypertensive heart disease	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 3	0	1 (2.8%)	1 (1.7%)	0	0	0
Cardiac valve disorders NEC	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	1 (3.1%)	1 (2.0%)
Cardiac valve disease	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	1 (3.1%)	1 (2.0%)
Left ventricular failures	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Cardiac hypertensive complications	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Hypertensive heart disease	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Cardiac valve disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Cardiac valve disease	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Left ventricular failures	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Left ventricular failures (cont)						
Left ventricular failure	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Mitral valvular disorders	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Mitral valve incompetence	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Injury, poisoning and procedural complications	3 (12.5%)	3 (8.3%)	6 (10.0%)	1 (5.3%)	2 (6.3%)	3 (5.9%)
Grade 1	2 (8.3%)	1 (2.8%)	3 (5.0%)	1 (5.3%)	0	1 (2.0%)
Grade 2	0	2 (5.6%)	2 (3.3%)	0	0	0
Grade 3	1 (4.2%)	0	1 (1.7%)	0	2 (6.3%)	2 (3.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Left ventricular failures (cont)						
Left ventricular failure	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0
Mitral valvular disorders	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0
Mitral valve incompetence	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0
Injury, poisoning and procedural complications	9 (14.5%)	12 (20.7%)	21 (17.5%)	5 (11.1%)	6 (11.5%)	11 (11.3%)
Grade 1	6 (9.7%)	8 (13.8%)	14 (11.7%)	3 (6.7%)	2 (3.8%)	5 (5.2%)
Grade 2	3 (4.8%)	3 (5.2%)	6 (5.0%)	2 (4.4%)	4 (7.7%)	6 (6.2%)
Grade 3	0	1 (1.7%)	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Skin injuries NEC	1 (4.2%)	2 (5.6%)	3 (5.0%)	1 (5.3%)	0	1 (2.0%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (5.3%)	0	1 (2.0%)
Grade 2	0	2 (5.6%)	2 (3.3%)	0	0	0
Contusion	1 (4.2%)	2 (5.6%)	3 (5.0%)	1 (5.3%)	0	1 (2.0%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (5.3%)	0	1 (2.0%)
Grade 2	0	2 (5.6%)	2 (3.3%)	0	0	0
Skin abrasion	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 1	0	1 (2.8%)	1 (1.7%)	0	0	0
Skin laceration	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Skin injuries NEC	7 (11.3%)	5 (8.6%)	12 (10.0%)	2 (4.4%)	3 (5.8%)	5 (5.2%)
Grade 1	6 (9.7%)	5 (8.6%)	11 (9.2%)	2 (4.4%)	2 (3.8%)	4 (4.1%)
Grade 2	1 (1.6%)	0	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Contusion	6 (9.7%)	2 (3.4%)	8 (6.7%)	2 (4.4%)	2 (3.8%)	4 (4.1%)
Grade 1	5 (8.1%)	2 (3.4%)	7 (5.8%)	2 (4.4%)	2 (3.8%)	4 (4.1%)
Grade 2	1 (1.6%)	0	1 (0.8%)	0	0	0
Skin abrasion	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	0	0
Grade 1	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	0	0
Skin laceration	0	2 (3.4%)	2 (1.7%)	0	1 (1.9%)	1 (1.0%)
Grade 1	0	2 (3.4%)	2 (1.7%)	0	0	0
Grade 2	0	0	0	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Non-site specific injuries NEC	1 (4.2%)	2 (5.6%)	3 (5.0%)	0	1 (3.1%)	1 (2.0%)
Grade 1	1 (4.2%)	2 (5.6%)	3 (5.0%)	0	1 (3.1%)	1 (2.0%)
Grade 2	0	0	0	0	0	0
Fall	1 (4.2%)	2 (5.6%)	3 (5.0%)	0	1 (3.1%)	1 (2.0%)
Grade 1	1 (4.2%)	2 (5.6%)	3 (5.0%)	0	1 (3.1%)	1 (2.0%)
Grade 2	0	0	0	0	0	0
Wound	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Non-site specific injuries NEC	3 (4.8%)	2 (3.4%)	5 (4.2%)	2 (4.4%)	3 (5.8%)	5 (5.2%)
Grade 1	3 (4.8%)	2 (3.4%)	5 (4.2%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 2	0	0	0	1 (2.2%)	2 (3.8%)	3 (3.1%)
Fall	3 (4.8%)	2 (3.4%)	5 (4.2%)	2 (4.4%)	3 (5.8%)	5 (5.2%)
Grade 1	3 (4.8%)	2 (3.4%)	5 (4.2%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 2	0	0	0	1 (2.2%)	2 (3.8%)	3 (3.1%)
Wound	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Non-site specific procedural complications	1 (4.2%)	0	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	1 (4.2%)	0	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Post procedural complication	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Post procedural contusion	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Procedural pain	1 (4.2%)	0	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Non-site specific procedural complications	2 (3.2%)	3 (5.2%)	5 (4.2%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	1 (1.6%)	2 (3.4%)	3 (2.5%)	0	0	0
Grade 3	0	1 (1.7%)	1 (0.8%)	0	0	0
Post procedural complication	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	1 (1.6%)	0	1 (0.8%)	0	0	0
Post procedural contusion	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Procedural pain	0	2 (3.4%)	2 (1.7%)	0	0	0
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Non-site specific procedural complications (cont)						
Procedural pain (cont)						
Grade 3	1 (4.2%)	0	1 (1.7%)	0	0	0
Post procedural haemorrhage	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 3	0	0	0	0	1 (3.1%)	1 (2.0%)
Seroma	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Site specific injuries NEC	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 1	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Non-site specific procedural complications (cont)						
Procedural pain (cont)						
Grade 3	0	1 (1.7%)	1 (0.8%)	0	0	0
Post procedural haemorrhage	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Seroma	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0
Site specific injuries NEC	2 (3.2%)	1 (1.7%)	3 (2.5%)	1 (2.2%)	2 (3.8%)	3 (3.1%)
Grade 1	1 (1.6%)	0	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Grade 2	1 (1.6%)	1 (1.7%)	2 (1.7%)	1 (2.2%)	1 (1.9%)	2 (2.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Site specific injuries NEC (cont)						
Limb injury	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Limb crushing injury	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 1	1 (4.2%)	0	1 (1.7%)	0	0	0
Head injury	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Mouth injury	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Site specific injuries NEC (cont)						
Limb injury	2 (3.2%)	0	2 (1.7%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 2	1 (1.6%)	0	1 (0.8%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Limb crushing injury	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Head injury	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Mouth injury	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Chest and respiratory tract injuries NEC	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 3	0	0	0	0	1 (3.1%)	1 (2.0%)
Traumatic haemothorax	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 3	0	0	0	0	1 (3.1%)	1 (2.0%)
Eye injuries NEC	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 1	0	1 (2.8%)	1 (1.7%)	0	0	0
Eye contusion	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 1	0	1 (2.8%)	1 (1.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Chest and respiratory tract injuries NEC	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Traumatic haemothorax	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Eye injuries NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Eye contusion	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Gastrointestinal and hepatobiliary procedural complications	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)
Procedural nausea	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)
Limb fractures and dislocations	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Patella fracture	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Muscle, tendon and ligament injuries	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Gastrointestinal and hepatobiliary procedural complications	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Procedural nausea	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Limb fractures and dislocations	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 2	0	0	0	0	1 (1.9%)	1 (1.0%)
Patella fracture	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 2	0	0	0	0	1 (1.9%)	1 (1.0%)
Muscle, tendon and ligament injuries	0	2 (3.4%)	2 (1.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Muscle, tendon and ligament injuries (cont)						
(cont)						
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Ligament rupture	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Ligament sprain	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Skull fractures, facial bone fractures and dislocations	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Muscle, tendon and ligament injuries (cont)						
(cont)						
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0
Ligament rupture	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0
Ligament sprain	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0
Skull fractures, facial bone fractures and dislocations	0	0	0	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Skull fractures, facial bone fractures and dislocations (cont) (cont)						
Grade 1	0	0	0	0	0	0
Facial bones fracture	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Transfusion related complications	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Transfusion reaction	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Skull fractures, facial bone fractures and dislocations (cont) (cont)						
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Facial bones fracture	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Transfusion related complications	0	2 (3.4%)	2 (1.7%)	0	0	0
Grade 1	0	2 (3.4%)	2 (1.7%)	0	0	0
Transfusion reaction	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Transfusion related complications (cont)						
Transfusion related complication	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Eye disorders	5 (20.8%)	2 (5.6%)	7 (11.7%)	4 (21.1%)	3 (9.4%)	7 (13.7%)
Grade 1	5 (20.8%)	1 (2.8%)	6 (10.0%)	4 (21.1%)	3 (9.4%)	7 (13.7%)
Grade 2	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 3	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Cataract conditions	1 (4.2%)	1 (2.8%)	2 (3.3%)	2 (10.5%)	1 (3.1%)	3 (5.9%)
Grade 1	1 (4.2%)	1 (2.8%)	2 (3.3%)	2 (10.5%)	1 (3.1%)	3 (5.9%)
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Transfusion related complications (cont)						
Transfusion related complication	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0
Eye disorders	5 (8.1%)	5 (8.6%)	10 (8.3%)	4 (8.9%)	1 (1.9%)	5 (5.2%)
Grade 1	4 (6.5%)	3 (5.2%)	7 (5.8%)	2 (4.4%)	1 (1.9%)	3 (3.1%)
Grade 2	1 (1.6%)	2 (3.4%)	3 (2.5%)	0	0	0
Grade 3	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 4	0	0	0	1 (2.2%)	0	1 (1.0%)
Cataract conditions	2 (3.2%)	0	2 (1.7%)	2 (4.4%)	0	2 (2.1%)
Grade 1	1 (1.6%)	0	1 (0.8%)	1 (2.2%)	0	1 (1.0%)
Grade 2	1 (1.6%)	0	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Cataract conditions (cont)						
(cont)						
Grade 3	0	0	0	0	0	0
Cataract	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Cataract cortical	0	0	0	1 (5.3%)	1 (3.1%)	2 (3.9%)
Grade 1	0	0	0	1 (5.3%)	1 (3.1%)	2 (3.9%)
Grade 2	0	0	0	0	0	0
Cataract nuclear	1 (4.2%)	1 (2.8%)	2 (3.3%)	1 (5.3%)	0	1 (2.0%)
Grade 1	1 (4.2%)	1 (2.8%)	2 (3.3%)	1 (5.3%)	0	1 (2.0%)
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Cataract conditions (cont)						
(cont)						
Grade 3	0	0	0	1 (2.2%)	0	1 (1.0%)
Cataract	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Cataract cortical	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	1 (1.6%)	0	1 (0.8%)	0	0	0
Cataract nuclear	0	0	0	2 (4.4%)	0	2 (2.1%)
Grade 1	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 3	0	0	0	1 (2.2%)	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Cataract conditions (cont)						
Cataract subcapsular	0	1 (2.8%)	1 (1.7%)	1 (5.3%)	0	1 (2.0%)
Grade 1	0	1 (2.8%)	1 (1.7%)	1 (5.3%)	0	1 (2.0%)
Visual disorders NEC	1 (4.2%)	0	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Grade 1	1 (4.2%)	0	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Vision blurred	1 (4.2%)	0	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Grade 1	1 (4.2%)	0	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Diplopia	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Cataract conditions (cont)						
Cataract subcapsular	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Visual disorders NEC	2 (3.2%)	2 (3.4%)	4 (3.3%)	1 (2.2%)	0	1 (1.0%)
Grade 1	2 (3.2%)	0	2 (1.7%)	0	0	0
Grade 2	0	2 (3.4%)	2 (1.7%)	0	0	0
Grade 3	0	0	0	1 (2.2%)	0	1 (1.0%)
Vision blurred	2 (3.2%)	1 (1.7%)	3 (2.5%)	1 (2.2%)	0	1 (1.0%)
Grade 1	2 (3.2%)	0	2 (1.7%)	0	0	0
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 3	0	0	0	1 (2.2%)	0	1 (1.0%)
Diplopia	0	1 (1.7%)	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Visual disorders NEC (cont)						
Diplopia (cont)						
Grade 2	0	0	0	0	0	0
Lacrimation disorders	1 (4.2%)	1 (2.8%)	2 (3.3%)	0	0	0
Grade 1	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 2	0	1 (2.8%)	1 (1.7%)	0	0	0
Lacrimation increased	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 1	1 (4.2%)	0	1 (1.7%)	0	0	0
Dry eye	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (2.8%)	1 (1.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Visual disorders NEC (cont)						
Diplopia (cont)						
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0
Lacrimation disorders	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	1 (1.9%)	1 (1.0%)
Grade 1	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	1 (1.9%)	1 (1.0%)
Grade 2	0	0	0	0	0	0
Lacrimation increased	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Dry eye	0	1 (1.7%)	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Grade 1	0	1 (1.7%)	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Choroid and vitreous structural change, deposit and degeneration	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 1	1 (4.2%)	0	1 (1.7%)	0	0	0
Hyalosis asteroid	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 1	1 (4.2%)	0	1 (1.7%)	0	0	0
Corneal infections, oedemas and inflammations	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 1	1 (4.2%)	0	1 (1.7%)	0	0	0
Keratitis	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 1	1 (4.2%)	0	1 (1.7%)	0	0	0
Ocular disorders NEC	1 (4.2%)	0	1 (1.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Choroid and vitreous structural change, deposit and degeneration	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hyalosis asteroid	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Corneal infections, oedemas and inflammations	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Keratitis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Ocular disorders NEC	0	1 (1.7%)	1 (0.8%)	1 (2.2%)	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Ocular disorders NEC (cont)						
(cont)						
Grade 1	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 3	0	0	0	0	0	0
Periorbital oedema	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 1	1 (4.2%)	0	1 (1.7%)	0	0	0
Eye oedema	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Eye pain	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Ocular disorders NEC (cont)						
(cont)						
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 3	0	0	0	1 (2.2%)	0	1 (1.0%)
Periorbital oedema	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Eye oedema	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0
Eye pain	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 3	0	0	0	1 (2.2%)	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Retinal bleeding and vascular disorders (excl retinopathy)	0	0	0	1 (5.3%)	0	1 (2.0%)
Grade 1	0	0	0	1 (5.3%)	0	1 (2.0%)
Retinal haemorrhage	0	0	0	1 (5.3%)	0	1 (2.0%)
Grade 1	0	0	0	1 (5.3%)	0	1 (2.0%)
Retinal structural change, deposit and degeneration	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Macular degeneration	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Retinal bleeding and vascular disorders (excl retinopathy)	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Retinal haemorrhage	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Retinal structural change, deposit and degeneration	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Macular degeneration	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Visual impairment and blindness (excl colour blindness)	1 (4.2%)	1 (2.8%)	2 (3.3%)	0	0	0
Grade 1	1 (4.2%)	1 (2.8%)	2 (3.3%)	0	0	0
Visual acuity reduced	1 (4.2%)	1 (2.8%)	2 (3.3%)	0	0	0
Grade 1	1 (4.2%)	1 (2.8%)	2 (3.3%)	0	0	0
Visual impairment	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Conjunctival and corneal bleeding and vascular disorders	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	1 (3.1%)	1 (2.0%)
Conjunctival haemorrhage	0	0	0	0	1 (3.1%)	1 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Visual impairment and blindness (excl colour blindness)	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0
Visual acuity reduced	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Visual impairment	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0
Conjunctival and corneal bleeding and vascular disorders	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 1	0	0	0	1 (2.2%)	0	1 (1.0%)
Conjunctival haemorrhage	0	0	0	1 (2.2%)	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Conjunctival and corneal bleeding and vascular disorders (cont)						
Conjunctival haemorrhage (cont)						
Grade 1	0	0	0	0	1 (3.1%)	1 (2.0%)
Eyelid movement disorders	0	0	0	1 (5.3%)	0	1 (2.0%)
Grade 1	0	0	0	1 (5.3%)	0	1 (2.0%)
Eyelid ptosis	0	0	0	1 (5.3%)	0	1 (2.0%)
Grade 1	0	0	0	1 (5.3%)	0	1 (2.0%)
Lid, lash and lacrimal infections, irritations and inflammations	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	1 (3.1%)	1 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Conjunctival and corneal bleeding and vascular disorders (cont)						
Conjunctival haemorrhage (cont)						
Grade 1	0	0	0	1 (2.2%)	0	1 (1.0%)
Eyelid movement disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Eyelid ptosis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Lid, lash and lacrimal infections, irritations and inflammations	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Lid, lash and lacrimal infections, irritations and inflammations (cont)						
Eyelid oedema	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	1 (3.1%)	1 (2.0%)
Ocular bleeding and vascular disorders NEC	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Eye haemorrhage	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Psychiatric disorders	2 (8.3%)	1 (2.8%)	3 (5.0%)	3 (15.8%)	1 (3.1%)	4 (7.8%)
Grade 1	1 (4.2%)	1 (2.8%)	2 (3.3%)	1 (5.3%)	1 (3.1%)	2 (3.9%)
Grade 2	1 (4.2%)	0	1 (1.7%)	2 (10.5%)	0	2 (3.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Lid, lash and lacrimal infections, irritations and inflammations (cont)						
Eyelid oedema	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Ocular bleeding and vascular disorders NEC	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 4	0	0	0	1 (2.2%)	0	1 (1.0%)
Eye haemorrhage	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 4	0	0	0	1 (2.2%)	0	1 (1.0%)
Psychiatric disorders	6 (9.7%)	5 (8.6%)	11 (9.2%)	3 (6.7%)	7 (13.5%)	10 (10.3%)
Grade 1	3 (4.8%)	3 (5.2%)	6 (5.0%)	3 (6.7%)	2 (3.8%)	5 (5.2%)
Grade 2	3 (4.8%)	2 (3.4%)	5 (4.2%)	0	5 (9.6%)	5 (5.2%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Anxiety symptoms	2 (8.3%)	0	2 (3.3%)	1 (5.3%)	0	1 (2.0%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (5.3%)	0	1 (2.0%)
Grade 2	1 (4.2%)	0	1 (1.7%)	0	0	0
Anxiety	2 (8.3%)	0	2 (3.3%)	1 (5.3%)	0	1 (2.0%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (5.3%)	0	1 (2.0%)
Grade 2	1 (4.2%)	0	1 (1.7%)	0	0	0
Depressive disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Depression	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Anxiety symptoms	1 (1.6%)	3 (5.2%)	4 (3.3%)	0	0	0
Grade 1	0	2 (3.4%)	2 (1.7%)	0	0	0
Grade 2	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	0	0
Anxiety	1 (1.6%)	3 (5.2%)	4 (3.3%)	0	0	0
Grade 1	0	2 (3.4%)	2 (1.7%)	0	0	0
Grade 2	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	0	0
Depressive disorders	3 (4.8%)	0	3 (2.5%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 1	1 (1.6%)	0	1 (0.8%)	1 (2.2%)	0	1 (1.0%)
Grade 2	2 (3.2%)	0	2 (1.7%)	0	1 (1.9%)	1 (1.0%)
Depression	3 (4.8%)	0	3 (2.5%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 1	1 (1.6%)	0	1 (0.8%)	1 (2.2%)	0	1 (1.0%)
Grade 2	2 (3.2%)	0	2 (1.7%)	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Confusion and disorientation	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Confusional state	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Disturbances in initiating and maintaining sleep	0	1 (2.8%)	1 (1.7%)	1 (5.3%)	1 (3.1%)	2 (3.9%)
Grade 1	0	1 (2.8%)	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Grade 2	0	0	0	1 (5.3%)	0	1 (2.0%)
Insomnia	0	1 (2.8%)	1 (1.7%)	1 (5.3%)	1 (3.1%)	2 (3.9%)
Grade 1	0	1 (2.8%)	1 (1.7%)	0	1 (3.1%)	1 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Confusion and disorientation	1 (1.6%)	0	1 (0.8%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 1	1 (1.6%)	0	1 (0.8%)	1 (2.2%)	0	1 (1.0%)
Grade 2	0	0	0	0	1 (1.9%)	1 (1.0%)
Confusional state	1 (1.6%)	0	1 (0.8%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 1	1 (1.6%)	0	1 (0.8%)	1 (2.2%)	0	1 (1.0%)
Grade 2	0	0	0	0	1 (1.9%)	1 (1.0%)
Disturbances in initiating and maintaining sleep	1 (1.6%)	1 (1.7%)	2 (1.7%)	1 (2.2%)	3 (5.8%)	4 (4.1%)
Grade 1	1 (1.6%)	0	1 (0.8%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 2	0	1 (1.7%)	1 (0.8%)	0	2 (3.8%)	2 (2.1%)
Insomnia	1 (1.6%)	1 (1.7%)	2 (1.7%)	1 (2.2%)	3 (5.8%)	4 (4.1%)
Grade 1	1 (1.6%)	0	1 (0.8%)	1 (2.2%)	1 (1.9%)	2 (2.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-db.pdf 29AUG2023: 9:42

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Disturbances in initiating and maintaining sleep (cont)						
Insomnia (cont)						
Grade 2	0	0	0	1 (5.3%)	0	1 (2.0%)
Hallucinations (excl sleep-related)	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hallucination	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Mental disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Mental status changes	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Disturbances in initiating and maintaining sleep (cont)						
Insomnia (cont)						
Grade 2	0	1 (1.7%)	1 (0.8%)	0	2 (3.8%)	2 (2.1%)
Hallucinations (excl sleep-related)	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Hallucination	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Mental disorders NEC	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Mental status changes	1 (1.6%)	0	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Mental disorders NEC (cont)						
Mental status changes (cont)						
Grade 1	0	0	0	0	0	0
Anxiety disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Anxiety disorder	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Parasomnias	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Nightmare	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Mental disorders NEC (cont)						
Mental status changes (cont)						
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Anxiety disorders NEC	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0
Anxiety disorder	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0
Parasomnias	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0
Nightmare	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Sexual desire disorders	0	0	0	1 (5.3%)	0	1 (2.0%)
Grade 1	0	0	0	1 (5.3%)	0	1 (2.0%)
Grade 2	0	0	0	0	0	0
Libido decreased	0	0	0	1 (5.3%)	0	1 (2.0%)
Grade 1	0	0	0	1 (5.3%)	0	1 (2.0%)
Grade 2	0	0	0	0	0	0
Sleep disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Sleep disorder	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Suicidal and self-injurious behaviour	0	0	0	1 (5.3%)	0	1 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Sexual desire disorders	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (1.9%)	1 (1.0%)
Libido decreased	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (1.9%)	1 (1.0%)
Sleep disorders NEC	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Sleep disorder	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Suicidal and self-injurious behaviour	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Suicidal and self-injurious behaviour (cont)						
(cont)						
Grade 2	0	0	0	1 (5.3%)	0	1 (2.0%)
Suicidal ideation	0	0	0	1 (5.3%)	0	1 (2.0%)
Grade 2	0	0	0	1 (5.3%)	0	1 (2.0%)
Ear and labyrinth disorders	1 (4.2%)	1 (2.8%)	2 (3.3%)	0	1 (3.1%)	1 (2.0%)
Grade 1	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 2	1 (4.2%)	0	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Grade 3	0	0	0	0	0	0
Inner ear signs and symptoms	0	1 (2.8%)	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Grade 1	0	1 (2.8%)	1 (1.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Suicidal and self-injurious behaviour (cont)						
(cont)						
Grade 2	0	0	0	0	0	0
Suicidal ideation	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Ear and labyrinth disorders	4 (6.5%)	5 (8.6%)	9 (7.5%)	3 (6.7%)	2 (3.8%)	5 (5.2%)
Grade 1	3 (4.8%)	4 (6.9%)	7 (5.8%)	1 (2.2%)	2 (3.8%)	3 (3.1%)
Grade 2	1 (1.6%)	0	1 (0.8%)	2 (4.4%)	0	2 (2.1%)
Grade 3	0	1 (1.7%)	1 (0.8%)	0	0	0
Inner ear signs and symptoms	4 (6.5%)	3 (5.2%)	7 (5.8%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 1	3 (4.8%)	2 (3.4%)	5 (4.2%)	1 (2.2%)	1 (1.9%)	2 (2.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Ear and labyrinth disorders (cont)						
Inner ear signs and symptoms (cont)						
(cont)						
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 3	0	0	0	0	0	0
Vertigo	0	1 (2.8%)	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Grade 1	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 2	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 3	0	0	0	0	0	0
Motion sickness	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hearing losses	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Ear and labyrinth disorders (cont)						
Inner ear signs and symptoms (cont)						
(cont)						
Grade 2	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 3	0	1 (1.7%)	1 (0.8%)	0	0	0
Vertigo	4 (6.5%)	3 (5.2%)	7 (5.8%)	0	1 (1.9%)	1 (1.0%)
Grade 1	3 (4.8%)	2 (3.4%)	5 (4.2%)	0	1 (1.9%)	1 (1.0%)
Grade 2	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 3	0	1 (1.7%)	1 (0.8%)	0	0	0
Motion sickness	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 1	0	0	0	1 (2.2%)	0	1 (1.0%)
Hearing losses	0	0	0	2 (4.4%)	1 (1.9%)	3 (3.1%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Ear and labyrinth disorders (cont)						
Hearing losses (cont)						
(cont)						
Grade 2	1 (4.2%)	0	1 (1.7%)	0	0	0
Hypoacusis	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	1 (4.2%)	0	1 (1.7%)	0	0	0
Deafness	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Sudden hearing loss	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Ear disorders NEC	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Ear and labyrinth disorders (cont)						
Hearing losses (cont)						
(cont)						
Grade 2	0	0	0	2 (4.4%)	0	2 (2.1%)
Hypoacusis	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 2	0	0	0	0	0	0
Deafness	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 2	0	0	0	1 (2.2%)	0	1 (1.0%)
Sudden hearing loss	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 2	0	0	0	1 (2.2%)	0	1 (1.0%)
Ear disorders NEC	0	2 (3.4%)	2 (1.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Ear and labyrinth disorders (cont)						
Ear disorders NEC (cont)						
(cont)						
Grade 1	0	0	0	0	0	0
Ear discomfort	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Ear pain	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Ear and labyrinth disorders (cont)						
Ear disorders NEC (cont)						
(cont)						
Grade 1	0	2 (3.4%)	2 (1.7%)	0	0	0
Ear discomfort	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0
Ear pain	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (8.3%)	2 (5.6%)	4 (6.7%)	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 3	1 (4.2%)	0	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Grade 4	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 5	0	1 (2.8%)	1 (1.7%)	0	0	0
Leukaemias acute myeloid	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 4	1 (4.2%)	0	1 (1.7%)	0	0	0
Acute myeloid leukaemia	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 4	1 (4.2%)	0	1 (1.7%)	0	0	0
Ovarian neoplasms malignant (excl germ cell)	1 (4.2%)	0	1 (1.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (1.6%)	4 (6.9%)	5 (4.2%)	2 (4.4%)	4 (7.7%)	6 (6.2%)
Grade 1	0	1 (1.7%)	1 (0.8%)	0	3 (5.8%)	3 (3.1%)
Grade 2	0	2 (3.4%)	2 (1.7%)	0	1 (1.9%)	1 (1.0%)
Grade 3	0	1 (1.7%)	1 (0.8%)	2 (4.4%)	0	2 (2.1%)
Grade 4	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 5	0	0	0	0	0	0
Leukaemias acute myeloid	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Acute myeloid leukaemia	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Ovarian neoplasms malignant (excl germ cell)	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Ovarian neoplasms malignant (excl germ cell) (cont) (cont)						
Grade 3	1 (4.2%)	0	1 (1.7%)	0	0	0
Ovarian clear cell carcinoma	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 3	1 (4.2%)	0	1 (1.7%)	0	0	0
Splenic marginal zone lymphomas	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Splenic marginal zone lymphoma	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Ovarian neoplasms malignant (excl germ cell) (cont) (cont)						
Grade 3	0	0	0	0	0	0
Ovarian clear cell carcinoma	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Splenic marginal zone lymphomas	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 4	1 (1.6%)	0	1 (0.8%)	0	0	0
Splenic marginal zone lymphoma	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 4	1 (1.6%)	0	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Uterine neoplasms malignant NEC	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 3	1 (4.2%)	0	1 (1.7%)	0	0	0
Uterine cancer	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 3	1 (4.2%)	0	1 (1.7%)	0	0	0
Bone neoplasms benign (excl cysts)	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Haemangioma of bone	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Colorectal neoplasms malignant	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Uterine neoplasms malignant NEC	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Uterine cancer	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Bone neoplasms benign (excl cysts)	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Haemangioma of bone	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Colorectal neoplasms malignant	0	0	0	1 (2.2%)	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Colorectal neoplasms malignant (cont) (cont)						
Grade 3	0	0	0	0	0	0
Rectal cancer	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Mantle cell lymphomas	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 5	0	1 (2.8%)	1 (1.7%)	0	0	0
Mantle cell lymphoma recurrent	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 5	0	1 (2.8%)	1 (1.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Colorectal neoplasms malignant (cont) (cont)						
Grade 3	0	0	0	1 (2.2%)	0	1 (1.0%)
Rectal cancer	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 3	0	0	0	1 (2.2%)	0	1 (1.0%)
Mantle cell lymphomas	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Mantle cell lymphoma recurrent	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cists and polyps) (cont)						
Myeloproliferative disorders (excl leukaemias)	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Leukoerythroblastosis	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Nasal and paranasal sinus neoplasms benign	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	1 (3.1%)	1 (2.0%)
Nasal neoplasm benign	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Myeloproliferative disorders (excl leukaemias)	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 3	0	0	0	1 (2.2%)	0	1 (1.0%)
Leukoerythroblastosis	0	0	0	1 (2.2%)	0	1 (1.0%)
Grade 3	0	0	0	1 (2.2%)	0	1 (1.0%)
Nasal and paranasal sinus neoplasms benign	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 3	0	0	0	0	0	0
Nasal neoplasm benign	0	1 (1.7%)	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Nasal and paranasal sinus neoplasms benign (cont)						
Nasal neoplasm benign (cont)						
Grade 1	0	0	0	0	0	0
Sinonasal papilloma	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 3	0	0	0	0	1 (3.1%)	1 (2.0%)
Neoplasms malignant site unspecified NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Metastatic squamous cell carcinoma	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Nasal and paranasal sinus neoplasms benign (cont)						
Nasal neoplasm benign (cont)						
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0
Sinonasal papilloma	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Neoplasms malignant site unspecified NEC	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Metastatic squamous cell carcinoma	0	0	0	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Neoplasms malignant site unspecified NEC (cont)						
Metastatic squamous cell carcinoma (cont)						
Grade 1	0	0	0	0	0	0
Prostatic neoplasms malignant	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Prostate cancer recurrent	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Skin neoplasms benign	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Neoplasms malignant site unspecified NEC (cont)						
Metastatic squamous cell carcinoma (cont)						
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Prostatic neoplasms malignant	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0
Prostate cancer recurrent	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0
Skin neoplasms benign	0	0	0	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Skin neoplasms benign (cont) (cont)						
Grade 1	0	0	0	0	0	0
Seborrhoeic keratosis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Skin neoplasms malignant and unspecified (excl melanoma)	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 2	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 3	0	0	0	0	0	0
Squamous cell carcinoma of skin	0	1 (2.8%)	1 (1.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Skin neoplasms benign (cont) (cont)						
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Seborrhoeic keratosis	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Skin neoplasms malignant and unspecified (excl melanoma)	0	2 (3.4%)	2 (1.7%)	0	1 (1.9%)	1 (1.0%)
Grade 2	0	1 (1.7%)	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Grade 3	0	1 (1.7%)	1 (0.8%)	0	0	0
Squamous cell carcinoma of skin	0	2 (3.4%)	2 (1.7%)	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Skin neoplasms malignant and unspecified (excl melanoma) (cont)						
Squamous cell carcinoma of skin (cont)						
Grade 2	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 3	0	0	0	0	0	0
Uterine neoplasms benign	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Uterine leiomyoma	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Skin neoplasms malignant and unspecified (excl melanoma) (cont)						
Squamous cell carcinoma of skin (cont)						
Grade 2	0	1 (1.7%)	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Grade 3	0	1 (1.7%)	1 (0.8%)	0	0	0
Uterine neoplasms benign	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)
Uterine leiomyoma	0	0	0	0	1 (1.9%)	1 (1.0%)
Grade 1	0	0	0	0	1 (1.9%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Reproductive system and breast disorders	2 (8.3%)	0	2 (3.3%)	0	0	0
Grade 1	2 (8.3%)	0	2 (3.3%)	0	0	0
Grade 3	0	0	0	0	0	0
Prostatic neoplasms and hypertrophy	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Benign prostatic hyperplasia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Vulvovaginal disorders NEC	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 1	1 (4.2%)	0	1 (1.7%)	0	0	0
Vaginal haemorrhage	1 (4.2%)	0	1 (1.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Reproductive system and breast disorders	1 (1.6%)	1 (1.7%)	2 (1.7%)	0	1 (1.9%)	1 (1.0%)
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 3	0	1 (1.7%)	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Prostatic neoplasms and hypertrophy	1 (1.6%)	0	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 3	0	0	0	0	1 (1.9%)	1 (1.0%)
Benign prostatic hyperplasia	1 (1.6%)	0	1 (0.8%)	0	1 (1.9%)	1 (1.0%)
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 3	0	0	0	0	1 (1.9%)	1 (1.0%)
Vulvovaginal disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Vaginal haemorrhage	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Reproductive system and breast disorders (cont)						
Vulvovaginal disorders NEC (cont)						
Vaginal haemorrhage (cont)						
Grade 1	1 (4.2%)	0	1 (1.7%)	0	0	0
Vulvovaginal signs and symptoms	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 1	1 (4.2%)	0	1 (1.7%)	0	0	0
Vulvovaginal pain	1 (4.2%)	0	1 (1.7%)	0	0	0
Grade 1	1 (4.2%)	0	1 (1.7%)	0	0	0
Scrotal disorders NEC	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Scrotal oedema	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Reproductive system and breast disorders (cont)						
Vulvovaginal disorders NEC (cont)						
Vaginal haemorrhage (cont)						
Grade 1	0	0	0	0	0	0
Vulvovaginal signs and symptoms	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Vulvovaginal pain	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Scrotal disorders NEC	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 3	0	1 (1.7%)	1 (0.8%)	0	0	0
Scrotal oedema	0	1 (1.7%)	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Reproductive system and breast disorders (cont)						
Scrotal disorders NEC (cont)						
Scrotal oedema (cont)						
Grade 3	0	0	0	0	0	0
Surgical and medical procedures	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dental and gingival therapeutic procedures	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Tooth extraction	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Reproductive system and breast disorders (cont)						
Scrotal disorders NEC (cont)						
Scrotal oedema (cont)						
Grade 3	0	1 (1.7%)	1 (0.8%)	0	0	0
Surgical and medical procedures	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Dental and gingival therapeutic procedures	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0
Tooth extraction	1 (1.6%)	0	1 (0.8%)	0	0	0
Grade 1	1 (1.6%)	0	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Congenital, familial and genetic disorders	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 1	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 2	0	0	0	0	0	0
Male reproductive tract disorders congenital	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 1	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 2	0	0	0	0	0	0
Hydrocele	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 1	0	1 (2.8%)	1 (1.7%)	0	0	0
Phimosis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Congenital, familial and genetic disorders	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0
Male reproductive tract disorders congenital	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0
Hydrocele	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Phimosis	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Hepatobiliary disorders	0	1 (2.8%)	1 (1.7%)	0	1 (3.1%)	1 (2.0%)
Grade 1	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	1 (3.1%)	1 (2.0%)
Bile duct infections and inflammations	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Biliary colic	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Cholestasis and jaundice	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Hepatobiliary disorders	0	3 (5.2%)	3 (2.5%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 1	0	1 (1.7%)	1 (0.8%)	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 3	0	1 (1.7%)	1 (0.8%)	0	0	0
Bile duct infections and inflammations	0	2 (3.4%)	2 (1.7%)	0	0	0
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 3	0	1 (1.7%)	1 (0.8%)	0	0	0
Biliary colic	0	2 (3.4%)	2 (1.7%)	0	0	0
Grade 1	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 3	0	1 (1.7%)	1 (0.8%)	0	0	0
Cholestasis and jaundice	0	0	0	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 1	0	0	0	1 (2.2%)	1 (1.9%)	2 (2.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Hepatobiliary disorders (cont)						
Cholestasis and jaundice (cont)						
Ocular icterus	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hepatic enzymes and function abnormalities	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 1	0	1 (2.8%)	1 (1.7%)	0	0	0
Hepatic function abnormal	0	1 (2.8%)	1 (1.7%)	0	0	0
Grade 1	0	1 (2.8%)	1 (1.7%)	0	0	0
Hepatic vascular disorders	0	0	0	0	1 (3.1%)	1 (2.0%)
Grade 3	0	0	0	0	1 (3.1%)	1 (2.0%)
Portal hypertension	0	0	0	0	1 (3.1%)	1 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Hepatobiliary disorders (cont)						
Cholestasis and jaundice (cont)						
Ocular icterus	0	0	0	1 (2.2%)	1 (1.9%)	2 (2.1%)
Grade 1	0	0	0	1 (2.2%)	1 (1.9%)	2 (2.1%)
Hepatic enzymes and function abnormalities	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hepatic function abnormal	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hepatic vascular disorders	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Portal hypertension	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	<65 Years					
	DB Phase MMB (N=24)	DB Phase RUX (N=36)	DB Phase Total (N=60)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 - 48) Total (N=51)
Number of Subjects with Any Treatment-Emergent AE	21 (87.5%)	33 (91.7%)	54 (90.0%)	16 (84.2%)	28 (87.5%)	44 (86.3%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Hepatobiliary disorders (cont)						
Hepatic vascular disorders (cont)						
Portal hypertension (cont)						
Grade 3	0	0	0	0	1 (3.1%)	1 (2.0%)
Hepatocellular damage and hepatitis NEC	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Hepatocellular injury	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0803: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	DB Phase MMB (N=62)	DB Phase RUX (N=58)	DB Phase Total (N=120)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 - 48) Total (N=97)
Number of Subjects with Any Treatment-Emergent AE	60 (96.8%)	58 (100.0%)	118 (98.3%)	37 (82.2%)	46 (88.5%)	83 (85.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Hepatobiliary disorders (cont)						
Hepatic vascular disorders (cont)						
Portal hypertension (cont)						
Grade 3	0	0	0	0	0	0
Hepatocellular damage and hepatitis NEC	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0
Hepatocellular injury	0	1 (1.7%)	1 (0.8%)	0	0	0
Grade 2	0	1 (1.7%)	1 (0.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders	9 (47.4%)	19 (59.4%)	28 (54.9%)	35 (62.5%)
Grade 1	6 (31.6%)	7 (21.9%)	13 (25.5%)	16 (28.6%)
Grade 2	2 (10.5%)	8 (25.0%)	10 (19.6%)	12 (21.4%)
Grade 3	1 (5.3%)	4 (12.5%)	5 (9.8%)	6 (10.7%)
Grade 4	0	0	0	0
Grade 5	0	0	0	1 (1.8%)
Diarrhoea (excl infective)	4 (21.1%)	10 (31.3%)	14 (27.5%)	19 (33.9%)
Grade 1	4 (21.1%)	6 (18.8%)	10 (19.6%)	11 (19.6%)
Grade 2	0	2 (6.3%)	2 (3.9%)	5 (8.9%)
Grade 3	0	2 (6.3%)	2 (3.9%)	3 (5.4%)
Diarrhoea	4 (21.1%)	10 (31.3%)	14 (27.5%)	19 (33.9%)
Grade 1	4 (21.1%)	6 (18.8%)	10 (19.6%)	11 (19.6%)
Grade 2	0	2 (6.3%)	2 (3.9%)	5 (8.9%)
Grade 3	0	2 (6.3%)	2 (3.9%)	3 (5.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders	21 (46.7%)	35 (67.3%)	56 (57.7%)	77 (67.5%)
Grade 1	13 (28.9%)	12 (23.1%)	25 (25.8%)	37 (32.5%)
Grade 2	7 (15.6%)	17 (32.7%)	24 (24.7%)	29 (25.4%)
Grade 3	0	5 (9.6%)	5 (5.2%)	9 (7.9%)
Grade 4	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 5	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Diarrhoea (excl infective)	10 (22.2%)	11 (21.2%)	21 (21.6%)	31 (27.2%)
Grade 1	8 (17.8%)	6 (11.5%)	14 (14.4%)	19 (16.7%)
Grade 2	2 (4.4%)	3 (5.8%)	5 (5.2%)	9 (7.9%)
Grade 3	0	2 (3.8%)	2 (2.1%)	3 (2.6%)
Diarrhoea	10 (22.2%)	11 (21.2%)	21 (21.6%)	31 (27.2%)
Grade 1	8 (17.8%)	6 (11.5%)	14 (14.4%)	19 (16.7%)
Grade 2	2 (4.4%)	3 (5.8%)	5 (5.2%)	9 (7.9%)
Grade 3	0	2 (3.8%)	2 (2.1%)	3 (2.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Nausea and vomiting symptoms	2 (10.5%)	6 (18.8%)	8 (15.7%)	14 (25.0%)
Grade 1	2 (10.5%)	4 (12.5%)	6 (11.8%)	8 (14.3%)
Grade 2	0	2 (6.3%)	2 (3.9%)	4 (7.1%)
Grade 3	0	0	0	2 (3.6%)
Nausea	2 (10.5%)	3 (9.4%)	5 (9.8%)	11 (19.6%)
Grade 1	2 (10.5%)	2 (6.3%)	4 (7.8%)	8 (14.3%)
Grade 2	0	1 (3.1%)	1 (2.0%)	2 (3.6%)
Grade 3	0	0	0	1 (1.8%)
Vomiting	2 (10.5%)	3 (9.4%)	5 (9.8%)	7 (12.5%)
Grade 1	2 (10.5%)	2 (6.3%)	4 (7.8%)	3 (5.4%)
Grade 2	0	1 (3.1%)	1 (2.0%)	3 (5.4%)
Grade 3	0	0	0	1 (1.8%)
Retching	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Nausea and vomiting symptoms	5 (11.1%)	12 (23.1%)	17 (17.5%)	30 (26.3%)
Grade 1	4 (8.9%)	8 (15.4%)	12 (12.4%)	22 (19.3%)
Grade 2	1 (2.2%)	3 (5.8%)	4 (4.1%)	7 (6.1%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Nausea	4 (8.9%)	10 (19.2%)	14 (14.4%)	25 (21.9%)
Grade 1	4 (8.9%)	8 (15.4%)	12 (12.4%)	21 (18.4%)
Grade 2	0	2 (3.8%)	2 (2.1%)	4 (3.5%)
Grade 3	0	0	0	0
Vomiting	3 (6.7%)	5 (9.6%)	8 (8.2%)	12 (10.5%)
Grade 1	2 (4.4%)	1 (1.9%)	3 (3.1%)	6 (5.3%)
Grade 2	1 (2.2%)	3 (5.8%)	4 (4.1%)	5 (4.4%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Retching	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Nausea and vomiting symptoms (cont)				
Retching (cont)				
Grade 1	0	0	0	0
Gastrointestinal and abdominal pains (excl oral and throat)	3 (15.8%)	5 (15.6%)	8 (15.7%)	13 (23.2%)
Grade 1	2 (10.5%)	2 (6.3%)	4 (7.8%)	7 (12.5%)
Grade 2	0	2 (6.3%)	2 (3.9%)	3 (5.4%)
Grade 3	1 (5.3%)	1 (3.1%)	2 (3.9%)	3 (5.4%)
Abdominal pain	1 (5.3%)	3 (9.4%)	4 (7.8%)	10 (17.9%)
Grade 1	0	2 (6.3%)	2 (3.9%)	6 (10.7%)
Grade 2	0	1 (3.1%)	1 (2.0%)	2 (3.6%)
Grade 3	1 (5.3%)	0	1 (2.0%)	2 (3.6%)
Abdominal pain upper	2 (10.5%)	2 (6.3%)	4 (7.8%)	4 (7.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Nausea and vomiting symptoms (cont)				
Retching (cont)				
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Gastrointestinal and abdominal pains (excl oral and throat)	6 (13.3%)	10 (19.2%)	16 (16.5%)	22 (19.3%)
Grade 1	4 (8.9%)	4 (7.7%)	8 (8.2%)	12 (10.5%)
Grade 2	2 (4.4%)	5 (9.6%)	7 (7.2%)	8 (7.0%)
Grade 3	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Abdominal pain	3 (6.7%)	8 (15.4%)	11 (11.3%)	16 (14.0%)
Grade 1	3 (6.7%)	3 (5.8%)	6 (6.2%)	8 (7.0%)
Grade 2	0	4 (7.7%)	4 (4.1%)	6 (5.3%)
Grade 3	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Abdominal pain upper	3 (6.7%)	3 (5.8%)	6 (6.2%)	9 (7.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal and abdominal pains (excl oral and throat) (cont)				
Abdominal pain upper (cont)				
Grade 1	2 (10.5%)	0	2 (3.9%)	2 (3.6%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 3	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Abdominal rigidity	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Gastrointestinal atonic and hypomotility disorders NEC	3 (15.8%)	4 (12.5%)	7 (13.7%)	9 (16.1%)
Grade 1	2 (10.5%)	2 (6.3%)	4 (7.8%)	5 (8.9%)
Grade 2	1 (5.3%)	2 (6.3%)	3 (5.9%)	4 (7.1%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal and abdominal pains (excl oral and throat) (cont)				
Abdominal pain upper (cont)				
Grade 1	1 (2.2%)	1 (1.9%)	2 (2.1%)	5 (4.4%)
Grade 2	2 (4.4%)	2 (3.8%)	4 (4.1%)	4 (3.5%)
Grade 3	0	0	0	0
Abdominal rigidity	0	0	0	0
Grade 1	0	0	0	0
Gastrointestinal atonic and hypomotility disorders NEC	2 (4.4%)	10 (19.2%)	12 (12.4%)	23 (20.2%)
Grade 1	1 (2.2%)	6 (11.5%)	7 (7.2%)	17 (14.9%)
Grade 2	1 (2.2%)	3 (5.8%)	4 (4.1%)	5 (4.4%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal atonic and hypomotility disorders NEC (cont)				
Constipation	3 (15.8%)	3 (9.4%)	6 (11.8%)	8 (14.3%)
Grade 1	2 (10.5%)	1 (3.1%)	3 (5.9%)	5 (8.9%)
Grade 2	1 (5.3%)	2 (6.3%)	3 (5.9%)	3 (5.4%)
Grade 3	0	0	0	0
Gastrooesophageal reflux disease	1 (5.3%)	1 (3.1%)	2 (3.9%)	4 (7.1%)
Grade 1	0	1 (3.1%)	1 (2.0%)	2 (3.6%)
Grade 2	1 (5.3%)	0	1 (2.0%)	2 (3.6%)
Flatulence, bloating and distension	0	1 (3.1%)	1 (2.0%)	2 (3.6%)
Grade 1	0	1 (3.1%)	1 (2.0%)	2 (3.6%)
Grade 2	0	0	0	0
Abdominal distension	0	1 (3.1%)	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal atonic and hypomotility disorders NEC (cont)				
Constipation	1 (2.2%)	7 (13.5%)	8 (8.2%)	17 (14.9%)
Grade 1	1 (2.2%)	4 (7.7%)	5 (5.2%)	14 (12.3%)
Grade 2	0	2 (3.8%)	2 (2.1%)	2 (1.8%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Gastrooesophageal reflux disease	1 (2.2%)	4 (7.7%)	5 (5.2%)	7 (6.1%)
Grade 1	0	3 (5.8%)	3 (3.1%)	4 (3.5%)
Grade 2	1 (2.2%)	1 (1.9%)	2 (2.1%)	3 (2.6%)
Flatulence, bloating and distension	0	4 (7.7%)	4 (4.1%)	8 (7.0%)
Grade 1	0	3 (5.8%)	3 (3.1%)	5 (4.4%)
Grade 2	0	1 (1.9%)	1 (1.0%)	3 (2.6%)
Abdominal distension	0	3 (5.8%)	3 (3.1%)	6 (5.3%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Flatulence, bloating and distension (cont)				
Abdominal distension (cont)				
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	0	0	0
Flatulence	0	0	0	1 (1.8%)
Grade 1	0	0	0	1 (1.8%)
Grade 2	0	0	0	0
Gastrointestinal signs and symptoms NEC	1 (5.3%)	2 (6.3%)	3 (5.9%)	3 (5.4%)
Grade 1	1 (5.3%)	2 (6.3%)	3 (5.9%)	3 (5.4%)
Grade 2	0	0	0	0
Abdominal discomfort	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 1	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Flatulence, bloating and distension (cont)				
Abdominal distension (cont)				
Grade 1	0	3 (5.8%)	3 (3.1%)	4 (3.5%)
Grade 2	0	0	0	2 (1.8%)
Flatulence	0	1 (1.9%)	1 (1.0%)	3 (2.6%)
Grade 1	0	0	0	2 (1.8%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Gastrointestinal signs and symptoms NEC	0	2 (3.8%)	2 (2.1%)	6 (5.3%)
Grade 1	0	1 (1.9%)	1 (1.0%)	5 (4.4%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Abdominal discomfort	0	1 (1.9%)	1 (1.0%)	4 (3.5%)
Grade 1	0	1 (1.9%)	1 (1.0%)	4 (3.5%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal signs and symptoms NEC (cont)				
Anal incontinence	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	0	0	0
Dysphagia	0	0	0	0
Grade 1	0	0	0	0
Dyspeptic signs and symptoms	0	4 (12.5%)	4 (7.8%)	4 (7.1%)
Grade 1	0	3 (9.4%)	3 (5.9%)	3 (5.4%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Dyspepsia	0	4 (12.5%)	4 (7.8%)	4 (7.1%)
Grade 1	0	3 (9.4%)	3 (5.9%)	3 (5.4%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal signs and symptoms NEC (cont)				
Anal incontinence	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	0	0	0
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Dysphagia	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)
Dyspeptic signs and symptoms	2 (4.4%)	1 (1.9%)	3 (3.1%)	4 (3.5%)
Grade 1	2 (4.4%)	0	2 (2.1%)	3 (2.6%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Dyspepsia	2 (4.4%)	1 (1.9%)	3 (3.1%)	4 (3.5%)
Grade 1	2 (4.4%)	0	2 (2.1%)	3 (2.6%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Dyspeptic signs and symptoms (cont)				
Epigastric discomfort	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Intestinal haemorrhages	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Rectal haemorrhage	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	0	0	0
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 3	0	0	0	0
Lower gastrointestinal haemorrhage	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Dyspeptic signs and symptoms (cont)				
Epigastric discomfort	0	0	0	0
Grade 1	0	0	0	0
Intestinal haemorrhages	0	3 (5.8%)	3 (3.1%)	5 (4.4%)
Grade 1	0	2 (3.8%)	2 (2.1%)	2 (1.8%)
Grade 2	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Grade 3	0	0	0	1 (0.9%)
Rectal haemorrhage	0	2 (3.8%)	2 (2.1%)	4 (3.5%)
Grade 1	0	2 (3.8%)	2 (2.1%)	2 (1.8%)
Grade 2	0	0	0	1 (0.9%)
Grade 3	0	0	0	1 (0.9%)
Lower gastrointestinal haemorrhage	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Intestinal haemorrhages (cont)				
Small intestinal haemorrhage	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 3	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Oral dryness and saliva altered	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Dry mouth	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Peritoneal and retroperitoneal disorders	1 (5.3%)	1 (3.1%)	2 (3.9%)	3 (5.4%)
Grade 2	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 3	0	0	0	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Intestinal haemorrhages (cont)				
Small intestinal haemorrhage	0	0	0	0
Grade 3	0	0	0	0
Oral dryness and saliva altered	2 (4.4%)	2 (3.8%)	4 (4.1%)	6 (5.3%)
Grade 1	2 (4.4%)	0	2 (2.1%)	4 (3.5%)
Grade 2	0	2 (3.8%)	2 (2.1%)	2 (1.8%)
Dry mouth	2 (4.4%)	2 (3.8%)	4 (4.1%)	6 (5.3%)
Grade 1	2 (4.4%)	0	2 (2.1%)	4 (3.5%)
Grade 2	0	2 (3.8%)	2 (2.1%)	2 (1.8%)
Peritoneal and retroperitoneal disorders	2 (4.4%)	1 (1.9%)	3 (3.1%)	3 (2.6%)
Grade 2	2 (4.4%)	1 (1.9%)	3 (3.1%)	3 (2.6%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Peritoneal and retroperitoneal disorders (cont)				
Ascites	1 (5.3%)	1 (3.1%)	2 (3.9%)	3 (5.4%)
Grade 2	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 3	0	0	0	1 (1.8%)
Haemorrhoids and gastrointestinal varices (excl oesophageal)	0	1 (3.1%)	1 (2.0%)	2 (3.6%)
Grade 1	0	0	0	1 (1.8%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Haemorrhoids	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	0	0	0
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Haemorrhoidal haemorrhage	0	0	0	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Peritoneal and retroperitoneal disorders (cont)				
Ascites	2 (4.4%)	1 (1.9%)	3 (3.1%)	3 (2.6%)
Grade 2	2 (4.4%)	1 (1.9%)	3 (3.1%)	3 (2.6%)
Grade 3	0	0	0	0
Haemorrhoids and gastrointestinal varices (excl oesophageal)	0	1 (1.9%)	1 (1.0%)	3 (2.6%)
Grade 1	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Grade 2	0	0	0	1 (0.9%)
Haemorrhoids	0	1 (1.9%)	1 (1.0%)	3 (2.6%)
Grade 1	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Grade 2	0	0	0	1 (0.9%)
Haemorrhoidal haemorrhage	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Haemorrhoids and gastrointestinal varices (excl oesophageal) (cont)				
Haemorrhoidal haemorrhage (cont)				
Grade 1	0	0	0	1 (1.8%)
Oesophageal varices	2 (10.5%)	2 (6.3%)	4 (7.8%)	4 (7.1%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 3	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Varices oesophageal	2 (10.5%)	2 (6.3%)	4 (7.8%)	4 (7.1%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 3	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Oral soft tissue haemorrhages	0	3 (9.4%)	3 (5.9%)	3 (5.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Haemorrhoids and gastrointestinal varices (excl oesophageal) (cont)				
Haemorrhoidal haemorrhage (cont)				
Grade 1	0	0	0	0
Oesophageal varices	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Varices oesophageal	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Oral soft tissue haemorrhages	1 (2.2%)	0	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Oral soft tissue haemorrhages (cont) (cont)				
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	2 (6.3%)	2 (3.9%)	2 (3.6%)
Mouth haemorrhage	0	3 (9.4%)	3 (5.9%)	3 (5.4%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	2 (6.3%)	2 (3.9%)	2 (3.6%)
Oral mucosa haematoma	0	0	0	0
Grade 1	0	0	0	0
Stomatitis and ulceration	2 (10.5%)	0	2 (3.9%)	2 (3.6%)
Grade 1	2 (10.5%)	0	2 (3.9%)	2 (3.6%)
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Oral soft tissue haemorrhages (cont)				
(cont)				
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	0	0	0	0
Mouth haemorrhage	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Oral mucosa haematoma	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Stomatitis and ulceration	1 (2.2%)	0	1 (1.0%)	2 (1.8%)
Grade 1	0	0	0	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Stomatitis and ulceration (cont)				
Stomatitis	2 (10.5%)	0	2 (3.9%)	2 (3.6%)
Grade 1	2 (10.5%)	0	2 (3.9%)	2 (3.6%)
Aphthous ulcer	0	0	0	0
Grade 2	0	0	0	0
Mouth ulceration	0	0	0	0
Grade 1	0	0	0	0
Dental pain and sensation disorders	0	1 (3.1%)	1 (2.0%)	2 (3.6%)
Grade 1	0	1 (3.1%)	1 (2.0%)	2 (3.6%)
Toothache	0	1 (3.1%)	1 (2.0%)	2 (3.6%)
Grade 1	0	1 (3.1%)	1 (2.0%)	2 (3.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Stomatitis and ulceration (cont)				
Stomatitis	0	0	0	0
Grade 1	0	0	0	0
Aphthous ulcer	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Mouth ulceration	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)
Dental pain and sensation disorders	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Toothache	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastritis (excl infective)	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Gastritis	0	0	0	0
Grade 1	0	0	0	0
Chronic gastritis	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Non-site specific gastrointestinal haemorrhages	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Gastrointestinal haemorrhage	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastritis (excl infective)	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)
Grade 1	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)
Gastritis	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)
Grade 1	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)
Chronic gastritis	0	0	0	0
Grade 1	0	0	0	0
Non-site specific gastrointestinal haemorrhages	2 (4.4%)	1 (1.9%)	3 (3.1%)	3 (2.6%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 4	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Gastrointestinal haemorrhage	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Non-site specific gastrointestinal haemorrhages (cont)				
Gastrointestinal haemorrhage (cont)				
Grade 3	0	0	0	0
Haematemesis	0	0	0	0
Grade 4	0	0	0	0
Melaena	0	0	0	0
Grade 1	0	0	0	0
Oral soft tissue disorders NEC	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 2	0	0	0	0
Cheilitis	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Non-site specific gastrointestinal haemorrhages (cont)				
Gastrointestinal haemorrhage (cont)				
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Haematemesis	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 4	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Melaena	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Oral soft tissue disorders NEC	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Grade 1	0	0	0	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Cheilitis	0	1 (1.9%)	1 (1.0%)	2 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Oral soft tissue disorders NEC (cont)				
Cheilitis (cont)				
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Angina bullosa haemorrhagica	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Oral soft tissue pain and paraesthesia	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	0	0	0
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 3	0	0	0	0
Lip pain	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Oral soft tissue disorders NEC (cont)				
Cheilitis (cont)				
Grade 1	0	0	0	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Angina bullosa haemorrhagica	0	0	0	0
Grade 1	0	0	0	0
Oral soft tissue pain and paraesthesia	0	0	0	2 (1.8%)
Grade 1	0	0	0	1 (0.9%)
Grade 2	0	0	0	0
Grade 3	0	0	0	1 (0.9%)
Lip pain	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Oral soft tissue pain and paraesthesia (cont)				
Odynophagia	0	0	0	0
Grade 3	0	0	0	0
Oral pain	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Anal and rectal pains	0	0	0	0
Grade 2	0	0	0	0
Proctalgia	0	0	0	0
Grade 2	0	0	0	0
Dental disorders NEC	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Oral soft tissue pain and paraesthesia (cont)				
Odynophagia	0	0	0	1 (0.9%)
Grade 3	0	0	0	1 (0.9%)
Oral pain	0	0	0	0
Grade 2	0	0	0	0
Anal and rectal pains	0	0	0	2 (1.8%)
Grade 2	0	0	0	2 (1.8%)
Proctalgia	0	0	0	2 (1.8%)
Grade 2	0	0	0	2 (1.8%)
Dental disorders NEC	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Dental disorders NEC (cont)				
(cont)				
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Periodontal disease	0	0	0	0
Grade 1	0	0	0	0
Tooth impacted	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Gastric and oesophageal haemorrhages	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 3	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Gastric haemorrhage	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 3	0	1 (3.1%)	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Dental disorders NEC (cont)				
(cont)				
Grade 2	0	0	0	0
Periodontal disease	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Tooth impacted	0	0	0	0
Grade 2	0	0	0	0
Gastric and oesophageal haemorrhages	0	0	0	0
Grade 3	0	0	0	0
Gastric haemorrhage	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastric and oesophageal haemorrhages (cont)				
Oesophageal varices haemorrhage	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 3	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Gastric ulcers and perforation	0	0	0	1 (1.8%)
Grade 1	0	0	0	0
Grade 2	0	0	0	1 (1.8%)
Gastric ulcer	0	0	0	1 (1.8%)
Grade 2	0	0	0	1 (1.8%)
Gastritis erosive	0	0	0	0
Grade 1	0	0	0	0
Gastrointestinal vascular occlusion and infarction	0	0	0	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastric and oesophageal haemorrhages (cont)				
Oesophageal varices haemorrhage	0	0	0	0
Grade 3	0	0	0	0
Gastric ulcers and perforation	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	0	0	0
Gastric ulcer	0	0	0	0
Grade 2	0	0	0	0
Gastritis erosive	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Gastrointestinal vascular occlusion and infarction	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal vascular occlusion and infarction (cont) (cont)				
Grade 5	0	0	0	1 (1.8%)
Intestinal infarction	0	0	0	0
Grade 5	0	0	0	0
Mesenteric vein thrombosis	0	0	0	1 (1.8%)
Grade 5	0	0	0	1 (1.8%)
Oral soft tissue infections	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 2	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Angular cheilitis	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 2	1 (5.3%)	0	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal vascular occlusion and infarction (cont) (cont)				
Grade 5	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Intestinal infarction	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 5	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Mesenteric vein thrombosis	0	0	0	0
Grade 5	0	0	0	0
Oral soft tissue infections	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Angular cheilitis	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Colitis (excl infective)	0	0	0	0
Grade 2	0	0	0	0
Colitis	0	0	0	0
Grade 2	0	0	0	0
Cystic pancreatic disorders	0	0	0	0
Grade 1	0	0	0	0
Pancreatic cyst	0	0	0	0
Grade 1	0	0	0	0
Dental and periodontal infections and inflammations	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Colitis (excl infective)	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Colitis	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Cystic pancreatic disorders	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Pancreatic cyst	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Dental and periodontal infections and inflammations	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Dental and periodontal infections and inflammations (cont)				
Dental caries	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Diaphragmatic hernias	0	0	0	0
Grade 1	0	0	0	0
Hiatus hernia	0	0	0	0
Grade 1	0	0	0	0
Diverticula	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Diverticulum	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Dental and periodontal infections and inflammations (cont)				
Dental caries	0	0	0	0
Grade 1	0	0	0	0
Diaphragmatic hernias	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Hiatus hernia	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Diverticula	0	0	0	0
Grade 2	0	0	0	0
Diverticulum	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Faecal abnormalities NEC	0	0	0	0
Grade 1	0	0	0	0
Abnormal faeces	0	0	0	0
Grade 1	0	0	0	0
Gastrointestinal spastic and hypermotility disorders	0	0	0	0
Grade 1	0	0	0	0
Defaecation urgency	0	0	0	0
Grade 1	0	0	0	0
Gingival disorders, signs and symptoms NEC	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 2	1 (5.3%)	0	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Faecal abnormalities NEC	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Abnormal faeces	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Gastrointestinal spastic and hypermotility disorders	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Defaecation urgency	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Gingival disorders, signs and symptoms NEC	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gingival disorders, signs and symptoms NEC (cont)				
Gingival ulceration	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 2	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Gingival haemorrhages	0	0	0	0
Grade 2	0	0	0	0
Gingival bleeding	0	0	0	0
Grade 2	0	0	0	0
Inguinal hernias	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 2	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Inguinal hernia	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 2	1 (5.3%)	0	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gingival disorders, signs and symptoms NEC (cont)				
Gingival ulceration	0	0	0	0
Grade 2	0	0	0	0
Gingival haemorrhages	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Gingival bleeding	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Inguinal hernias	0	0	0	0
Grade 2	0	0	0	0
Inguinal hernia	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Pancreatic disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Pancreatic steatosis	0	0	0	0
Grade 1	0	0	0	0
Infections and infestations	12 (63.2%)	20 (62.5%)	32 (62.7%)	35 (62.5%)
Grade 1	1 (5.3%)	5 (15.6%)	6 (11.8%)	7 (12.5%)
Grade 2	7 (36.8%)	10 (31.3%)	17 (33.3%)	18 (32.1%)
Grade 3	3 (15.8%)	4 (12.5%)	7 (13.7%)	8 (14.3%)
Grade 4	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 5	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Pancreatic disorders NEC	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Pancreatic steatosis	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Infections and infestations	25 (55.6%)	32 (61.5%)	57 (58.8%)	72 (63.2%)
Grade 1	3 (6.7%)	4 (7.7%)	7 (7.2%)	12 (10.5%)
Grade 2	9 (20.0%)	14 (26.9%)	23 (23.7%)	24 (21.1%)
Grade 3	8 (17.8%)	12 (23.1%)	20 (20.6%)	27 (23.7%)
Grade 4	2 (4.4%)	0	2 (2.1%)	3 (2.6%)
Grade 5	3 (6.7%)	2 (3.8%)	5 (5.2%)	6 (5.3%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Lower respiratory tract and lung infections	5 (26.3%)	4 (12.5%)	9 (17.6%)	9 (16.1%)
Grade 1	0	0	0	0
Grade 2	2 (10.5%)	2 (6.3%)	4 (7.8%)	4 (7.1%)
Grade 3	3 (15.8%)	1 (3.1%)	4 (7.8%)	4 (7.1%)
Grade 4	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 5	0	0	0	0
Pneumonia	4 (21.1%)	3 (9.4%)	7 (13.7%)	7 (12.5%)
Grade 2	2 (10.5%)	1 (3.1%)	3 (5.9%)	3 (5.4%)
Grade 3	2 (10.5%)	1 (3.1%)	3 (5.9%)	3 (5.4%)
Grade 4	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 5	0	0	0	0
Bronchitis	0	2 (6.3%)	2 (3.9%)	2 (3.6%)
Grade 1	0	0	0	0
Grade 2	0	2 (6.3%)	2 (3.9%)	2 (3.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Lower respiratory tract and lung infections	11 (24.4%)	13 (25.0%)	24 (24.7%)	31 (27.2%)
Grade 1	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Grade 2	1 (2.2%)	5 (9.6%)	6 (6.2%)	7 (6.1%)
Grade 3	7 (15.6%)	6 (11.5%)	13 (13.4%)	18 (15.8%)
Grade 4	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 5	2 (4.4%)	1 (1.9%)	3 (3.1%)	3 (2.6%)
Pneumonia	8 (17.8%)	9 (17.3%)	17 (17.5%)	21 (18.4%)
Grade 2	0	3 (5.8%)	3 (3.1%)	3 (2.6%)
Grade 3	6 (13.3%)	5 (9.6%)	11 (11.3%)	15 (13.2%)
Grade 4	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 5	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)
Bronchitis	3 (6.7%)	3 (5.8%)	6 (6.2%)	6 (5.3%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	3 (6.7%)	1 (1.9%)	4 (4.1%)	4 (3.5%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Lower respiratory tract and lung infections (cont)				
Bronchitis (cont)				
Grade 3	0	0	0	0
Lower respiratory tract infection	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Lung infection	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 3	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 5	0	0	0	0
Upper respiratory tract infections	7 (36.8%)	8 (25.0%)	15 (29.4%)	16 (28.6%)
Grade 1	1 (5.3%)	2 (6.3%)	3 (5.9%)	4 (7.1%)
Grade 2	5 (26.3%)	6 (18.8%)	11 (21.6%)	11 (19.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Lower respiratory tract and lung infections (cont)				
Bronchitis (cont)				
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Lower respiratory tract infection	0	1 (1.9%)	1 (1.0%)	4 (3.5%)
Grade 1	0	0	0	2 (1.8%)
Grade 2	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Lung infection	2 (4.4%)	0	2 (2.1%)	3 (2.6%)
Grade 3	1 (2.2%)	0	1 (1.0%)	2 (1.8%)
Grade 5	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Upper respiratory tract infections	5 (11.1%)	9 (17.3%)	14 (14.4%)	18 (15.8%)
Grade 1	3 (6.7%)	2 (3.8%)	5 (5.2%)	9 (7.9%)
Grade 2	2 (4.4%)	7 (13.5%)	9 (9.3%)	9 (7.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Upper respiratory tract infections (cont) (cont)				
Grade 3	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Upper respiratory tract infection	4 (21.1%)	5 (15.6%)	9 (17.6%)	10 (17.9%)
Grade 1	0	1 (3.1%)	1 (2.0%)	2 (3.6%)
Grade 2	4 (21.1%)	4 (12.5%)	8 (15.7%)	8 (14.3%)
Nasopharyngitis	2 (10.5%)	2 (6.3%)	4 (7.8%)	4 (7.1%)
Grade 1	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 2	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Sinusitis	1 (5.3%)	2 (6.3%)	3 (5.9%)	3 (5.4%)
Grade 1	0	0	0	0
Grade 2	0	2 (6.3%)	2 (3.9%)	2 (3.6%)
Grade 3	1 (5.3%)	0	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Upper respiratory tract infections (cont) (cont)				
Grade 3	0	0	0	0
Upper respiratory tract infection	2 (4.4%)	4 (7.7%)	6 (6.2%)	9 (7.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	4 (3.5%)
Grade 2	1 (2.2%)	4 (7.7%)	5 (5.2%)	5 (4.4%)
Nasopharyngitis	2 (4.4%)	3 (5.8%)	5 (5.2%)	6 (5.3%)
Grade 1	2 (4.4%)	2 (3.8%)	4 (4.1%)	5 (4.4%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Sinusitis	1 (2.2%)	2 (3.8%)	3 (3.1%)	3 (2.6%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Upper respiratory tract infections (cont)				
Laryngitis	0	0	0	1 (1.8%)
Grade 2	0	0	0	1 (1.8%)
Tonsillitis	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Pharyngitis	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Urinary tract infections	2 (10.5%)	1 (3.1%)	3 (5.9%)	3 (5.4%)
Grade 1	0	0	0	0
Grade 2	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 3	1 (5.3%)	0	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Upper respiratory tract infections (cont)				
Laryngitis	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Tonsillitis	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Pharyngitis	0	0	0	0
Grade 1	0	0	0	0
Urinary tract infections	9 (20.0%)	9 (17.3%)	18 (18.6%)	22 (19.3%)
Grade 1	0	0	0	1 (0.9%)
Grade 2	7 (15.6%)	7 (13.5%)	14 (14.4%)	16 (14.0%)
Grade 3	2 (4.4%)	2 (3.8%)	4 (4.1%)	5 (4.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Urinary tract infections (cont)				
Urinary tract infection	2 (10.5%)	1 (3.1%)	3 (5.9%)	3 (5.4%)
Grade 1	0	0	0	0
Grade 2	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 3	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Cystitis	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Pyelocystitis	0	0	0	0
Grade 2	0	0	0	0
Pyelonephritis	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Urinary tract infections (cont)				
Urinary tract infection	7 (15.6%)	7 (13.5%)	14 (14.4%)	17 (14.9%)
Grade 1	0	0	0	1 (0.9%)
Grade 2	5 (11.1%)	6 (11.5%)	11 (11.3%)	13 (11.4%)
Grade 3	2 (4.4%)	1 (1.9%)	3 (3.1%)	3 (2.6%)
Cystitis	3 (6.7%)	1 (1.9%)	4 (4.1%)	6 (5.3%)
Grade 2	3 (6.7%)	1 (1.9%)	4 (4.1%)	5 (4.4%)
Grade 3	0	0	0	1 (0.9%)
Pyelocystitis	0	0	0	1 (0.9%)
Grade 2	0	0	0	1 (0.9%)
Pyelonephritis	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Herpes viral infections	1 (5.3%)	3 (9.4%)	4 (7.8%)	5 (8.9%)
Grade 1	0	0	0	1 (1.8%)
Grade 2	1 (5.3%)	3 (9.4%)	4 (7.8%)	4 (7.1%)
Herpes zoster	1 (5.3%)	1 (3.1%)	2 (3.9%)	3 (5.4%)
Grade 1	1 (5.3%)	0	1 (2.0%)	2 (3.6%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Oral herpes	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	0	0	0
Genital herpes	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Herpes viral infections	4 (8.9%)	2 (3.8%)	6 (6.2%)	8 (7.0%)
Grade 1	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)
Grade 2	3 (6.7%)	1 (1.9%)	4 (4.1%)	6 (5.3%)
Herpes zoster	2 (4.4%)	0	2 (2.1%)	3 (2.6%)
Grade 1	0	0	0	0
Grade 2	2 (4.4%)	0	2 (2.1%)	3 (2.6%)
Oral herpes	2 (4.4%)	1 (1.9%)	3 (3.1%)	4 (3.5%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	1 (1.9%)	2 (2.1%)	3 (2.6%)
Genital herpes	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Herpes viral infections (cont)				
Herpes simplex	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 2	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Nasal herpes	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 2	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Varicella zoster virus infection	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Infections NEC	1 (5.3%)	1 (3.1%)	2 (3.9%)	3 (5.4%)
Grade 1	0	0	0	0
Grade 2	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 3	0	1 (3.1%)	1 (2.0%)	2 (3.6%)
Respiratory tract infection	1 (5.3%)	0	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Herpes viral infections (cont)				
Herpes simplex	0	0	0	0
Grade 2	0	0	0	0
Nasal herpes	0	0	0	0
Grade 2	0	0	0	0
Varicella zoster virus infection	0	0	0	0
Grade 2	0	0	0	0
Infections NEC	1 (2.2%)	2 (3.8%)	3 (3.1%)	5 (4.4%)
Grade 1	0	0	0	1 (0.9%)
Grade 2	1 (2.2%)	1 (1.9%)	2 (2.1%)	3 (2.6%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Respiratory tract infection	0	1 (1.9%)	1 (1.0%)	2 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Infections NEC (cont)				
Respiratory tract infection (cont)				
Grade 1	0	0	0	0
Grade 2	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Localised infection	0	0	0	0
Grade 2	0	0	0	0
Device related infection	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 3	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Infection	0	0	0	1 (1.8%)
Grade 3	0	0	0	1 (1.8%)
Wound infection	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Infections NEC (cont)				
Respiratory tract infection (cont)				
Grade 1	0	0	0	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Localised infection	1 (2.2%)	0	1 (1.0%)	2 (1.8%)
Grade 2	1 (2.2%)	0	1 (1.0%)	2 (1.8%)
Device related infection	0	0	0	0
Grade 3	0	0	0	0
Infection	0	0	0	0
Grade 3	0	0	0	0
Wound infection	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Abdominal and gastrointestinal infections	1 (5.3%)	3 (9.4%)	4 (7.8%)	4 (7.1%)
Grade 1	0	0	0	0
Grade 2	1 (5.3%)	2 (6.3%)	3 (5.9%)	3 (5.4%)
Grade 3	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Gastroenteritis	1 (5.3%)	2 (6.3%)	3 (5.9%)	3 (5.4%)
Grade 1	0	0	0	0
Grade 2	1 (5.3%)	2 (6.3%)	3 (5.9%)	3 (5.4%)
Anal abscess	0	0	0	0
Grade 3	0	0	0	0
Diverticulitis	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 3	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Enterocolitis infectious	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Abdominal and gastrointestinal infections	1 (2.2%)	0	1 (1.0%)	3 (2.6%)
Grade 1	0	0	0	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 3	0	0	0	1 (0.9%)
Gastroenteritis	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)
Grade 2	0	0	0	0
Anal abscess	0	0	0	1 (0.9%)
Grade 3	0	0	0	1 (0.9%)
Diverticulitis	0	0	0	0
Grade 3	0	0	0	0
Enterocolitis infectious	1 (2.2%)	0	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Abdominal and gastrointestinal infections (cont)				
Enterocolitis infectious (cont)				
Grade 2	0	0	0	0
Sepsis, bacteraemia, viraemia and fungaemia NEC	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 3	0	0	0	0
Grade 4	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 5	0	0	0	0
Sepsis	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 3	0	0	0	0
Grade 4	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 5	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Abdominal and gastrointestinal infections (cont)				
Enterocolitis infectious (cont)				
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Sepsis, bacteraemia, viraemia and fungaemia NEC	2 (4.4%)	2 (3.8%)	4 (4.1%)	6 (5.3%)
Grade 3	1 (2.2%)	1 (1.9%)	2 (2.1%)	3 (2.6%)
Grade 4	0	0	0	0
Grade 5	1 (2.2%)	1 (1.9%)	2 (2.1%)	3 (2.6%)
Sepsis	2 (4.4%)	1 (1.9%)	3 (3.1%)	5 (4.4%)
Grade 3	1 (2.2%)	1 (1.9%)	2 (2.1%)	3 (2.6%)
Grade 4	0	0	0	0
Grade 5	1 (2.2%)	0	1 (1.0%)	2 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Sepsis, bacteraemia, viraemia and fungaemia NEC (cont)				
Bacteraemia	0	0	0	0
Grade 3	0	0	0	0
Septic shock	0	0	0	0
Grade 5	0	0	0	0
Influenza viral infections	0	3 (9.4%)	3 (5.9%)	3 (5.4%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 3	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Influenza	0	3 (9.4%)	3 (5.9%)	3 (5.4%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Sepsis, bacteraemia, viraemia and fungaemia NEC (cont)				
Bacteraemia	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Septic shock	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 5	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Influenza viral infections	1 (2.2%)	1 (1.9%)	2 (2.1%)	3 (2.6%)
Grade 1	0	0	0	1 (0.9%)
Grade 2	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)
Grade 3	0	0	0	0
Influenza	1 (2.2%)	1 (1.9%)	2 (2.1%)	3 (2.6%)
Grade 1	0	0	0	1 (0.9%)
Grade 2	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Influenza viral infections (cont)				
Influenza (cont)				
Grade 3	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Skin structures and soft tissue infections	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	0	0	0	0
Grade 2	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 3	0	0	0	0
Skin infection	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Folliculitis	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Influenza viral infections (cont)				
Influenza (cont)				
Grade 3	0	0	0	0
Skin structures and soft tissue infections	2 (4.4%)	0	2 (2.1%)	5 (4.4%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	3 (2.6%)
Grade 3	0	0	0	1 (0.9%)
Skin infection	0	0	0	3 (2.6%)
Grade 2	0	0	0	2 (1.8%)
Grade 3	0	0	0	1 (0.9%)
Folliculitis	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Skin structures and soft tissue infections (cont)				
Infected dermal cyst	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 2	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Infected skin ulcer	0	0	0	0
Grade 1	0	0	0	0
Subcutaneous abscess	0	0	0	0
Grade 2	0	0	0	0
Viral infections NEC	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Skin structures and soft tissue infections (cont)				
Infected dermal cyst	0	0	0	0
Grade 2	0	0	0	0
Infected skin ulcer	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Subcutaneous abscess	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Viral infections NEC	1 (2.2%)	3 (5.8%)	4 (4.1%)	4 (3.5%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Viral infections NEC (cont)				
Viral infection	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Gastroenteritis viral	0	0	0	0
Grade 1	0	0	0	0
Pneumonia viral	0	0	0	0
Grade 3	0	0	0	0
Vestibular neuronitis	0	0	0	0
Grade 2	0	0	0	0
Viral uveitis	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Viral infections NEC (cont)				
Viral infection	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Gastroenteritis viral	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Pneumonia viral	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Vestibular neuronitis	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Viral uveitis	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Dental and oral soft tissue infections	1 (5.3%)	1 (3.1%)	2 (3.9%)	4 (7.1%)
Grade 1	1 (5.3%)	1 (3.1%)	2 (3.9%)	4 (7.1%)
Periodontitis	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Gingivitis	0	0	0	1 (1.8%)
Grade 1	0	0	0	1 (1.8%)
Lip infection	0	0	0	1 (1.8%)
Grade 1	0	0	0	1 (1.8%)
Tooth abscess	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Dental and oral soft tissue infections	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)
Periodontitis	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)
Gingivitis	0	0	0	0
Grade 1	0	0	0	0
Lip infection	0	0	0	0
Grade 1	0	0	0	0
Tooth abscess	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Bacterial infections NEC	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Cellulitis	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Gangrene	0	0	0	0
Grade 3	0	0	0	0
Pneumonia bacterial	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Bacterial infections NEC	1 (2.2%)	1 (1.9%)	2 (2.1%)	4 (3.5%)
Grade 1	0	0	0	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 3	1 (2.2%)	0	1 (1.0%)	2 (1.8%)
Cellulitis	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Grade 1	0	0	0	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Gangrene	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Pneumonia bacterial	0	0	0	1 (0.9%)
Grade 3	0	0	0	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Clostridia infections	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Clostridium difficile colitis	0	0	0	0
Grade 3	0	0	0	0
Clostridium difficile infection	0	0	0	0
Grade 2	0	0	0	0
Tetanus	0	0	0	0
Grade 4	0	0	0	0
Ear infections	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Clostridia infections	1 (2.2%)	2 (3.8%)	3 (3.1%)	3 (2.6%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 4	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Clostridium difficile colitis	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Clostridium difficile infection	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Tetanus	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 4	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Ear infections	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Ear infections (cont)				
(cont)				
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Ear infection	0	0	0	0
Grade 1	0	0	0	0
Labyrinthitis	0	0	0	0
Grade 1	0	0	0	0
Otitis externa	0	0	0	0
Grade 2	0	0	0	0
Otitis media	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Ear infections (cont)				
(cont)				
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Ear infection	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Labyrinthitis	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Otitis externa	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Otitis media	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Escherichia infections	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Escherichia urinary tract infection	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Escherichia infection	0	0	0	0
Grade 2	0	0	0	0
Escherichia sepsis	0	0	0	0
Grade 4	0	0	0	0
Fungal infections NEC	0	0	0	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Escherichia infections	1 (2.2%)	1 (1.9%)	2 (2.1%)	3 (2.6%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 4	0	0	0	1 (0.9%)
Escherichia urinary tract infection	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Escherichia infection	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Escherichia sepsis	0	0	0	1 (0.9%)
Grade 4	0	0	0	1 (0.9%)
Fungal infections NEC	1 (2.2%)	0	1 (1.0%)	2 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Fungal infections NEC (cont)				
(cont)				
Grade 1	0	0	0	1 (1.8%)
Fungal skin infection	0	0	0	1 (1.8%)
Grade 1	0	0	0	1 (1.8%)
Fungal infection	0	0	0	0
Grade 1	0	0	0	0
Borrelial infections	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Borrelia infection	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Fungal infections NEC (cont)				
(cont)				
Grade 1	1 (2.2%)	0	1 (1.0%)	2 (1.8%)
Fungal skin infection	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Fungal infection	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)
Borrelial infections	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Grade 1	0	0	0	1 (0.9%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Borrelia infection	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Borrelial infections (cont)				
Lyme disease	0	0	0	0
Grade 1	0	0	0	0
Neuroborreliosis	0	0	0	0
Grade 3	0	0	0	0
Candida infections	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	0	0	0
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Gastrointestinal candidiasis	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Oral candidiasis	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Borrelial infections (cont)				
Lyme disease	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)
Neuroborreliosis	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Candida infections	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)
Grade 2	0	0	0	0
Gastrointestinal candidiasis	0	0	0	0
Grade 2	0	0	0	0
Oral candidiasis	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Staphylococcal infections	0	0	0	0
Grade 1	0	0	0	0
Furuncle	0	0	0	0
Grade 1	0	0	0	0
Bordetella infections	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Pertussis	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Eye and eyelid infections	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 2	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Eye infection	1 (5.3%)	0	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Staphylococcal infections	2 (4.4%)	0	2 (2.1%)	2 (1.8%)
Grade 1	2 (4.4%)	0	2 (2.1%)	2 (1.8%)
Furuncle	2 (4.4%)	0	2 (2.1%)	2 (1.8%)
Grade 1	2 (4.4%)	0	2 (2.1%)	2 (1.8%)
Bordetella infections	0	0	0	0
Grade 1	0	0	0	0
Pertussis	0	0	0	0
Grade 1	0	0	0	0
Eye and eyelid infections	0	0	0	0
Grade 2	0	0	0	0
Eye infection	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Eye and eyelid infections (cont)				
Eye infection (cont)				
Grade 2	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Male reproductive tract infections	0	0	0	1 (1.8%)
Grade 2	0	0	0	1 (1.8%)
Scrotal abscess	0	0	0	1 (1.8%)
Grade 2	0	0	0	1 (1.8%)
Streptococcal infections	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Erysipelas	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Eye and eyelid infections (cont)				
Eye infection (cont)				
Grade 2	0	0	0	0
Male reproductive tract infections	0	0	0	0
Grade 2	0	0	0	0
Scrotal abscess	0	0	0	0
Grade 2	0	0	0	0
Streptococcal infections	0	0	0	0
Grade 2	0	0	0	0
Erysipelas	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Tinea infections	0	0	0	1 (1.8%)
Grade 1	0	0	0	1 (1.8%)
Tinea versicolour	0	0	0	1 (1.8%)
Grade 1	0	0	0	1 (1.8%)
Tuberculous infections	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 2	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Tuberculosis	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 2	1 (5.3%)	0	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Tinea infections	0	0	0	0
Grade 1	0	0	0	0
Tinea versicolour	0	0	0	0
Grade 1	0	0	0	0
Tuberculous infections	0	0	0	0
Grade 2	0	0	0	0
Tuberculosis	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions	9 (47.4%)	11 (34.4%)	20 (39.2%)	27 (48.2%)
Grade 1	4 (21.1%)	6 (18.8%)	10 (19.6%)	13 (23.2%)
Grade 2	5 (26.3%)	3 (9.4%)	8 (15.7%)	11 (19.6%)
Grade 3	0	2 (6.3%)	2 (3.9%)	3 (5.4%)
Grade 5	0	0	0	0
Asthenic conditions	2 (10.5%)	5 (15.6%)	7 (13.7%)	11 (19.6%)
Grade 1	0	3 (9.4%)	3 (5.9%)	5 (8.9%)
Grade 2	2 (10.5%)	1 (3.1%)	3 (5.9%)	5 (8.9%)
Grade 3	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Fatigue	1 (5.3%)	5 (15.6%)	6 (11.8%)	8 (14.3%)
Grade 1	0	3 (9.4%)	3 (5.9%)	4 (7.1%)
Grade 2	1 (5.3%)	1 (3.1%)	2 (3.9%)	3 (5.4%)
Grade 3	0	1 (3.1%)	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions	20 (44.4%)	20 (38.5%)	40 (41.2%)	59 (51.8%)
Grade 1	11 (24.4%)	4 (7.7%)	15 (15.5%)	29 (25.4%)
Grade 2	6 (13.3%)	14 (26.9%)	20 (20.6%)	23 (20.2%)
Grade 3	2 (4.4%)	2 (3.8%)	4 (4.1%)	5 (4.4%)
Grade 5	1 (2.2%)	0	1 (1.0%)	2 (1.8%)
Asthenic conditions	10 (22.2%)	13 (25.0%)	23 (23.7%)	36 (31.6%)
Grade 1	5 (11.1%)	2 (3.8%)	7 (7.2%)	19 (16.7%)
Grade 2	4 (8.9%)	9 (17.3%)	13 (13.4%)	14 (12.3%)
Grade 3	1 (2.2%)	2 (3.8%)	3 (3.1%)	3 (2.6%)
Fatigue	5 (11.1%)	7 (13.5%)	12 (12.4%)	22 (19.3%)
Grade 1	2 (4.4%)	2 (3.8%)	4 (4.1%)	13 (11.4%)
Grade 2	2 (4.4%)	5 (9.6%)	7 (7.2%)	8 (7.0%)
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Asthenic conditions (cont)				
Asthenia	0	0	0	2 (3.6%)
Grade 1	0	0	0	1 (1.8%)
Grade 2	0	0	0	1 (1.8%)
Grade 3	0	0	0	0
Malaise	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	0	0	0	0
Grade 2	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 3	0	0	0	0
Febrile disorders	5 (26.3%)	3 (9.4%)	8 (15.7%)	9 (16.1%)
Grade 1	1 (5.3%)	2 (6.3%)	3 (5.9%)	3 (5.4%)
Grade 2	4 (21.1%)	1 (3.1%)	5 (9.8%)	5 (8.9%)
Grade 3	0	0	0	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Asthenic conditions (cont)				
Asthenia	5 (11.1%)	5 (9.6%)	10 (10.3%)	12 (10.5%)
Grade 1	3 (6.7%)	0	3 (3.1%)	5 (4.4%)
Grade 2	2 (4.4%)	4 (7.7%)	6 (6.2%)	6 (5.3%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Malaise	0	2 (3.8%)	2 (2.1%)	4 (3.5%)
Grade 1	0	0	0	2 (1.8%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Febrile disorders	6 (13.3%)	3 (5.8%)	9 (9.3%)	16 (14.0%)
Grade 1	3 (6.7%)	3 (5.8%)	6 (6.2%)	12 (10.5%)
Grade 2	2 (4.4%)	0	2 (2.1%)	3 (2.6%)
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Febrile disorders (cont)				
Pyrexia	5 (26.3%)	3 (9.4%)	8 (15.7%)	9 (16.1%)
Grade 1	1 (5.3%)	2 (6.3%)	3 (5.9%)	3 (5.4%)
Grade 2	4 (21.1%)	1 (3.1%)	5 (9.8%)	5 (8.9%)
Grade 3	0	0	0	1 (1.8%)
Oedema NEC	2 (10.5%)	3 (9.4%)	5 (9.8%)	7 (12.5%)
Grade 1	1 (5.3%)	3 (9.4%)	4 (7.8%)	5 (8.9%)
Grade 2	1 (5.3%)	0	1 (2.0%)	2 (3.6%)
Oedema peripheral	2 (10.5%)	2 (6.3%)	4 (7.8%)	5 (8.9%)
Grade 1	1 (5.3%)	2 (6.3%)	3 (5.9%)	3 (5.4%)
Grade 2	1 (5.3%)	0	1 (2.0%)	2 (3.6%)
Oedema	0	1 (3.1%)	1 (2.0%)	2 (3.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Febrile disorders (cont)				
Pyrexia	6 (13.3%)	3 (5.8%)	9 (9.3%)	16 (14.0%)
Grade 1	3 (6.7%)	3 (5.8%)	6 (6.2%)	12 (10.5%)
Grade 2	2 (4.4%)	0	2 (2.1%)	3 (2.6%)
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Oedema NEC	6 (13.3%)	1 (1.9%)	7 (7.2%)	11 (9.6%)
Grade 1	5 (11.1%)	0	5 (5.2%)	7 (6.1%)
Grade 2	1 (2.2%)	1 (1.9%)	2 (2.1%)	4 (3.5%)
Oedema peripheral	6 (13.3%)	1 (1.9%)	7 (7.2%)	11 (9.6%)
Grade 1	5 (11.1%)	0	5 (5.2%)	8 (7.0%)
Grade 2	1 (2.2%)	1 (1.9%)	2 (2.1%)	3 (2.6%)
Oedema	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Oedema NEC (cont)				
Oedema (cont)				
Grade 1	0	1 (3.1%)	1 (2.0%)	2 (3.6%)
Generalised oedema	0	0	0	0
Grade 2	0	0	0	0
General signs and symptoms NEC	3 (15.8%)	3 (9.4%)	6 (11.8%)	7 (12.5%)
Grade 1	3 (15.8%)	1 (3.1%)	4 (7.8%)	5 (8.9%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 3	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 5	0	0	0	0
Influenza like illness	1 (5.3%)	2 (6.3%)	3 (5.9%)	4 (7.1%)
Grade 1	1 (5.3%)	1 (3.1%)	2 (3.9%)	3 (5.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Oedema NEC (cont)				
Oedema (cont)				
Grade 1	0	0	0	0
Generalised oedema	0	0	0	1 (0.9%)
Grade 2	0	0	0	1 (0.9%)
General signs and symptoms NEC	3 (6.7%)	2 (3.8%)	5 (5.2%)	8 (7.0%)
Grade 1	1 (2.2%)	2 (3.8%)	3 (3.1%)	5 (4.4%)
Grade 2	1 (2.2%)	0	1 (1.0%)	2 (1.8%)
Grade 3	0	0	0	0
Grade 5	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Influenza like illness	1 (2.2%)	1 (1.9%)	2 (2.1%)	3 (2.6%)
Grade 1	0	1 (1.9%)	1 (1.0%)	2 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
General signs and symptoms NEC (cont)				
Influenza like illness (cont)				
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Peripheral swelling	2 (10.5%)	0	2 (3.9%)	2 (3.6%)
Grade 1	2 (10.5%)	0	2 (3.9%)	2 (3.6%)
Grade 2	0	0	0	0
Crepitations	0	0	0	0
Grade 1	0	0	0	0
General physical health deterioration	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 3	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Multiple organ dysfunction syndrome	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
General signs and symptoms NEC (cont)				
Influenza like illness (cont)				
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Peripheral swelling	0	1 (1.9%)	1 (1.0%)	4 (3.5%)
Grade 1	0	1 (1.9%)	1 (1.0%)	3 (2.6%)
Grade 2	0	0	0	1 (0.9%)
Crepitations	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)
General physical health deterioration	0	0	0	0
Grade 3	0	0	0	0
Multiple organ dysfunction syndrome	1 (2.2%)	0	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
General signs and symptoms NEC (cont)				
Multiple organ dysfunction syndrome (cont)				
Grade 5	0	0	0	0
Swelling	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Xerosis	0	0	0	0
Grade 1	0	0	0	0
Pain and discomfort NEC	0	2 (6.3%)	2 (3.9%)	5 (8.9%)
Grade 1	0	1 (3.1%)	1 (2.0%)	3 (5.4%)
Grade 2	0	0	0	1 (1.8%)
Grade 3	0	1 (3.1%)	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
General signs and symptoms NEC (cont)				
Multiple organ dysfunction syndrome (cont)				
Grade 5	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Swelling	0	0	0	0
Grade 1	0	0	0	0
Xerosis	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Pain and discomfort NEC	1 (2.2%)	2 (3.8%)	3 (3.1%)	7 (6.1%)
Grade 1	1 (2.2%)	1 (1.9%)	2 (2.1%)	5 (4.4%)
Grade 2	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Pain and discomfort NEC (cont)				
Chest pain	0	1 (3.1%)	1 (2.0%)	3 (5.4%)
Grade 1	0	0	0	2 (3.6%)
Grade 2	0	0	0	0
Grade 3	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Pain	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Facial pain	0	0	0	1 (1.8%)
Grade 2	0	0	0	1 (1.8%)
Non-cardiac chest pain	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Pain and discomfort NEC (cont)				
Chest pain	1 (2.2%)	2 (3.8%)	3 (3.1%)	5 (4.4%)
Grade 1	1 (2.2%)	1 (1.9%)	2 (2.1%)	4 (3.5%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 3	0	0	0	0
Pain	0	0	0	2 (1.8%)
Grade 1	0	0	0	1 (0.9%)
Grade 2	0	0	0	1 (0.9%)
Facial pain	0	0	0	0
Grade 2	0	0	0	0
Non-cardiac chest pain	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Feelings and sensations NEC	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 1	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Chills	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Early satiety	0	0	0	0
Grade 1	0	0	0	0
Feeling hot	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Healing abnormal NEC	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Feelings and sensations NEC	1 (2.2%)	1 (1.9%)	2 (2.1%)	3 (2.6%)
Grade 1	1 (2.2%)	1 (1.9%)	2 (2.1%)	3 (2.6%)
Chills	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Grade 1	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Early satiety	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Feeling hot	0	0	0	0
Grade 1	0	0	0	0
Healing abnormal NEC	0	2 (3.8%)	2 (2.1%)	2 (1.8%)
Grade 2	0	2 (3.8%)	2 (2.1%)	2 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Healing abnormal NEC (cont)				
Impaired healing	0	0	0	0
Grade 2	0	0	0	0
Mucosal findings abnormal	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Mucosal inflammation	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Death and sudden death	0	0	0	0
Grade 5	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Healing abnormal NEC (cont)				
Impaired healing	0	2 (3.8%)	2 (2.1%)	2 (1.8%)
Grade 2	0	2 (3.8%)	2 (2.1%)	2 (1.8%)
Mucosal findings abnormal	1 (2.2%)	0	1 (1.0%)	2 (1.8%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 3	0	0	0	1 (0.9%)
Mucosal inflammation	1 (2.2%)	0	1 (1.0%)	2 (1.8%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 3	0	0	0	1 (0.9%)
Death and sudden death	0	0	0	1 (0.9%)
Grade 5	0	0	0	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Death and sudden death (cont)				
Sudden death	0	0	0	0
Grade 5	0	0	0	0
Gait disturbances	0	0	0	0
Grade 1	0	0	0	0
Gait disturbance	0	0	0	0
Grade 1	0	0	0	0
Implant and catheter site reactions	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Catheter site pain	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Death and sudden death (cont)				
Sudden death	0	0	0	1 (0.9%)
Grade 5	0	0	0	1 (0.9%)
Gait disturbances	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)
Gait disturbance	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)
Implant and catheter site reactions	0	0	0	0
Grade 2	0	0	0	0
Catheter site pain	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Withdrawal and rebound effects	0	0	0	0
Grade 2	0	0	0	0
Drug withdrawal syndrome	0	0	0	0
Grade 2	0	0	0	0
Blood and lymphatic system disorders	9 (47.4%)	16 (50.0%)	25 (49.0%)	31 (55.4%)
Grade 1	0	0	0	0
Grade 2	0	7 (21.9%)	7 (13.7%)	11 (19.6%)
Grade 3	7 (36.8%)	7 (21.9%)	14 (27.5%)	15 (26.8%)
Grade 4	2 (10.5%)	2 (6.3%)	4 (7.8%)	5 (8.9%)
Grade 5	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Withdrawal and rebound effects	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Drug withdrawal syndrome	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Blood and lymphatic system disorders	15 (33.3%)	22 (42.3%)	37 (38.1%)	54 (47.4%)
Grade 1	2 (4.4%)	4 (7.7%)	6 (6.2%)	9 (7.9%)
Grade 2	3 (6.7%)	7 (13.5%)	10 (10.3%)	14 (12.3%)
Grade 3	8 (17.8%)	9 (17.3%)	17 (17.5%)	25 (21.9%)
Grade 4	2 (4.4%)	1 (1.9%)	3 (3.1%)	5 (4.4%)
Grade 5	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Thrombocytopenias	4 (21.1%)	8 (25.0%)	12 (23.5%)	16 (28.6%)
Grade 1	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 2	0	1 (3.1%)	1 (2.0%)	4 (7.1%)
Grade 3	2 (10.5%)	4 (12.5%)	6 (11.8%)	6 (10.7%)
Grade 4	1 (5.3%)	2 (6.3%)	3 (5.9%)	4 (7.1%)
Thrombocytopenia	4 (21.1%)	8 (25.0%)	12 (23.5%)	16 (28.6%)
Grade 1	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 2	0	1 (3.1%)	1 (2.0%)	4 (7.1%)
Grade 3	2 (10.5%)	4 (12.5%)	6 (11.8%)	6 (10.7%)
Grade 4	1 (5.3%)	2 (6.3%)	3 (5.9%)	4 (7.1%)
Anaemias NEC	8 (42.1%)	9 (28.1%)	17 (33.3%)	19 (33.9%)
Grade 2	0	6 (18.8%)	6 (11.8%)	7 (12.5%)
Grade 3	6 (31.6%)	3 (9.4%)	9 (17.6%)	10 (17.9%)
Grade 4	2 (10.5%)	0	2 (3.9%)	2 (3.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Thrombocytopenias	8 (17.8%)	8 (15.4%)	16 (16.5%)	27 (23.7%)
Grade 1	3 (6.7%)	2 (3.8%)	5 (5.2%)	6 (5.3%)
Grade 2	0	1 (1.9%)	1 (1.0%)	4 (3.5%)
Grade 3	5 (11.1%)	5 (9.6%)	10 (10.3%)	15 (13.2%)
Grade 4	0	0	0	2 (1.8%)
Thrombocytopenia	8 (17.8%)	8 (15.4%)	16 (16.5%)	27 (23.7%)
Grade 1	3 (6.7%)	2 (3.8%)	5 (5.2%)	6 (5.3%)
Grade 2	0	1 (1.9%)	1 (1.0%)	4 (3.5%)
Grade 3	5 (11.1%)	5 (9.6%)	10 (10.3%)	15 (13.2%)
Grade 4	0	0	0	2 (1.8%)
Anaemias NEC	8 (17.8%)	6 (11.5%)	14 (14.4%)	22 (19.3%)
Grade 2	3 (6.7%)	3 (5.8%)	6 (6.2%)	8 (7.0%)
Grade 3	4 (8.9%)	3 (5.8%)	7 (7.2%)	13 (11.4%)
Grade 4	1 (2.2%)	0	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Anaemias NEC (cont)				
Anaemia	8 (42.1%)	9 (28.1%)	17 (33.3%)	19 (33.9%)
Grade 2	0	6 (18.8%)	6 (11.8%)	7 (12.5%)
Grade 3	6 (31.6%)	3 (9.4%)	9 (17.6%)	10 (17.9%)
Grade 4	2 (10.5%)	0	2 (3.9%)	2 (3.6%)
Leukocytoses NEC	2 (10.5%)	3 (9.4%)	5 (9.8%)	5 (8.9%)
Grade 1	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 2	0	2 (6.3%)	2 (3.9%)	2 (3.6%)
Grade 3	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Leukocytosis	2 (10.5%)	3 (9.4%)	5 (9.8%)	5 (8.9%)
Grade 1	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 2	0	2 (6.3%)	2 (3.9%)	2 (3.6%)
Grade 3	1 (5.3%)	0	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Anaemias NEC (cont)				
Anaemia	8 (17.8%)	6 (11.5%)	14 (14.4%)	22 (19.3%)
Grade 2	3 (6.7%)	3 (5.8%)	6 (6.2%)	8 (7.0%)
Grade 3	4 (8.9%)	3 (5.8%)	7 (7.2%)	13 (11.4%)
Grade 4	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Leukocytoses NEC	1 (2.2%)	4 (7.7%)	5 (5.2%)	6 (5.3%)
Grade 1	1 (2.2%)	2 (3.8%)	3 (3.1%)	4 (3.5%)
Grade 2	0	2 (3.8%)	2 (2.1%)	2 (1.8%)
Grade 3	0	0	0	0
Leukocytosis	1 (2.2%)	4 (7.7%)	5 (5.2%)	6 (5.3%)
Grade 1	1 (2.2%)	2 (3.8%)	3 (3.1%)	4 (3.5%)
Grade 2	0	2 (3.8%)	2 (2.1%)	2 (1.8%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Leukocytoses NEC (cont)				
Neutrophilia	0	0	0	0
Grade 1	0	0	0	0
Neutropenias	1 (5.3%)	1 (3.1%)	2 (3.9%)	4 (7.1%)
Grade 1	0	0	0	0
Grade 3	1 (5.3%)	1 (3.1%)	2 (3.9%)	4 (7.1%)
Grade 4	0	0	0	0
Neutropenia	1 (5.3%)	1 (3.1%)	2 (3.9%)	3 (5.4%)
Grade 1	0	0	0	0
Grade 3	1 (5.3%)	1 (3.1%)	2 (3.9%)	3 (5.4%)
Grade 4	0	0	0	0
Febrile neutropenia	1 (5.3%)	0	1 (2.0%)	2 (3.6%)
Grade 3	1 (5.3%)	0	1 (2.0%)	2 (3.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Leukocytoses NEC (cont)				
Neutrophilia	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Neutropenias	1 (2.2%)	2 (3.8%)	3 (3.1%)	5 (4.4%)
Grade 1	1 (2.2%)	0	1 (1.0%)	2 (1.8%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 4	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Neutropenia	1 (2.2%)	2 (3.8%)	3 (3.1%)	5 (4.4%)
Grade 1	1 (2.2%)	0	1 (1.0%)	2 (1.8%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 4	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Febrile neutropenia	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Leukopenias NEC	1 (5.3%)	0	1 (2.0%)	2 (3.6%)
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	1 (1.8%)
Grade 4	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Leukopenia	1 (5.3%)	0	1 (2.0%)	2 (3.6%)
Grade 1	0	0	0	0
Grade 3	1 (5.3%)	0	1 (2.0%)	2 (3.6%)
Lymphopenia	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 2	0	0	0	0
Grade 4	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Spleen disorders	2 (10.5%)	0	2 (3.9%)	2 (3.6%)
Grade 3	2 (10.5%)	0	2 (3.9%)	2 (3.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Leukopenias NEC	0	2 (3.8%)	2 (2.1%)	3 (2.6%)
Grade 1	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Leukopenia	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Grade 1	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Grade 3	0	0	0	0
Lymphopenia	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 4	0	0	0	0
Spleen disorders	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Grade 3	0	0	0	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Spleen disorders (cont)				
(cont)				
Grade 5	0	0	0	0
Splenomegaly	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 3	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Splenic haematoma	0	0	0	0
Grade 5	0	0	0	0
Splenic infarction	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 3	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Thrombocytoses	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Spleen disorders (cont)				
(cont)				
Grade 5	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Splenomegaly	0	0	0	1 (0.9%)
Grade 3	0	0	0	1 (0.9%)
Splenic haematoma	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 5	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Splenic infarction	0	0	0	0
Grade 3	0	0	0	0
Thrombocytoses	0	3 (5.8%)	3 (3.1%)	3 (2.6%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Thrombocytoses (cont)				
(cont)				
Grade 3	0	0	0	0
Thrombocytosis	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Bleeding tendencies	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Increased tendency to bruise	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Anaemias haemolytic NEC	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Thrombocytoses (cont)				
(cont)				
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Thrombocytosis	0	3 (5.8%)	3 (3.1%)	3 (2.6%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Bleeding tendencies	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)
Increased tendency to bruise	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)
Anaemias haemolytic NEC	1 (2.2%)	0	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Anaemias haemolytic NEC (cont)				
(cont)				
Grade 4	0	0	0	0
Haemolytic anaemia	0	0	0	0
Grade 4	0	0	0	0
Coagulation factor deficiencies	0	0	0	1 (1.8%)
Grade 2	0	0	0	1 (1.8%)
Hypoprothrombinaemia	0	0	0	1 (1.8%)
Grade 2	0	0	0	1 (1.8%)
Haemolyses NEC	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Anaemias haemolytic NEC (cont)				
(cont)				
Grade 4	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Haemolytic anaemia	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 4	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Coagulation factor deficiencies	0	0	0	0
Grade 2	0	0	0	0
Hypoprothrombinaemia	0	0	0	0
Grade 2	0	0	0	0
Haemolyses NEC	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Haemolyses NEC (cont)				
Haemolysis	0	0	0	0
Grade 3	0	0	0	0
Respiratory, thoracic and mediastinal disorders	9 (47.4%)	16 (50.0%)	25 (49.0%)	27 (48.2%)
Grade 1	3 (15.8%)	7 (21.9%)	10 (19.6%)	11 (19.6%)
Grade 2	5 (26.3%)	4 (12.5%)	9 (17.6%)	10 (17.9%)
Grade 3	0	4 (12.5%)	4 (7.8%)	4 (7.1%)
Grade 4	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 5	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Coughing and associated symptoms	4 (21.1%)	8 (25.0%)	12 (23.5%)	16 (28.6%)
Grade 1	1 (5.3%)	6 (18.8%)	7 (13.7%)	10 (17.9%)
Grade 2	3 (15.8%)	2 (6.3%)	5 (9.8%)	6 (10.7%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Haemolyses NEC (cont)				
Haemolysis	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Respiratory, thoracic and mediastinal disorders	17 (37.8%)	20 (38.5%)	37 (38.1%)	54 (47.4%)
Grade 1	9 (20.0%)	8 (15.4%)	17 (17.5%)	27 (23.7%)
Grade 2	5 (11.1%)	9 (17.3%)	14 (14.4%)	18 (15.8%)
Grade 3	1 (2.2%)	3 (5.8%)	4 (4.1%)	5 (4.4%)
Grade 4	1 (2.2%)	0	1 (1.0%)	3 (2.6%)
Grade 5	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Coughing and associated symptoms	9 (20.0%)	8 (15.4%)	17 (17.5%)	25 (21.9%)
Grade 1	7 (15.6%)	4 (7.7%)	11 (11.3%)	17 (14.9%)
Grade 2	2 (4.4%)	2 (3.8%)	4 (4.1%)	6 (5.3%)
Grade 3	0	2 (3.8%)	2 (2.1%)	2 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Coughing and associated symptoms (cont)				
Cough	4 (21.1%)	8 (25.0%)	12 (23.5%)	16 (28.6%)
Grade 1	1 (5.3%)	6 (18.8%)	7 (13.7%)	10 (17.9%)
Grade 2	3 (15.8%)	2 (6.3%)	5 (9.8%)	6 (10.7%)
Grade 3	0	0	0	0
Productive cough	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Haemoptysis	0	0	0	0
Grade 2	0	0	0	0
Breathing abnormalities	3 (15.8%)	6 (18.8%)	9 (17.6%)	11 (19.6%)
Grade 1	1 (5.3%)	2 (6.3%)	3 (5.9%)	5 (8.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Coughing and associated symptoms (cont)				
Cough	8 (17.8%)	8 (15.4%)	16 (16.5%)	23 (20.2%)
Grade 1	7 (15.6%)	4 (7.7%)	11 (11.3%)	17 (14.9%)
Grade 2	1 (2.2%)	2 (3.8%)	3 (3.1%)	4 (3.5%)
Grade 3	0	2 (3.8%)	2 (2.1%)	2 (1.8%)
Productive cough	1 (2.2%)	0	1 (1.0%)	2 (1.8%)
Grade 1	0	0	0	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Haemoptysis	0	0	0	1 (0.9%)
Grade 2	0	0	0	1 (0.9%)
Breathing abnormalities	4 (8.9%)	5 (9.6%)	9 (9.3%)	23 (20.2%)
Grade 1	4 (8.9%)	2 (3.8%)	6 (6.2%)	18 (15.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Breathing abnormalities (cont) (cont)				
Grade 2	2 (10.5%)	0	2 (3.9%)	2 (3.6%)
Grade 3	0	4 (12.5%)	4 (7.8%)	4 (7.1%)
Dyspnoea	3 (15.8%)	5 (15.6%)	8 (15.7%)	9 (16.1%)
Grade 1	1 (5.3%)	1 (3.1%)	2 (3.9%)	3 (5.4%)
Grade 2	2 (10.5%)	0	2 (3.9%)	2 (3.6%)
Grade 3	0	4 (12.5%)	4 (7.8%)	4 (7.1%)
Dyspnoea exertional	0	0	0	1 (1.8%)
Grade 1	0	0	0	1 (1.8%)
Hypoventilation	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Breathing abnormalities (cont) (cont)				
Grade 2	0	2 (3.8%)	2 (2.1%)	4 (3.5%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Dyspnoea	3 (6.7%)	4 (7.7%)	7 (7.2%)	17 (14.9%)
Grade 1	3 (6.7%)	1 (1.9%)	4 (4.1%)	12 (10.5%)
Grade 2	0	2 (3.8%)	2 (2.1%)	4 (3.5%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Dyspnoea exertional	1 (2.2%)	1 (1.9%)	2 (2.1%)	6 (5.3%)
Grade 1	1 (2.2%)	1 (1.9%)	2 (2.1%)	6 (5.3%)
Hypoventilation	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Breathing abnormalities (cont)				
Tachypnoea	0	0	0	0
Grade 1	0	0	0	0
Nasal disorders NEC	3 (15.8%)	1 (3.1%)	4 (7.8%)	4 (7.1%)
Grade 1	2 (10.5%)	0	2 (3.9%)	2 (3.6%)
Grade 2	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Epistaxis	3 (15.8%)	1 (3.1%)	4 (7.8%)	4 (7.1%)
Grade 1	2 (10.5%)	0	2 (3.9%)	2 (3.6%)
Grade 2	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Nasal dryness	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Breathing abnormalities (cont)				
Tachypnoea	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Nasal disorders NEC	3 (6.7%)	2 (3.8%)	5 (5.2%)	8 (7.0%)
Grade 1	2 (4.4%)	2 (3.8%)	4 (4.1%)	5 (4.4%)
Grade 2	1 (2.2%)	0	1 (1.0%)	3 (2.6%)
Epistaxis	2 (4.4%)	2 (3.8%)	4 (4.1%)	7 (6.1%)
Grade 1	1 (2.2%)	2 (3.8%)	3 (3.1%)	4 (3.5%)
Grade 2	1 (2.2%)	0	1 (1.0%)	3 (2.6%)
Nasal dryness	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Upper respiratory tract signs and symptoms	0	2 (6.3%)	2 (3.9%)	2 (3.6%)
Grade 1	0	2 (6.3%)	2 (3.9%)	2 (3.6%)
Grade 2	0	0	0	0
Dysphonia	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Rhinorrhoea	0	0	0	0
Grade 1	0	0	0	0
Oropharyngeal discomfort	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Oropharyngeal pain	0	1 (3.1%)	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Upper respiratory tract signs and symptoms	2 (4.4%)	1 (1.9%)	3 (3.1%)	7 (6.1%)
Grade 1	2 (4.4%)	0	2 (2.1%)	6 (5.3%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Dysphonia	1 (2.2%)	1 (1.9%)	2 (2.1%)	4 (3.5%)
Grade 1	1 (2.2%)	0	1 (1.0%)	3 (2.6%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Rhinorrhoea	1 (2.2%)	0	1 (1.0%)	2 (1.8%)
Grade 1	1 (2.2%)	0	1 (1.0%)	2 (1.8%)
Oropharyngeal discomfort	0	0	0	0
Grade 1	0	0	0	0
Oropharyngeal pain	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Upper respiratory tract signs and symptoms (cont)				
Oropharyngeal pain (cont)				
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Throat tightness	0	0	0	0
Grade 1	0	0	0	0
Bronchospasm and obstruction	2 (10.5%)	0	2 (3.9%)	2 (3.6%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 2	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 3	0	0	0	0
Bronchitis chronic	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Upper respiratory tract signs and symptoms (cont)				
Oropharyngeal pain (cont)				
Grade 1	0	0	0	0
Throat tightness	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)
Bronchospasm and obstruction	2 (4.4%)	2 (3.8%)	4 (4.1%)	5 (4.4%)
Grade 1	2 (4.4%)	1 (1.9%)	3 (3.1%)	3 (2.6%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 3	0	0	0	1 (0.9%)
Bronchitis chronic	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)
Grade 1	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Bronchospasm and obstruction (cont)				
Chronic obstructive pulmonary disease	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Wheezing	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Asthma	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 2	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Pneumothorax and pleural effusions NEC	1 (5.3%)	3 (9.4%)	4 (7.8%)	4 (7.1%)
Grade 1	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 3	0	1 (3.1%)	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Bronchospasm and obstruction (cont)				
Chronic obstructive pulmonary disease	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 3	0	0	0	1 (0.9%)
Wheezing	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Asthma	0	0	0	0
Grade 2	0	0	0	0
Pneumothorax and pleural effusions NEC	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	0	0	0
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Pneumothorax and pleural effusions NEC (cont)				
Pleural effusion	1 (5.3%)	3 (9.4%)	4 (7.8%)	4 (7.1%)
Grade 1	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 3	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Lower respiratory tract signs and symptoms	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Rales	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Pneumothorax and pleural effusions NEC (cont)				
Pleural effusion	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	0	0	0
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 3	0	0	0	0
Lower respiratory tract signs and symptoms	2 (4.4%)	0	2 (2.1%)	4 (3.5%)
Grade 1	2 (4.4%)	0	2 (2.1%)	3 (2.6%)
Grade 2	0	0	0	1 (0.9%)
Rales	1 (2.2%)	0	1 (1.0%)	3 (2.6%)
Grade 1	1 (2.2%)	0	1 (1.0%)	2 (1.8%)
Grade 2	0	0	0	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Lower respiratory tract signs and symptoms (cont)				
Hiccups	0	0	0	0
Grade 1	0	0	0	0
Respiratory failures (excl neonatal)	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 3	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 4	0	0	0	0
Grade 5	0	0	0	0
Respiratory failure	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 3	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 4	0	0	0	0
Grade 5	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Lower respiratory tract signs and symptoms (cont)				
Hiccups	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Respiratory failures (excl neonatal)	2 (4.4%)	0	2 (2.1%)	3 (2.6%)
Grade 3	0	0	0	0
Grade 4	1 (2.2%)	0	1 (1.0%)	2 (1.8%)
Grade 5	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Respiratory failure	2 (4.4%)	0	2 (2.1%)	3 (2.6%)
Grade 3	0	0	0	0
Grade 4	1 (2.2%)	0	1 (1.0%)	2 (1.8%)
Grade 5	1 (2.2%)	0	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Lower respiratory tract inflammatory and immunologic conditions	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Alveolitis	0	0	0	0
Grade 2	0	0	0	0
Pneumonia aspiration	0	0	0	0
Grade 3	0	0	0	0
Pulmonary granuloma	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Lower respiratory tract inflammatory and immunologic conditions	1 (2.2%)	2 (3.8%)	3 (3.1%)	3 (2.6%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Alveolitis	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Pneumonia aspiration	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Pulmonary granuloma	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Pulmonary thrombotic and embolic conditions	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 2	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 3	0	0	0	0
Grade 5	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Pulmonary embolism	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 2	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 3	0	0	0	0
Grade 5	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Conditions associated with abnormal gas exchange	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 4	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Hypoxia	1 (5.3%)	0	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Pulmonary thrombotic and embolic conditions	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	0	0	0	0
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 5	0	0	0	0
Pulmonary embolism	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	0	0	0	0
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 5	0	0	0	0
Conditions associated with abnormal gas exchange	0	0	0	1 (0.9%)
Grade 4	0	0	0	1 (0.9%)
Hypoxia	0	0	0	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Conditions associated with abnormal gas exchange (cont)				
Hypoxia (cont)				
Grade 4	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Laryngeal inflammation	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Reflux laryngitis	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Conditions associated with abnormal gas exchange (cont)				
Hypoxia (cont)				
Grade 4	0	0	0	1 (0.9%)
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)	0	0	0	1 (0.9%)
Grade 2	0	0	0	1 (0.9%)
Laryngeal inflammation	0	0	0	0
Grade 2	0	0	0	0
Reflux laryngitis	0	0	0	1 (0.9%)
Grade 2	0	0	0	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Parenchymal lung disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Emphysema	0	0	0	0
Grade 1	0	0	0	0
Lung consolidation	0	0	0	0
Grade 2	0	0	0	0
Pleural infections and inflammations	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Pleurisy	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Parenchymal lung disorders NEC	2 (4.4%)	0	2 (2.1%)	2 (1.8%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Emphysema	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Lung consolidation	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Pleural infections and inflammations	0	2 (3.8%)	2 (2.1%)	2 (1.8%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Pleurisy	0	2 (3.8%)	2 (2.1%)	2 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Pleural infections and inflammations (cont)				
Pleurisy (cont)				
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Paranasal sinus disorders (excl infections and neoplasms)	0	0	0	0
Grade 1	0	0	0	0
Sinus congestion	0	0	0	0
Grade 1	0	0	0	0
Pharyngeal disorders (excl infections and neoplasms)	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Pleural infections and inflammations (cont)				
Pleurisy (cont)				
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Paranasal sinus disorders (excl infections and neoplasms)	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Sinus congestion	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Pharyngeal disorders (excl infections and neoplasms)	0	0	0	1 (0.9%)
Grade 3	0	0	0	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Pharyngeal disorders (excl infections and neoplasms) (cont)				
Pharyngeal ulceration	0	0	0	0
Grade 3	0	0	0	0
Pulmonary oedemas	0	0	0	0
Grade 2	0	0	0	0
Pulmonary oedema	0	0	0	0
Grade 2	0	0	0	0
Respiratory tract disorders NEC	0	0	0	0
Grade 2	0	0	0	0
Lung disorder	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Pharyngeal disorders (excl infections and neoplasms) (cont)				
Pharyngeal ulceration	0	0	0	1 (0.9%)
Grade 3	0	0	0	1 (0.9%)
Pulmonary oedemas	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Pulmonary oedema	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Respiratory tract disorders NEC	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Lung disorder	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Respiratory tract disorders NEC (cont)				
Lung disorder (cont)				
Grade 2	0	0	0	0
Nervous system disorders	9 (47.4%)	10 (31.3%)	19 (37.3%)	25 (44.6%)
Grade 1	4 (21.1%)	6 (18.8%)	10 (19.6%)	14 (25.0%)
Grade 2	3 (15.8%)	3 (9.4%)	6 (11.8%)	7 (12.5%)
Grade 3	1 (5.3%)	1 (3.1%)	2 (3.9%)	3 (5.4%)
Grade 4	0	0	0	0
Grade 5	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Neurological signs and symptoms NEC	2 (10.5%)	3 (9.4%)	5 (9.8%)	9 (16.1%)
Grade 1	1 (5.3%)	3 (9.4%)	4 (7.8%)	8 (14.3%)
Grade 2	1 (5.3%)	0	1 (2.0%)	0
Grade 3	0	0	0	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Respiratory tract disorders NEC (cont)				
Lung disorder (cont)				
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Nervous system disorders	18 (40.0%)	22 (42.3%)	40 (41.2%)	54 (47.4%)
Grade 1	9 (20.0%)	10 (19.2%)	19 (19.6%)	25 (21.9%)
Grade 2	2 (4.4%)	8 (15.4%)	10 (10.3%)	16 (14.0%)
Grade 3	6 (13.3%)	4 (7.7%)	10 (10.3%)	12 (10.5%)
Grade 4	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 5	0	0	0	0
Neurological signs and symptoms NEC	5 (11.1%)	11 (21.2%)	16 (16.5%)	26 (22.8%)
Grade 1	5 (11.1%)	7 (13.5%)	12 (12.4%)	19 (16.7%)
Grade 2	0	3 (5.8%)	3 (3.1%)	6 (5.3%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Neurological signs and symptoms NEC (cont)				
Dizziness	1 (5.3%)	3 (9.4%)	4 (7.8%)	9 (16.1%)
Grade 1	1 (5.3%)	3 (9.4%)	4 (7.8%)	9 (16.1%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Presyncope	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	0	0	0	0
Grade 2	1 (5.3%)	0	1 (2.0%)	0
Grade 3	0	0	0	1 (1.8%)
Peripheral neuropathies NEC	1 (5.3%)	4 (12.5%)	5 (9.8%)	10 (17.9%)
Grade 1	0	3 (9.4%)	3 (5.9%)	6 (10.7%)
Grade 2	1 (5.3%)	1 (3.1%)	2 (3.9%)	4 (7.1%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Neurological signs and symptoms NEC (cont)				
Dizziness	5 (11.1%)	11 (21.2%)	16 (16.5%)	25 (21.9%)
Grade 1	5 (11.1%)	7 (13.5%)	12 (12.4%)	19 (16.7%)
Grade 2	0	3 (5.8%)	3 (3.1%)	5 (4.4%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Presyncope	0	0	0	2 (1.8%)
Grade 1	0	0	0	1 (0.9%)
Grade 2	0	0	0	1 (0.9%)
Grade 3	0	0	0	0
Peripheral neuropathies NEC	8 (17.8%)	9 (17.3%)	17 (17.5%)	21 (18.4%)
Grade 1	5 (11.1%)	3 (5.8%)	8 (8.2%)	11 (9.6%)
Grade 2	1 (2.2%)	4 (7.7%)	5 (5.2%)	6 (5.3%)
Grade 3	2 (4.4%)	2 (3.8%)	4 (4.1%)	4 (3.5%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Peripheral neuropathies NEC (cont)				
Peripheral sensory neuropathy	0	4 (12.5%)	4 (7.8%)	9 (16.1%)
Grade 1	0	3 (9.4%)	3 (5.9%)	6 (10.7%)
Grade 2	0	1 (3.1%)	1 (2.0%)	3 (5.4%)
Grade 3	0	0	0	0
Neuropathy peripheral	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 2	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Peripheral sensorimotor neuropathy	0	0	0	0
Grade 3	0	0	0	0
Paraesthesias and dysaesthesias	2 (10.5%)	3 (9.4%)	5 (9.8%)	8 (14.3%)
Grade 1	1 (5.3%)	2 (6.3%)	3 (5.9%)	6 (10.7%)
Grade 2	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Peripheral neuropathies NEC (cont)				
Peripheral sensory neuropathy	7 (15.6%)	9 (17.3%)	16 (16.5%)	20 (17.5%)
Grade 1	5 (11.1%)	3 (5.8%)	8 (8.2%)	11 (9.6%)
Grade 2	1 (2.2%)	4 (7.7%)	5 (5.2%)	6 (5.3%)
Grade 3	1 (2.2%)	2 (3.8%)	3 (3.1%)	3 (2.6%)
Neuropathy peripheral	0	0	0	0
Grade 2	0	0	0	0
Peripheral sensorimotor neuropathy	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Paraesthesias and dysaesthesias	4 (8.9%)	4 (7.7%)	8 (8.2%)	10 (8.8%)
Grade 1	3 (6.7%)	1 (1.9%)	4 (4.1%)	6 (5.3%)
Grade 2	0	3 (5.8%)	3 (3.1%)	3 (2.6%)
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Paraesthesias and dysaesthesias (cont)				
Paraesthesia	0	2 (6.3%)	2 (3.9%)	5 (8.9%)
Grade 1	0	2 (6.3%)	2 (3.9%)	5 (8.9%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Hypoaesthesia	2 (10.5%)	1 (3.1%)	3 (5.9%)	3 (5.4%)
Grade 1	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 2	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Burning sensation	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Dysaesthesia	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Paraesthesias and dysaesthesias (cont)				
Paraesthesia	3 (6.7%)	3 (5.8%)	6 (6.2%)	8 (7.0%)
Grade 1	2 (4.4%)	0	2 (2.1%)	4 (3.5%)
Grade 2	0	3 (5.8%)	3 (3.1%)	3 (2.6%)
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Hypoaesthesia	3 (6.7%)	1 (1.9%)	4 (4.1%)	4 (3.5%)
Grade 1	3 (6.7%)	0	3 (3.1%)	3 (2.6%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Burning sensation	0	0	0	0
Grade 2	0	0	0	0
Dysaesthesia	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Headaches NEC	1 (5.3%)	1 (3.1%)	2 (3.9%)	8 (14.3%)
Grade 1	1 (5.3%)	0	1 (2.0%)	5 (8.9%)
Grade 2	0	0	0	2 (3.6%)
Grade 3	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Headache	1 (5.3%)	1 (3.1%)	2 (3.9%)	8 (14.3%)
Grade 1	1 (5.3%)	0	1 (2.0%)	5 (8.9%)
Grade 2	0	0	0	2 (3.6%)
Grade 3	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Sinus headache	0	0	0	0
Grade 1	0	0	0	0
Disturbances in consciousness NEC	1 (5.3%)	2 (6.3%)	3 (5.9%)	3 (5.4%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Headaches NEC	1 (2.2%)	3 (5.8%)	4 (4.1%)	8 (7.0%)
Grade 1	1 (2.2%)	2 (3.8%)	3 (3.1%)	6 (5.3%)
Grade 2	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Grade 3	0	0	0	0
Headache	1 (2.2%)	2 (3.8%)	3 (3.1%)	7 (6.1%)
Grade 1	1 (2.2%)	1 (1.9%)	2 (2.1%)	5 (4.4%)
Grade 2	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Grade 3	0	0	0	0
Sinus headache	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Disturbances in consciousness NEC	2 (4.4%)	1 (1.9%)	3 (3.1%)	6 (5.3%)
Grade 1	0	0	0	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Disturbances in consciousness NEC (cont) (cont)				
Grade 3	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Syncope	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 2	0	0	0	0
Grade 3	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Somnolence	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 3	0	0	0	0
Lethargy	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Disturbances in consciousness NEC (cont) (cont)				
Grade 3	2 (4.4%)	0	2 (2.1%)	4 (3.5%)
Syncope	0	1 (1.9%)	1 (1.0%)	3 (2.6%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 3	0	0	0	2 (1.8%)
Somnolence	1 (2.2%)	0	1 (1.0%)	2 (1.8%)
Grade 1	0	0	0	1 (0.9%)
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Lethargy	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	0	0	0	0
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Coordination and balance disturbances	0	0	0	1 (1.8%)
Grade 1	0	0	0	1 (1.8%)
Grade 2	0	0	0	0
Balance disorder	0	0	0	1 (1.8%)
Grade 1	0	0	0	1 (1.8%)
Grade 2	0	0	0	0
Ataxia	0	0	0	0
Grade 1	0	0	0	0
Sensory abnormalities NEC	2 (10.5%)	1 (3.1%)	3 (5.9%)	3 (5.4%)
Grade 1	2 (10.5%)	1 (3.1%)	3 (5.9%)	3 (5.4%)
Dysgeusia	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 1	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Coordination and balance disturbances	3 (6.7%)	2 (3.8%)	5 (5.2%)	6 (5.3%)
Grade 1	1 (2.2%)	2 (3.8%)	3 (3.1%)	4 (3.5%)
Grade 2	2 (4.4%)	0	2 (2.1%)	2 (1.8%)
Balance disorder	3 (6.7%)	1 (1.9%)	4 (4.1%)	5 (4.4%)
Grade 1	1 (2.2%)	1 (1.9%)	2 (2.1%)	3 (2.6%)
Grade 2	2 (4.4%)	0	2 (2.1%)	2 (1.8%)
Ataxia	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Sensory abnormalities NEC	0	2 (3.8%)	2 (2.1%)	4 (3.5%)
Grade 1	0	2 (3.8%)	2 (2.1%)	4 (3.5%)
Dysgeusia	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Sensory abnormalities NEC (cont)				
Sensory disturbance	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Taste disorder	0	0	0	0
Grade 1	0	0	0	0
Ageusia	0	0	0	0
Grade 1	0	0	0	0
Restless legs syndrome	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Sensory abnormalities NEC (cont)				
Sensory disturbance	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Taste disorder	0	0	0	2 (1.8%)
Grade 1	0	0	0	2 (1.8%)
Ageusia	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Restless legs syndrome	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Central nervous system haemorrhages and cerebrovascular accidents	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Grade 5	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Cerebrovascular accident	0	0	0	0
Grade 2	0	0	0	0
Grade 4	0	0	0	0
Cerebellar stroke	0	0	0	0
Grade 3	0	0	0	0
Cerebral ischaemia	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Central nervous system haemorrhages and cerebrovascular accidents	4 (8.9%)	0	4 (4.1%)	5 (4.4%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	2 (1.8%)
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 4	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 5	0	0	0	0
Cerebrovascular accident	2 (4.4%)	0	2 (2.1%)	2 (1.8%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 4	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Cerebellar stroke	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Cerebral ischaemia	0	0	0	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Central nervous system haemorrhages and cerebrovascular accidents (cont)				
Cerebral ischaemia (cont)				
Grade 2	0	0	0	0
Haemorrhagic stroke	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 5	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Lacunar infarction	0	0	0	0
Grade 1	0	0	0	0
Memory loss (excl dementia)	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Amnesia	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Central nervous system haemorrhages and cerebrovascular accidents (cont)				
Cerebral ischaemia (cont)				
Grade 2	0	0	0	1 (0.9%)
Haemorrhagic stroke	0	0	0	0
Grade 5	0	0	0	0
Lacunar infarction	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Memory loss (excl dementia)	1 (2.2%)	3 (5.8%)	4 (4.1%)	6 (5.3%)
Grade 1	0	1 (1.9%)	1 (1.0%)	3 (2.6%)
Grade 2	1 (2.2%)	2 (3.8%)	3 (3.1%)	3 (2.6%)
Amnesia	1 (2.2%)	2 (3.8%)	3 (3.1%)	4 (3.5%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Memory loss (excl dementia) (cont)				
Amnesia (cont)				
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Memory impairment	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Central nervous system vascular disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Cerebral microangiopathy	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Memory loss (excl dementia) (cont)				
Amnesia (cont)				
Grade 1	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Grade 2	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)
Memory impairment	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Grade 1	0	0	0	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Central nervous system vascular disorders NEC	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Cerebral microangiopathy	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Central nervous system vascular disorders NEC (cont)				
Cerebrovascular insufficiency	0	0	0	0
Grade 2	0	0	0	0
Transient cerebrovascular events	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Transient ischaemic attack	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Dementia (excl Alzheimer's type)	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Central nervous system vascular disorders NEC (cont)				
Cerebrovascular insufficiency	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Transient cerebrovascular events	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Transient ischaemic attack	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Dementia (excl Alzheimer's type)	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Dementia (excl Alzheimer's type) (cont)				
Dementia	0	0	0	0
Grade 2	0	0	0	0
Demyelinating disorders NEC	0	0	0	0
Grade 2	0	0	0	0
Demyelination	0	0	0	0
Grade 2	0	0	0	0
Encephalopathies NEC	0	0	0	0
Grade 2	0	0	0	0
Leukoencephalopathy	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Dementia (excl Alzheimer's type) (cont)				
Dementia	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Demyelinating disorders NEC	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Demyelination	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Encephalopathies NEC	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Leukoencephalopathy	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Lumbar spinal cord and nerve root disorders	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Sciatica	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Muscle tone abnormal	0	0	0	0
Grade 1	0	0	0	0
Myotonia	0	0	0	0
Grade 1	0	0	0	0
Parkinson's disease and parkinsonism	0	0	0	0
Grade 2	0	0	0	0
Parkinson's disease	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Lumbar spinal cord and nerve root disorders	0	0	0	0
Grade 2	0	0	0	0
Sciatica	0	0	0	0
Grade 2	0	0	0	0
Muscle tone abnormal	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Myotonia	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Parkinson's disease and parkinsonism	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Parkinson's disease	1 (2.2%)	0	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Parkinson's disease and parkinsonism (cont)				
Parkinson's disease (cont)				
Grade 2	0	0	0	0
Structural brain disorders NEC	0	0	0	0
Grade 2	0	0	0	0
Cerebral atrophy	0	0	0	0
Grade 2	0	0	0	0
Tremor (excl congenital)	0	0	0	0
Grade 1	0	0	0	0
Tremor	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Parkinson's disease and parkinsonism (cont)				
Parkinson's disease (cont)				
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Structural brain disorders NEC	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Cerebral atrophy	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Tremor (excl congenital)	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Tremor	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders	8 (42.1%)	13 (40.6%)	21 (41.2%)	26 (46.4%)
Grade 1	4 (21.1%)	6 (18.8%)	10 (19.6%)	12 (21.4%)
Grade 2	2 (10.5%)	7 (21.9%)	9 (17.6%)	11 (19.6%)
Grade 3	2 (10.5%)	0	2 (3.9%)	3 (5.4%)
Grade 4	0	0	0	0
Disorders of purine metabolism	0	5 (15.6%)	5 (9.8%)	6 (10.7%)
Grade 1	0	5 (15.6%)	5 (9.8%)	6 (10.7%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Hyperuricaemia	0	5 (15.6%)	5 (9.8%)	6 (10.7%)
Grade 1	0	5 (15.6%)	5 (9.8%)	6 (10.7%)
Grade 4	0	0	0	0
Gout	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders	18 (40.0%)	22 (42.3%)	40 (41.2%)	52 (45.6%)
Grade 1	6 (13.3%)	7 (13.5%)	13 (13.4%)	15 (13.2%)
Grade 2	5 (11.1%)	10 (19.2%)	15 (15.5%)	19 (16.7%)
Grade 3	4 (8.9%)	3 (5.8%)	7 (7.2%)	11 (9.6%)
Grade 4	3 (6.7%)	2 (3.8%)	5 (5.2%)	7 (6.1%)
Disorders of purine metabolism	6 (13.3%)	4 (7.7%)	10 (10.3%)	15 (13.2%)
Grade 1	1 (2.2%)	1 (1.9%)	2 (2.1%)	4 (3.5%)
Grade 2	1 (2.2%)	1 (1.9%)	2 (2.1%)	3 (2.6%)
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 4	3 (6.7%)	2 (3.8%)	5 (5.2%)	7 (6.1%)
Hyperuricaemia	4 (8.9%)	3 (5.8%)	7 (7.2%)	11 (9.6%)
Grade 1	1 (2.2%)	1 (1.9%)	2 (2.1%)	4 (3.5%)
Grade 4	3 (6.7%)	2 (3.8%)	5 (5.2%)	7 (6.1%)
Gout	2 (4.4%)	1 (1.9%)	3 (3.1%)	4 (3.5%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Disorders of purine metabolism (cont)				
Gout (cont)				
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Water soluble vitamin deficiencies	2 (10.5%)	2 (6.3%)	4 (7.8%)	6 (10.7%)
Grade 1	1 (5.3%)	1 (3.1%)	2 (3.9%)	3 (5.4%)
Grade 2	1 (5.3%)	1 (3.1%)	2 (3.9%)	3 (5.4%)
Vitamin B1 deficiency	2 (10.5%)	2 (6.3%)	4 (7.8%)	5 (8.9%)
Grade 1	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 2	1 (5.3%)	1 (3.1%)	2 (3.9%)	3 (5.4%)
Vitamin B complex deficiency	0	0	0	1 (1.8%)
Grade 1	0	0	0	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Disorders of purine metabolism (cont)				
Gout (cont)				
Grade 2	1 (2.2%)	1 (1.9%)	2 (2.1%)	3 (2.6%)
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Water soluble vitamin deficiencies	6 (13.3%)	6 (11.5%)	12 (12.4%)	15 (13.2%)
Grade 1	1 (2.2%)	3 (5.8%)	4 (4.1%)	5 (4.4%)
Grade 2	5 (11.1%)	3 (5.8%)	8 (8.2%)	10 (8.8%)
Vitamin B1 deficiency	5 (11.1%)	6 (11.5%)	11 (11.3%)	14 (12.3%)
Grade 1	0	3 (5.8%)	3 (3.1%)	4 (3.5%)
Grade 2	5 (11.1%)	3 (5.8%)	8 (8.2%)	10 (8.8%)
Vitamin B complex deficiency	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Potassium imbalance	4 (21.1%)	1 (3.1%)	5 (9.8%)	8 (14.3%)
Grade 1	2 (10.5%)	1 (3.1%)	3 (5.9%)	4 (7.1%)
Grade 2	0	0	0	2 (3.6%)
Grade 3	2 (10.5%)	0	2 (3.9%)	2 (3.6%)
Hyperkalaemia	4 (21.1%)	0	4 (7.8%)	4 (7.1%)
Grade 1	2 (10.5%)	0	2 (3.9%)	2 (3.6%)
Grade 2	0	0	0	0
Grade 3	2 (10.5%)	0	2 (3.9%)	2 (3.6%)
Hypokalaemia	1 (5.3%)	1 (3.1%)	2 (3.9%)	5 (8.9%)
Grade 1	0	1 (3.1%)	1 (2.0%)	2 (3.6%)
Grade 2	0	0	0	2 (3.6%)
Grade 3	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Appetite disorders	1 (5.3%)	3 (9.4%)	4 (7.8%)	5 (8.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Potassium imbalance	5 (11.1%)	3 (5.8%)	8 (8.2%)	10 (8.8%)
Grade 1	2 (4.4%)	2 (3.8%)	4 (4.1%)	3 (2.6%)
Grade 2	0	1 (1.9%)	1 (1.0%)	3 (2.6%)
Grade 3	3 (6.7%)	0	3 (3.1%)	4 (3.5%)
Hyperkalaemia	4 (8.9%)	1 (1.9%)	5 (5.2%)	7 (6.1%)
Grade 1	1 (2.2%)	1 (1.9%)	2 (2.1%)	1 (0.9%)
Grade 2	0	0	0	2 (1.8%)
Grade 3	3 (6.7%)	0	3 (3.1%)	4 (3.5%)
Hypokalaemia	1 (2.2%)	2 (3.8%)	3 (3.1%)	3 (2.6%)
Grade 1	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 3	0	0	0	0
Appetite disorders	5 (11.1%)	4 (7.7%)	9 (9.3%)	12 (10.5%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Appetite disorders (cont)				
(cont)				
Grade 1	1 (5.3%)	1 (3.1%)	2 (3.9%)	3 (5.4%)
Grade 2	0	2 (6.3%)	2 (3.9%)	2 (3.6%)
Decreased appetite	1 (5.3%)	3 (9.4%)	4 (7.8%)	5 (8.9%)
Grade 1	1 (5.3%)	1 (3.1%)	2 (3.9%)	3 (5.4%)
Grade 2	0	2 (6.3%)	2 (3.9%)	2 (3.6%)
Magnesium metabolism disorders	1 (5.3%)	1 (3.1%)	2 (3.9%)	5 (8.9%)
Grade 1	0	1 (3.1%)	1 (2.0%)	3 (5.4%)
Grade 2	1 (5.3%)	0	1 (2.0%)	2 (3.6%)
Hypomagnesaemia	1 (5.3%)	1 (3.1%)	2 (3.9%)	5 (8.9%)
Grade 1	0	1 (3.1%)	1 (2.0%)	3 (5.4%)
Grade 2	1 (5.3%)	0	1 (2.0%)	2 (3.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Appetite disorders (cont)				
(cont)				
Grade 1	4 (8.9%)	2 (3.8%)	6 (6.2%)	8 (7.0%)
Grade 2	1 (2.2%)	2 (3.8%)	3 (3.1%)	4 (3.5%)
Decreased appetite	5 (11.1%)	4 (7.7%)	9 (9.3%)	12 (10.5%)
Grade 1	4 (8.9%)	2 (3.8%)	6 (6.2%)	8 (7.0%)
Grade 2	1 (2.2%)	2 (3.8%)	3 (3.1%)	4 (3.5%)
Magnesium metabolism disorders	0	0	0	2 (1.8%)
Grade 1	0	0	0	2 (1.8%)
Grade 2	0	0	0	0
Hypomagnesaemia	0	0	0	2 (1.8%)
Grade 1	0	0	0	2 (1.8%)
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Calcium metabolism disorders	1 (5.3%)	1 (3.1%)	2 (3.9%)	3 (5.4%)
Grade 2	1 (5.3%)	1 (3.1%)	2 (3.9%)	3 (5.4%)
Hypocalcaemia	1 (5.3%)	0	1 (2.0%)	2 (3.6%)
Grade 2	1 (5.3%)	0	1 (2.0%)	2 (3.6%)
Hypercalcaemia	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Diabetes mellitus (incl subtypes)	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	0	0	0
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Diabetes mellitus	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	0	0	0
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Calcium metabolism disorders	0	1 (1.9%)	1 (1.0%)	3 (2.6%)
Grade 2	0	1 (1.9%)	1 (1.0%)	3 (2.6%)
Hypocalcaemia	0	1 (1.9%)	1 (1.0%)	3 (2.6%)
Grade 2	0	1 (1.9%)	1 (1.0%)	3 (2.6%)
Hypercalcaemia	0	0	0	0
Grade 2	0	0	0	0
Diabetes mellitus (incl subtypes)	0	3 (5.8%)	3 (3.1%)	3 (2.6%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	2 (3.8%)	2 (2.1%)	2 (1.8%)
Diabetes mellitus	0	3 (5.8%)	3 (3.1%)	3 (2.6%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	2 (3.8%)	2 (2.1%)	2 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Fat soluble vitamin deficiencies and disorders	1 (5.3%)	0	1 (2.0%)	2 (3.6%)
Grade 1	1 (5.3%)	0	1 (2.0%)	2 (3.6%)
Grade 2	0	0	0	0
Vitamin D deficiency	1 (5.3%)	0	1 (2.0%)	2 (3.6%)
Grade 1	1 (5.3%)	0	1 (2.0%)	2 (3.6%)
Grade 2	0	0	0	0
Vitamin K deficiency	0	0	0	1 (1.8%)
Grade 1	0	0	0	1 (1.8%)
Hyperglycaemic conditions NEC	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	1 (5.3%)	0	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Fat soluble vitamin deficiencies and disorders	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Grade 1	0	0	0	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Vitamin D deficiency	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Grade 1	0	0	0	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Vitamin K deficiency	0	0	0	0
Grade 1	0	0	0	0
Hyperglycaemic conditions NEC	0	2 (3.8%)	2 (2.1%)	3 (2.6%)
Grade 1	0	0	0	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Hyperglycaemic conditions NEC (cont)				
Hyperglycaemia	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Iron excess	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	0	0	0	0
Grade 2	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 3	0	0	0	0
Iron overload	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	0	0	0	0
Grade 2	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Hyperglycaemic conditions NEC (cont)				
Hyperglycaemia	0	2 (3.8%)	2 (2.1%)	3 (2.6%)
Grade 1	0	0	0	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Iron excess	0	1 (1.9%)	1 (1.0%)	3 (2.6%)
Grade 1	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Grade 2	0	0	0	0
Grade 3	0	0	0	1 (0.9%)
Iron overload	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	0	0	0
Grade 3	0	0	0	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Iron excess (cont)				
Haemosiderosis	0	0	0	0
Grade 1	0	0	0	0
Total fluid volume decreased	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 3	0	0	0	0
Dehydration	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 3	0	0	0	0
Protein metabolism disorders NEC	0	1 (3.1%)	1 (2.0%)	2 (3.6%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	0	0	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Iron excess (cont)				
Haemosiderosis	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)
Total fluid volume decreased	1 (2.2%)	1 (1.9%)	2 (2.1%)	3 (2.6%)
Grade 2	0	0	0	0
Grade 3	1 (2.2%)	1 (1.9%)	2 (2.1%)	3 (2.6%)
Dehydration	1 (2.2%)	1 (1.9%)	2 (2.1%)	3 (2.6%)
Grade 2	0	0	0	0
Grade 3	1 (2.2%)	1 (1.9%)	2 (2.1%)	3 (2.6%)
Protein metabolism disorders NEC	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Protein metabolism disorders NEC (cont)				
Hypoalbuminaemia	0	1 (3.1%)	1 (2.0%)	2 (3.6%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	0	0	1 (1.8%)
Sodium imbalance	0	0	0	1 (1.8%)
Grade 3	0	0	0	1 (1.8%)
Hyponatraemia	0	0	0	1 (1.8%)
Grade 3	0	0	0	1 (1.8%)
Hypernatraemia	0	0	0	0
Grade 2	0	0	0	0
Hypoglycaemic conditions NEC	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Protein metabolism disorders NEC (cont)				
Hypoalbuminaemia	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	0	0	0	0
Sodium imbalance	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)
Grade 3	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)
Hyponatraemia	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)
Grade 3	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)
Hypernatraemia	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Hypoglycaemic conditions NEC	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Hypoglycaemic conditions NEC (cont)				
(cont)				
Grade 3	0	0	0	0
Hypoglycaemia	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Total fluid volume increased	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Fluid overload	0	0	0	0
Grade 1	0	0	0	0
Fluid retention	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Hypoglycaemic conditions NEC (cont)				
(cont)				
Grade 3	0	0	0	1 (0.9%)
Hypoglycaemia	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 3	0	0	0	1 (0.9%)
Total fluid volume increased	2 (4.4%)	0	2 (2.1%)	2 (1.8%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Fluid overload	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Fluid retention	1 (2.2%)	0	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Total fluid volume increased (cont)				
Fluid retention (cont)				
Grade 2	0	0	0	0
Electrolyte imbalance NEC	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Electrolyte imbalance	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Elevated triglycerides	0	0	0	0
Grade 3	0	0	0	0
Hypertriglyceridaemia	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Total fluid volume increased (cont)				
Fluid retention (cont)				
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Electrolyte imbalance NEC	0	0	0	0
Grade 1	0	0	0	0
Electrolyte imbalance	0	0	0	0
Grade 1	0	0	0	0
Elevated triglycerides	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Hypertriglyceridaemia	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
General nutritional disorders NEC	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Abnormal loss of weight	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Iron deficiencies	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Iron deficiency	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Lipid metabolism and deposit disorders NEC	0	0	0	0
Grade 2	0	0	0	0
Dyslipidaemia	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
General nutritional disorders NEC	0	0	0	0
Grade 2	0	0	0	0
Abnormal loss of weight	0	0	0	0
Grade 2	0	0	0	0
Iron deficiencies	0	0	0	0
Grade 2	0	0	0	0
Iron deficiency	0	0	0	0
Grade 2	0	0	0	0
Lipid metabolism and deposit disorders NEC	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Dyslipidaemia	1 (2.2%)	0	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Lipid metabolism and deposit disorders NEC (cont)				
Dyslipidaemia (cont)				
Grade 2	0	0	0	0
Phosphorus metabolism disorders	0	0	0	1 (1.8%)
Grade 3	0	0	0	1 (1.8%)
Hypophosphataemia	0	0	0	1 (1.8%)
Grade 3	0	0	0	1 (1.8%)
Skin and subcutaneous tissue disorders	9 (47.4%)	8 (25.0%)	17 (33.3%)	19 (33.9%)
Grade 1	9 (47.4%)	5 (15.6%)	14 (27.5%)	16 (28.6%)
Grade 2	0	3 (9.4%)	3 (5.9%)	3 (5.4%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Lipid metabolism and deposit disorders NEC (cont)				
Dyslipidaemia (cont)				
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Phosphorus metabolism disorders	0	0	0	0
Grade 3	0	0	0	0
Hypophosphataemia	0	0	0	0
Grade 3	0	0	0	0
Skin and subcutaneous tissue disorders	15 (33.3%)	17 (32.7%)	32 (33.0%)	43 (37.7%)
Grade 1	8 (17.8%)	13 (25.0%)	21 (21.6%)	29 (25.4%)
Grade 2	6 (13.3%)	3 (5.8%)	9 (9.3%)	12 (10.5%)
Grade 3	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Rashes, eruptions and exanthems NEC	4 (21.1%)	4 (12.5%)	8 (15.7%)	10 (17.9%)
Grade 1	4 (21.1%)	4 (12.5%)	8 (15.7%)	10 (17.9%)
Grade 2	0	0	0	0
Rash	3 (15.8%)	3 (9.4%)	6 (11.8%)	7 (12.5%)
Grade 1	3 (15.8%)	3 (9.4%)	6 (11.8%)	7 (12.5%)
Grade 2	0	0	0	0
Rash maculo-papular	0	0	0	2 (3.6%)
Grade 1	0	0	0	2 (3.6%)
Rash generalised	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 1	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Rash macular	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Rashes, eruptions and exanthems NEC	4 (8.9%)	5 (9.6%)	9 (9.3%)	13 (11.4%)
Grade 1	3 (6.7%)	5 (9.6%)	8 (8.2%)	11 (9.6%)
Grade 2	1 (2.2%)	0	1 (1.0%)	2 (1.8%)
Rash	4 (8.9%)	2 (3.8%)	6 (6.2%)	9 (7.9%)
Grade 1	3 (6.7%)	2 (3.8%)	5 (5.2%)	7 (6.1%)
Grade 2	1 (2.2%)	0	1 (1.0%)	2 (1.8%)
Rash maculo-papular	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Rash generalised	0	0	0	0
Grade 1	0	0	0	0
Rash macular	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Grade 1	0	1 (1.9%)	1 (1.0%)	2 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Rashes, eruptions and exanthems NEC (cont)				
Rash papular	0	0	0	0
Grade 1	0	0	0	0
Apocrine and eccrine gland disorders	2 (10.5%)	2 (6.3%)	4 (7.8%)	5 (8.9%)
Grade 1	2 (10.5%)	1 (3.1%)	3 (5.9%)	4 (7.1%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Night sweats	2 (10.5%)	2 (6.3%)	4 (7.8%)	5 (8.9%)
Grade 1	2 (10.5%)	1 (3.1%)	3 (5.9%)	4 (7.1%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Hyperhidrosis	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Cold sweat	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Rashes, eruptions and exanthems NEC (cont)				
Rash papular	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Apocrine and eccrine gland disorders	5 (11.1%)	6 (11.5%)	11 (11.3%)	14 (12.3%)
Grade 1	5 (11.1%)	5 (9.6%)	10 (10.3%)	13 (11.4%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Night sweats	5 (11.1%)	2 (3.8%)	7 (7.2%)	10 (8.8%)
Grade 1	5 (11.1%)	1 (1.9%)	6 (6.2%)	9 (7.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Hyperhidrosis	0	3 (5.8%)	3 (3.1%)	3 (2.6%)
Grade 1	0	3 (5.8%)	3 (3.1%)	3 (2.6%)
Cold sweat	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Apocrine and eccrine gland disorders (cont)				
Cold sweat (cont)				
Grade 1	0	0	0	0
Pruritus NEC	0	3 (9.4%)	3 (5.9%)	3 (5.4%)
Grade 1	0	3 (9.4%)	3 (5.9%)	3 (5.4%)
Grade 2	0	0	0	0
Pruritus	0	3 (9.4%)	3 (5.9%)	3 (5.4%)
Grade 1	0	3 (9.4%)	3 (5.9%)	3 (5.4%)
Grade 2	0	0	0	0
Pruritus generalised	0	0	0	0
Grade 1	0	0	0	0
Purpura and related conditions	1 (5.3%)	0	1 (2.0%)	2 (3.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Apocrine and eccrine gland disorders (cont)				
Cold sweat (cont)				
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Pruritus NEC	2 (4.4%)	5 (9.6%)	7 (7.2%)	9 (7.9%)
Grade 1	0	4 (7.7%)	4 (4.1%)	6 (5.3%)
Grade 2	2 (4.4%)	1 (1.9%)	3 (3.1%)	3 (2.6%)
Pruritus	2 (4.4%)	5 (9.6%)	7 (7.2%)	8 (7.0%)
Grade 1	0	4 (7.7%)	4 (4.1%)	5 (4.4%)
Grade 2	2 (4.4%)	1 (1.9%)	3 (3.1%)	3 (2.6%)
Pruritus generalised	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)
Purpura and related conditions	2 (4.4%)	1 (1.9%)	3 (3.1%)	5 (4.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Purpura and related conditions (cont)				
(cont)				
Grade 1	1 (5.3%)	0	1 (2.0%)	2 (3.6%)
Grade 2	0	0	0	0
Ecchymosis	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Petechiae	1 (5.3%)	0	1 (2.0%)	2 (3.6%)
Grade 1	1 (5.3%)	0	1 (2.0%)	2 (3.6%)
Purpura	0	0	0	0
Grade 1	0	0	0	0
Dermal and epidermal conditions NEC	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Purpura and related conditions (cont)				
(cont)				
Grade 1	1 (2.2%)	1 (1.9%)	2 (2.1%)	4 (3.5%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Ecchymosis	1 (2.2%)	1 (1.9%)	2 (2.1%)	3 (2.6%)
Grade 1	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Petechiae	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)
Purpura	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Dermal and epidermal conditions NEC	3 (6.7%)	0	3 (3.1%)	4 (3.5%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Dermal and epidermal conditions NEC (cont)				
(cont)				
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Dermatosis	0	0	0	0
Grade 2	0	0	0	0
Papule	0	0	0	0
Grade 1	0	0	0	0
Skin disorder	0	0	0	0
Grade 1	0	0	0	0
Skin fragility	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Dermal and epidermal conditions NEC (cont)				
(cont)				
Grade 1	2 (4.4%)	0	2 (2.1%)	2 (1.8%)
Grade 2	1 (2.2%)	0	1 (1.0%)	2 (1.8%)
Dermatosis	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Papule	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Skin disorder	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Skin fragility	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Dermal and epidermal conditions NEC (cont)				
Skin lesion	0	0	0	0
Grade 2	0	0	0	0
Dermatitis and eczema	1 (5.3%)	0	1 (2.0%)	2 (3.6%)
Grade 1	1 (5.3%)	0	1 (2.0%)	2 (3.6%)
Grade 3	0	0	0	0
Dermatitis contact	0	0	0	1 (1.8%)
Grade 1	0	0	0	1 (1.8%)
Dermatitis	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Dermatitis allergic	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Dermal and epidermal conditions NEC (cont)				
Skin lesion	0	0	0	1 (0.9%)
Grade 2	0	0	0	1 (0.9%)
Dermatitis and eczema	1 (2.2%)	0	1 (1.0%)	2 (1.8%)
Grade 1	0	0	0	1 (0.9%)
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Dermatitis contact	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)
Dermatitis	0	0	0	0
Grade 1	0	0	0	0
Dermatitis allergic	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Erythemas	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	0	0	0
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Erythema	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	0	0	0
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Alopecias	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Alopecia	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Bullous conditions	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Erythemas	1 (2.2%)	0	1 (1.0%)	2 (1.8%)
Grade 1	0	0	0	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Erythema	1 (2.2%)	0	1 (1.0%)	2 (1.8%)
Grade 1	0	0	0	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Alopecias	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)
Alopecia	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)
Bullous conditions	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Bullous conditions (cont)				
(cont)				
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Blister	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	0	0	0
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Blood blister	0	0	0	0
Grade 1	0	0	0	0
Dermatitis ascribed to specific agent	0	0	0	0
Grade 3	0	0	0	0
Drug eruption	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Bullous conditions (cont)				
(cont)				
Grade 2	0	0	0	0
Blister	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)
Grade 2	0	0	0	0
Blood blister	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)
Dermatitis ascribed to specific agent	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)
Grade 3	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)
Drug eruption	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Dermatitis ascribed to specific agent (cont)				
Toxic skin eruption	0	0	0	0
Grade 3	0	0	0	0
Hyperkeratoses	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Hyperkeratosis	0	0	0	0
Grade 2	0	0	0	0
Lichenoid keratosis	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Dermatitis ascribed to specific agent (cont)				
Toxic skin eruption	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Hyperkeratoses	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	0	0	1 (0.9%)
Hyperkeratosis	0	0	0	1 (0.9%)
Grade 2	0	0	0	1 (0.9%)
Lichenoid keratosis	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Nail and nail bed conditions (excl infections and infestations)	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Ingrowing nail	0	0	0	0
Grade 2	0	0	0	0
Nail discolouration	0	0	0	0
Grade 1	0	0	0	0
Skin preneoplastic conditions NEC	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 2	0	0	0	0
Actinic keratosis	1 (5.3%)	0	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Nail and nail bed conditions (excl infections and infestations)	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	0	0	1 (0.9%)
Ingrowing nail	0	0	0	1 (0.9%)
Grade 2	0	0	0	1 (0.9%)
Nail discolouration	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Skin preneoplastic conditions NEC	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	0	0	0	0
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Actinic keratosis	1 (2.2%)	0	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Skin preneoplastic conditions NEC (cont)				
Actinic keratosis (cont)				
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 2	0	0	0	0
Exfoliative conditions	0	0	0	0
Grade 1	0	0	0	0
Skin exfoliation	0	0	0	0
Grade 1	0	0	0	0
Skin cysts and polyps	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Dermal cyst	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Skin preneoplastic conditions NEC (cont)				
Actinic keratosis (cont)				
Grade 1	0	0	0	0
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Exfoliative conditions	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Skin exfoliation	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Skin cysts and polyps	0	0	0	0
Grade 1	0	0	0	0
Dermal cyst	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Skin haemorrhages	0	0	0	0
Grade 2	0	0	0	0
Skin haemorrhage	0	0	0	0
Grade 2	0	0	0	0
Skin vasculitides	0	0	0	0
Grade 2	0	0	0	0
Hypersensitivity vasculitis	0	0	0	0
Grade 2	0	0	0	0
Telangiectasia and related conditions	0	0	0	0
Grade 1	0	0	0	0
Telangiectasia	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Skin haemorrhages	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Skin haemorrhage	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Skin vasculitides	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Hypersensitivity vasculitis	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Telangiectasia and related conditions	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)
Telangiectasia	0	0	0	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Telangiectasia and related conditions (cont)				
Telangiectasia (cont)				
Grade 1	0	0	0	0
Musculoskeletal and connective tissue disorders	6 (31.6%)	14 (43.8%)	20 (39.2%)	24 (42.9%)
Grade 1	1 (5.3%)	9 (28.1%)	10 (19.6%)	11 (19.6%)
Grade 2	5 (26.3%)	3 (9.4%)	8 (15.7%)	11 (19.6%)
Grade 3	0	2 (6.3%)	2 (3.9%)	2 (3.6%)
Musculoskeletal and connective tissue pain and discomfort	4 (21.1%)	9 (28.1%)	13 (25.5%)	17 (30.4%)
Grade 1	1 (5.3%)	6 (18.8%)	7 (13.7%)	10 (17.9%)
Grade 2	3 (15.8%)	3 (9.4%)	6 (11.8%)	7 (12.5%)
Grade 3	0	0	0	0
Pain in extremity	2 (10.5%)	4 (12.5%)	6 (11.8%)	11 (19.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Telangiectasia and related conditions (cont)				
Telangiectasia (cont)				
Grade 1	0	0	0	1 (0.9%)
Musculoskeletal and connective tissue disorders	10 (22.2%)	16 (30.8%)	26 (26.8%)	37 (32.5%)
Grade 1	3 (6.7%)	2 (3.8%)	5 (5.2%)	13 (11.4%)
Grade 2	7 (15.6%)	13 (25.0%)	20 (20.6%)	22 (19.3%)
Grade 3	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Musculoskeletal and connective tissue pain and discomfort	8 (17.8%)	10 (19.2%)	18 (18.6%)	25 (21.9%)
Grade 1	3 (6.7%)	2 (3.8%)	5 (5.2%)	10 (8.8%)
Grade 2	5 (11.1%)	8 (15.4%)	13 (13.4%)	14 (12.3%)
Grade 3	0	0	0	1 (0.9%)
Pain in extremity	5 (11.1%)	2 (3.8%)	7 (7.2%)	10 (8.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Musculoskeletal and connective tissue pain and discomfort (cont)				
Pain in extremity (cont)				
Grade 1	0	4 (12.5%)	4 (7.8%)	8 (14.3%)
Grade 2	2 (10.5%)	0	2 (3.9%)	3 (5.4%)
Back pain	1 (5.3%)	5 (15.6%)	6 (11.8%)	7 (12.5%)
Grade 1	1 (5.3%)	2 (6.3%)	3 (5.9%)	4 (7.1%)
Grade 2	0	3 (9.4%)	3 (5.9%)	3 (5.4%)
Grade 3	0	0	0	0
Musculoskeletal pain	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	1 (5.3%)	0	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Musculoskeletal and connective tissue pain and discomfort (cont)				
Pain in extremity (cont)				
Grade 1	1 (2.2%)	0	1 (1.0%)	3 (2.6%)
Grade 2	4 (8.9%)	2 (3.8%)	6 (6.2%)	7 (6.1%)
Back pain	3 (6.7%)	6 (11.5%)	9 (9.3%)	13 (11.4%)
Grade 1	2 (4.4%)	2 (3.8%)	4 (4.1%)	7 (6.1%)
Grade 2	1 (2.2%)	4 (7.7%)	5 (5.2%)	5 (4.4%)
Grade 3	0	0	0	1 (0.9%)
Musculoskeletal pain	0	1 (1.9%)	1 (1.0%)	3 (2.6%)
Grade 1	0	0	0	2 (1.8%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Musculoskeletal and connective tissue pain and discomfort (cont)				
Flank pain	0	0	0	0
Grade 1	0	0	0	0
Musculoskeletal chest pain	0	0	0	0
Grade 1	0	0	0	0
Neck pain	0	0	0	0
Grade 2	0	0	0	0
Bone related signs and symptoms	2 (10.5%)	2 (6.3%)	4 (7.8%)	4 (7.1%)
Grade 1	0	2 (6.3%)	2 (3.9%)	2 (3.6%)
Grade 2	2 (10.5%)	0	2 (3.9%)	2 (3.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Musculoskeletal and connective tissue pain and discomfort (cont)				
Flank pain	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)
Musculoskeletal chest pain	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)
Neck pain	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Bone related signs and symptoms	2 (4.4%)	2 (3.8%)	4 (4.1%)	8 (7.0%)
Grade 1	2 (4.4%)	0	2 (2.1%)	5 (4.4%)
Grade 2	0	2 (3.8%)	2 (2.1%)	3 (2.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Bone related signs and symptoms (cont)				
Bone pain	2 (10.5%)	1 (3.1%)	3 (5.9%)	3 (5.4%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	2 (10.5%)	0	2 (3.9%)	2 (3.6%)
Pain in jaw	0	0	0	0
Grade 1	0	0	0	0
Spinal pain	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	0	0	0
Joint related signs and symptoms	2 (10.5%)	2 (6.3%)	4 (7.8%)	5 (8.9%)
Grade 1	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 2	1 (5.3%)	1 (3.1%)	2 (3.9%)	3 (5.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Bone related signs and symptoms (cont)				
Bone pain	1 (2.2%)	2 (3.8%)	3 (3.1%)	5 (4.4%)
Grade 1	1 (2.2%)	0	1 (1.0%)	3 (2.6%)
Grade 2	0	2 (3.8%)	2 (2.1%)	2 (1.8%)
Pain in jaw	1 (2.2%)	0	1 (1.0%)	2 (1.8%)
Grade 1	1 (2.2%)	0	1 (1.0%)	2 (1.8%)
Spinal pain	0	0	0	1 (0.9%)
Grade 1	0	0	0	0
Grade 2	0	0	0	1 (0.9%)
Joint related signs and symptoms	2 (4.4%)	2 (3.8%)	4 (4.1%)	5 (4.4%)
Grade 1	0	0	0	1 (0.9%)
Grade 2	2 (4.4%)	2 (3.8%)	4 (4.1%)	4 (3.5%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Joint related signs and symptoms (cont)				
Arthralgia	2 (10.5%)	2 (6.3%)	4 (7.8%)	5 (8.9%)
Grade 1	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 2	1 (5.3%)	1 (3.1%)	2 (3.9%)	3 (5.4%)
Joint effusion	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Joint swelling	0	0	0	0
Grade 2	0	0	0	0
Muscle related signs and symptoms NEC	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	1 (3.1%)	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Joint related signs and symptoms (cont)				
Arthralgia	2 (4.4%)	2 (3.8%)	4 (4.1%)	5 (4.4%)
Grade 1	0	0	0	1 (0.9%)
Grade 2	2 (4.4%)	2 (3.8%)	4 (4.1%)	4 (3.5%)
Joint effusion	0	0	0	0
Grade 2	0	0	0	0
Joint swelling	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Muscle related signs and symptoms NEC	0	2 (3.8%)	2 (2.1%)	4 (3.5%)
Grade 1	0	1 (1.9%)	1 (1.0%)	3 (2.6%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Muscle related signs and symptoms NEC (cont)				
Muscle spasms	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Muscle haemorrhage	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 3	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Arthropathies NEC	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Arthritis	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Muscle related signs and symptoms NEC (cont)				
Muscle spasms	0	2 (3.8%)	2 (2.1%)	4 (3.5%)
Grade 1	0	1 (1.9%)	1 (1.0%)	3 (2.6%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Muscle haemorrhage	0	0	0	0
Grade 3	0	0	0	0
Arthropathies NEC	2 (4.4%)	1 (1.9%)	3 (3.1%)	3 (2.6%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Arthritis	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Arthropathies NEC (cont)				
Arthritis (cont)				
Grade 3	0	0	0	0
Arthritis reactive	0	0	0	0
Grade 2	0	0	0	0
Muscle pains	1 (5.3%)	0	1 (2.0%)	2 (3.6%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 2	0	0	0	1 (1.8%)
Myalgia	1 (5.3%)	0	1 (2.0%)	2 (3.6%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 2	0	0	0	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Arthropathies NEC (cont)				
Arthritis (cont)				
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Arthritis reactive	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Muscle pains	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	0	0	0
Myalgia	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Muscle weakness conditions	0	0	0	0
Grade 2	0	0	0	0
Muscular weakness	0	0	0	0
Grade 2	0	0	0	0
Bone disorders NEC	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Bone lesion	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Osteosclerosis	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Muscle weakness conditions	2 (4.4%)	1 (1.9%)	3 (3.1%)	3 (2.6%)
Grade 2	2 (4.4%)	1 (1.9%)	3 (3.1%)	3 (2.6%)
Muscular weakness	2 (4.4%)	1 (1.9%)	3 (3.1%)	3 (2.6%)
Grade 2	2 (4.4%)	1 (1.9%)	3 (3.1%)	3 (2.6%)
Bone disorders NEC	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Bone lesion	0	0	0	0
Grade 1	0	0	0	0
Osteosclerosis	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Musculoskeletal and connective tissue conditions NEC	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	0	0	0
Mobility decreased	0	0	0	0
Grade 2	0	0	0	0
Musculoskeletal stiffness	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Osteoarthropathies	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	0	0	0
Grade 3	0	1 (3.1%)	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Musculoskeletal and connective tissue conditions NEC	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	0	0	0	0
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Mobility decreased	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Musculoskeletal stiffness	0	0	0	0
Grade 1	0	0	0	0
Osteoarthropathies	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Osteoarthropathies (cont)				
Osteoarthritis	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	0	0	0
Grade 3	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Soft tissue disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Groin pain	0	0	0	0
Grade 1	0	0	0	0
Bursal disorders	0	0	0	0
Grade 1	0	0	0	0
Bursal fluid accumulation	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Osteoarthropathies (cont)				
Osteoarthritis	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 3	0	0	0	0
Soft tissue disorders NEC	0	0	0	2 (1.8%)
Grade 1	0	0	0	2 (1.8%)
Groin pain	0	0	0	2 (1.8%)
Grade 1	0	0	0	2 (1.8%)
Bursal disorders	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)
Bursal fluid accumulation	0	0	0	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Bursal disorders (cont)				
Bursal fluid accumulation (cont)				
Grade 1	0	0	0	0
Cartilage disorders	0	0	0	0
Grade 2	0	0	0	0
Costochondritis	0	0	0	0
Grade 2	0	0	0	0
Crystal arthropathic disorders	0	0	0	0
Grade 2	0	0	0	0
Chondrocalcinosis pyrophosphate	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Bursal disorders (cont)				
Bursal fluid accumulation (cont)				
Grade 1	0	0	0	1 (0.9%)
Cartilage disorders	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Costochondritis	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Crystal arthropathic disorders	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Chondrocalcinosis pyrophosphate	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Crystal arthropathic disorders (cont)				
Gouty arthritis	0	0	0	0
Grade 2	0	0	0	0
Intervertebral disc disorders NEC	0	0	0	0
Grade 2	0	0	0	0
Intervertebral disc protrusion	0	0	0	0
Grade 2	0	0	0	0
Joint related disorders NEC	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Rotator cuff syndrome	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Crystal arthropathic disorders (cont)				
Gouty arthritis	0	0	0	1 (0.9%)
Grade 2	0	0	0	1 (0.9%)
Intervertebral disc disorders NEC	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Intervertebral disc protrusion	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Joint related disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Rotator cuff syndrome	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Metabolic bone disorders	0	0	0	0
Grade 2	0	0	0	0
Osteoporosis	0	0	0	0
Grade 2	0	0	0	0
Musculoskeletal and connective tissue infections and inflammations NEC	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Fasciitis	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Tendon disorders	0	0	0	1 (1.8%)
Grade 2	0	0	0	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Metabolic bone disorders	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Osteoporosis	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Musculoskeletal and connective tissue infections and inflammations NEC	0	0	0	0
Grade 1	0	0	0	0
Fasciitis	0	0	0	0
Grade 1	0	0	0	0
Tendon disorders	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Tendon disorders (cont)				
Tendonitis	0	0	0	1 (1.8%)
Grade 2	0	0	0	1 (1.8%)
Investigations	6 (31.6%)	3 (9.4%)	9 (17.6%)	12 (21.4%)
Grade 1	2 (10.5%)	0	2 (3.9%)	4 (7.1%)
Grade 2	1 (5.3%)	3 (9.4%)	4 (7.8%)	5 (8.9%)
Grade 3	2 (10.5%)	0	2 (3.9%)	2 (3.6%)
Grade 4	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Liver function analyses	2 (10.5%)	1 (3.1%)	3 (5.9%)	6 (10.7%)
Grade 1	0	0	0	2 (3.6%)
Grade 2	1 (5.3%)	1 (3.1%)	2 (3.9%)	3 (5.4%)
Grade 3	1 (5.3%)	0	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Tendon disorders (cont)				
Tendonitis	0	0	0	0
Grade 2	0	0	0	0
Investigations	11 (24.4%)	15 (28.8%)	26 (26.8%)	37 (32.5%)
Grade 1	2 (4.4%)	8 (15.4%)	10 (10.3%)	13 (11.4%)
Grade 2	7 (15.6%)	7 (13.5%)	14 (14.4%)	17 (14.9%)
Grade 3	2 (4.4%)	0	2 (2.1%)	6 (5.3%)
Grade 4	0	0	0	1 (0.9%)
Liver function analyses	3 (6.7%)	7 (13.5%)	10 (10.3%)	17 (14.9%)
Grade 1	1 (2.2%)	2 (3.8%)	3 (3.1%)	5 (4.4%)
Grade 2	1 (2.2%)	5 (9.6%)	6 (6.2%)	7 (6.1%)
Grade 3	1 (2.2%)	0	1 (1.0%)	5 (4.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Liver function analyses (cont)				
Alanine aminotransferase increased	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 1	0	0	0	0
Grade 2	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 3	0	0	0	0
Gamma-glutamyltransferase increased	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Aspartate aminotransferase increased	0	1 (3.1%)	1 (2.0%)	2 (3.6%)
Grade 1	0	1 (3.1%)	1 (2.0%)	2 (3.6%)
Grade 3	0	0	0	0
Blood bilirubin increased	0	0	0	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Liver function analyses (cont)				
Alanine aminotransferase increased	2 (4.4%)	3 (5.8%)	5 (5.2%)	11 (9.6%)
Grade 1	2 (4.4%)	3 (5.8%)	5 (5.2%)	7 (6.1%)
Grade 2	0	0	0	1 (0.9%)
Grade 3	0	0	0	3 (2.6%)
Gamma-glutamyltransferase increased	1 (2.2%)	4 (7.7%)	5 (5.2%)	9 (7.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	3 (2.6%)
Grade 2	1 (2.2%)	3 (5.8%)	4 (4.1%)	5 (4.4%)
Grade 3	0	0	0	1 (0.9%)
Aspartate aminotransferase increased	1 (2.2%)	2 (3.8%)	3 (3.1%)	5 (4.4%)
Grade 1	1 (2.2%)	2 (3.8%)	3 (3.1%)	4 (3.5%)
Grade 3	0	0	0	1 (0.9%)
Blood bilirubin increased	1 (2.2%)	2 (3.8%)	3 (3.1%)	3 (2.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Liver function analyses (cont)				
Blood bilirubin increased (cont)				
Grade 2	0	0	0	1 (1.8%)
Grade 3	0	0	0	0
Transaminases increased	0	0	0	1 (1.8%)
Grade 1	0	0	0	1 (1.8%)
Liver function test abnormal	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 3	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Renal function analyses	2 (10.5%)	1 (3.1%)	3 (5.9%)	3 (5.4%)
Grade 1	2 (10.5%)	0	2 (3.9%)	2 (3.6%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Blood creatinine increased	2 (10.5%)	1 (3.1%)	3 (5.9%)	3 (5.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Liver function analyses (cont)				
Blood bilirubin increased (cont)				
Grade 2	0	2 (3.8%)	2 (2.1%)	2 (1.8%)
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Transaminases increased	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Liver function test abnormal	0	0	0	0
Grade 3	0	0	0	0
Renal function analyses	6 (13.3%)	5 (9.6%)	11 (11.3%)	13 (11.4%)
Grade 1	2 (4.4%)	3 (5.8%)	5 (5.2%)	6 (5.3%)
Grade 2	4 (8.9%)	2 (3.8%)	6 (6.2%)	7 (6.1%)
Blood creatinine increased	4 (8.9%)	4 (7.7%)	8 (8.2%)	9 (7.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Renal function analyses (cont)				
Blood creatinine increased (cont)				
Grade 1	2 (10.5%)	0	2 (3.9%)	2 (3.6%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Creatinine renal clearance decreased	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Physical examination procedures and organ system status	2 (10.5%)	0	2 (3.9%)	4 (7.1%)
Grade 1	1 (5.3%)	0	1 (2.0%)	3 (5.4%)
Grade 2	0	0	0	0
Grade 3	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Weight decreased	2 (10.5%)	0	2 (3.9%)	2 (3.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Renal function analyses (cont)				
Blood creatinine increased (cont)				
Grade 1	2 (4.4%)	2 (3.8%)	4 (4.1%)	5 (4.4%)
Grade 2	2 (4.4%)	2 (3.8%)	4 (4.1%)	4 (3.5%)
Creatinine renal clearance decreased	2 (4.4%)	1 (1.9%)	3 (3.1%)	4 (3.5%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	2 (4.4%)	0	2 (2.1%)	3 (2.6%)
Physical examination procedures and organ system status	2 (4.4%)	2 (3.8%)	4 (4.1%)	7 (6.1%)
Grade 1	0	2 (3.8%)	2 (2.1%)	5 (4.4%)
Grade 2	2 (4.4%)	0	2 (2.1%)	2 (1.8%)
Grade 3	0	0	0	0
Weight decreased	1 (2.2%)	1 (1.9%)	2 (2.1%)	4 (3.5%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Physical examination procedures and organ system status (cont)				
Weight decreased (cont)				
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 2	0	0	0	0
Grade 3	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Weight increased	0	0	0	2 (3.6%)
Grade 1	0	0	0	2 (3.6%)
Grade 2	0	0	0	0
Lymph node palpable	0	0	0	0
Grade 1	0	0	0	0
Coagulation and bleeding analyses	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Physical examination procedures and organ system status (cont)				
Weight decreased (cont)				
Grade 1	0	1 (1.9%)	1 (1.0%)	3 (2.6%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 3	0	0	0	0
Weight increased	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Lymph node palpable	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)
Coagulation and bleeding analyses	0	3 (5.8%)	3 (3.1%)	3 (2.6%)
Grade 1	0	3 (5.8%)	3 (3.1%)	3 (2.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Coagulation and bleeding analyses (cont)				
Activated partial thromboplastin time prolonged	0	0	0	0
Grade 1	0	0	0	0
International normalised ratio increased	0	0	0	0
Grade 1	0	0	0	0
Prothrombin time prolonged	0	0	0	0
Grade 1	0	0	0	0
ECG investigations	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	0	0	0	0
Grade 4	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Electrocardiogram QT prolonged	1 (5.3%)	0	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Coagulation and bleeding analyses (cont)				
Activated partial thromboplastin time prolonged	0	2 (3.8%)	2 (2.1%)	2 (1.8%)
Grade 1	0	2 (3.8%)	2 (2.1%)	2 (1.8%)
International normalised ratio increased	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Prothrombin time prolonged	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
ECG investigations	0	0	0	2 (1.8%)
Grade 1	0	0	0	1 (0.9%)
Grade 4	0	0	0	1 (0.9%)
Electrocardiogram QT prolonged	0	0	0	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
ECG investigations (cont)				
Electrocardiogram QT prolonged (cont)				
Grade 4	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Electrocardiogram ST segment depression	0	0	0	0
Grade 1	0	0	0	0
Mineral and electrolyte analyses	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Blood bicarbonate decreased	0	0	0	0
Grade 2	0	0	0	0
Blood chloride increased	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
ECG investigations (cont)				
Electrocardiogram QT prolonged (cont)				
Grade 4	0	0	0	1 (0.9%)
Electrocardiogram ST segment depression	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)
Mineral and electrolyte analyses	0	0	0	1 (0.9%)
Grade 1	0	0	0	0
Grade 2	0	0	0	1 (0.9%)
Blood bicarbonate decreased	0	0	0	1 (0.9%)
Grade 2	0	0	0	1 (0.9%)
Blood chloride increased	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Mineral and electrolyte analyses (cont)				
Serum ferritin increased	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Tissue enzyme analyses NEC	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Blood alkaline phosphatase increased	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Blood lactate dehydrogenase increased	0	0	0	0
Grade 1	0	0	0	0
Protein analyses NEC	1 (5.3%)	0	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Mineral and electrolyte analyses (cont)				
Serum ferritin increased	0	0	0	0
Grade 2	0	0	0	0
Tissue enzyme analyses NEC	0	1 (1.9%)	1 (1.0%)	3 (2.6%)
Grade 1	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Grade 2	0	0	0	1 (0.9%)
Blood alkaline phosphatase increased	0	0	0	2 (1.8%)
Grade 1	0	0	0	1 (0.9%)
Grade 2	0	0	0	1 (0.9%)
Blood lactate dehydrogenase increased	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Protein analyses NEC	0	0	0	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Protein analyses NEC (cont)				
(cont)				
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Protein total increased	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Vitamin analyses	0	0	0	0
Grade 2	0	0	0	0
Blood folate decreased	0	0	0	0
Grade 2	0	0	0	0
Vitamin B1 decreased	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Protein analyses NEC (cont)				
(cont)				
Grade 1	0	0	0	1 (0.9%)
Protein total increased	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)
Vitamin analyses	2 (4.4%)	0	2 (2.1%)	2 (1.8%)
Grade 2	2 (4.4%)	0	2 (2.1%)	2 (1.8%)
Blood folate decreased	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Vitamin B1 decreased	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Autoimmunity analyses	0	0	0	0
Grade 2	0	0	0	0
Antiphospholipid antibodies positive	0	0	0	0
Grade 2	0	0	0	0
Blood gas and acid base analyses	0	0	0	1 (1.8%)
Grade 1	0	0	0	1 (1.8%)
Blood lactic acid increased	0	0	0	1 (1.8%)
Grade 1	0	0	0	1 (1.8%)
Haematological analyses NEC	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Blast cell count increased	1 (5.3%)	0	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Autoimmunity analyses	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Antiphospholipid antibodies positive	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Blood gas and acid base analyses	0	0	0	0
Grade 1	0	0	0	0
Blood lactic acid increased	0	0	0	0
Grade 1	0	0	0	0
Haematological analyses NEC	0	0	0	0
Grade 1	0	0	0	0
Blast cell count increased	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Haematological analyses NEC (cont)				
Blast cell count increased (cont)				
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Reproductive organ and breast imaging procedures	0	0	0	0
Grade 1	0	0	0	0
Computerised tomogram pelvis abnormal	0	0	0	0
Grade 1	0	0	0	0
Respiratory tract and thoracic imaging procedures	0	0	0	0
Grade 1	0	0	0	0
Chest X-ray abnormal	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Haematological analyses NEC (cont)				
Blast cell count increased (cont)				
Grade 1	0	0	0	0
Reproductive organ and breast imaging procedures	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Computerised tomogram pelvis abnormal	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Respiratory tract and thoracic imaging procedures	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Chest X-ray abnormal	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Respiratory tract and thoracic imaging procedures (cont)				
Chest X-ray abnormal (cont)				
Grade 1	0	0	0	0
Skeletal and cardiac muscle analyses	0	0	0	0
Grade 1	0	0	0	0
Blood creatine phosphokinase increased	0	0	0	0
Grade 1	0	0	0	0
Vascular tests NEC (incl blood pressure)	0	0	0	0
Grade 3	0	0	0	0
Blood pressure increased	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Respiratory tract and thoracic imaging procedures (cont)				
Chest X-ray abnormal (cont)				
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Skeletal and cardiac muscle analyses	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Blood creatine phosphokinase increased	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Vascular tests NEC (incl blood pressure)	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Blood pressure increased	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders	6 (31.6%)	2 (6.3%)	8 (15.7%)	10 (17.9%)
Grade 1	3 (15.8%)	1 (3.1%)	4 (7.8%)	5 (8.9%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 3	2 (10.5%)	0	2 (3.9%)	2 (3.6%)
Grade 4	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 5	0	0	0	1 (1.8%)
Renal failure and impairment	3 (15.8%)	1 (3.1%)	4 (7.8%)	5 (8.9%)
Grade 1	2 (10.5%)	0	2 (3.9%)	2 (3.6%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 3	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 4	0	0	0	0
Grade 5	0	0	0	1 (1.8%)
Acute kidney injury	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	0	0	0
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders	11 (24.4%)	14 (26.9%)	25 (25.8%)	34 (29.8%)
Grade 1	4 (8.9%)	2 (3.8%)	6 (6.2%)	11 (9.6%)
Grade 2	5 (11.1%)	5 (9.6%)	10 (10.3%)	11 (9.6%)
Grade 3	1 (2.2%)	6 (11.5%)	7 (7.2%)	9 (7.9%)
Grade 4	0	0	0	1 (0.9%)
Grade 5	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)
Renal failure and impairment	7 (15.6%)	7 (13.5%)	14 (14.4%)	18 (15.8%)
Grade 1	2 (4.4%)	0	2 (2.1%)	4 (3.5%)
Grade 2	3 (6.7%)	3 (5.8%)	6 (6.2%)	6 (5.3%)
Grade 3	1 (2.2%)	3 (5.8%)	4 (4.1%)	5 (4.4%)
Grade 4	0	0	0	1 (0.9%)
Grade 5	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)
Acute kidney injury	3 (6.7%)	2 (3.8%)	5 (5.2%)	7 (6.1%)
Grade 1	2 (4.4%)	0	2 (2.1%)	4 (3.5%)
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal failure and impairment (cont)				
Acute kidney injury (cont)				
Grade 3	0	0	0	0
Grade 5	0	0	0	0
Chronic kidney disease	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 2	0	0	0	0
Grade 3	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 4	0	0	0	0
Grade 5	0	0	0	0
Renal failure	0	0	0	1 (1.8%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Grade 5	0	0	0	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal failure and impairment (cont)				
Acute kidney injury (cont)				
Grade 3	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)
Grade 5	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Chronic kidney disease	2 (4.4%)	2 (3.8%)	4 (4.1%)	5 (4.4%)
Grade 2	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 4	0	0	0	1 (0.9%)
Grade 5	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Renal failure	1 (2.2%)	3 (5.8%)	4 (4.1%)	4 (3.5%)
Grade 2	1 (2.2%)	2 (3.8%)	3 (3.1%)	3 (2.6%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 5	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal failure and impairment (cont)				
Renal impairment	2 (10.5%)	0	2 (3.9%)	2 (3.6%)
Grade 1	2 (10.5%)	0	2 (3.9%)	2 (3.6%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Bladder and urethral symptoms	0	0	0	1 (1.8%)
Grade 1	0	0	0	1 (1.8%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Dysuria	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Pollakiuria	0	0	0	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal failure and impairment (cont)				
Renal impairment	1 (2.2%)	0	1 (1.0%)	3 (2.6%)
Grade 1	0	0	0	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 3	0	0	0	1 (0.9%)
Bladder and urethral symptoms	1 (2.2%)	2 (3.8%)	3 (3.1%)	7 (6.1%)
Grade 1	0	2 (3.8%)	2 (2.1%)	3 (2.6%)
Grade 2	1 (2.2%)	0	1 (1.0%)	3 (2.6%)
Grade 3	0	0	0	1 (0.9%)
Dysuria	1 (2.2%)	1 (1.9%)	2 (2.1%)	4 (3.5%)
Grade 1	0	1 (1.9%)	1 (1.0%)	3 (2.6%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Pollakiuria	0	0	0	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Bladder and urethral symptoms (cont)				
Pollakiuria (cont)				
Grade 1	0	0	0	1 (1.8%)
Grade 3	0	0	0	0
Micturition disorder	0	0	0	0
Grade 1	0	0	0	0
Urinary incontinence	0	0	0	0
Grade 2	0	0	0	0
Urinary retention	0	0	0	0
Grade 2	0	0	0	0
Urinary abnormalities	2 (10.5%)	0	2 (3.9%)	2 (3.6%)
Grade 1	2 (10.5%)	0	2 (3.9%)	2 (3.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Bladder and urethral symptoms (cont)				
Pollakiuria (cont)				
Grade 1	0	0	0	0
Grade 3	0	0	0	1 (0.9%)
Micturition disorder	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Urinary incontinence	0	0	0	1 (0.9%)
Grade 2	0	0	0	1 (0.9%)
Urinary retention	0	0	0	1 (0.9%)
Grade 2	0	0	0	1 (0.9%)
Urinary abnormalities	1 (2.2%)	2 (3.8%)	3 (3.1%)	4 (3.5%)
Grade 1	0	0	0	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Urinary abnormalities (cont)				
(cont)				
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Haematuria	2 (10.5%)	0	2 (3.9%)	2 (3.6%)
Grade 1	2 (10.5%)	0	2 (3.9%)	2 (3.6%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Chromaturia	0	0	0	0
Grade 1	0	0	0	0
Proteinuria	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Urinary abnormalities (cont)				
(cont)				
Grade 2	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Haematuria	0	2 (3.8%)	2 (2.1%)	3 (2.6%)
Grade 1	0	0	0	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Chromaturia	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)
Proteinuria	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Urinary tract signs and symptoms NEC	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Nocturia	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Renal colic	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Renal lithiasis	0	0	0	0
Grade 1	0	0	0	0
Nephrolithiasis	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Urinary tract signs and symptoms NEC	1 (2.2%)	2 (3.8%)	3 (3.1%)	5 (4.4%)
Grade 1	1 (2.2%)	0	1 (1.0%)	3 (2.6%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Nocturia	1 (2.2%)	0	1 (1.0%)	3 (2.6%)
Grade 1	1 (2.2%)	0	1 (1.0%)	3 (2.6%)
Renal colic	0	2 (3.8%)	2 (2.1%)	2 (1.8%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Renal lithiasis	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Grade 1	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Nephrolithiasis	0	1 (1.9%)	1 (1.0%)	2 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal lithiasis (cont)				
Nephrolithiasis (cont)				
Grade 1	0	0	0	0
Nephropathies and tubular disorders NEC	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 4	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Nephropathy	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 4	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Renal disorders NEC	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 3	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Renal disorder	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 3	1 (5.3%)	0	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal lithiasis (cont)				
Nephrolithiasis (cont)				
Grade 1	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Nephropathies and tubular disorders NEC	0	0	0	0
Grade 4	0	0	0	0
Nephropathy	0	0	0	0
Grade 4	0	0	0	0
Renal disorders NEC	0	0	0	0
Grade 3	0	0	0	0
Renal disorder	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal hypertension and related conditions	0	0	0	0
Grade 3	0	0	0	0
Hypertensive nephropathy	0	0	0	0
Grade 3	0	0	0	0
Renal neoplasms	0	0	0	0
Grade 1	0	0	0	0
Renal cyst	0	0	0	0
Grade 1	0	0	0	0
Renal vascular and ischaemic conditions	0	0	0	0
Grade 2	0	0	0	0
Renal tubular necrosis	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal hypertension and related conditions	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Hypertensive nephropathy	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Renal neoplasms	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Renal cyst	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Renal vascular and ischaemic conditions	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Renal tubular necrosis	1 (2.2%)	0	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal vascular and ischaemic conditions (cont)				
Renal tubular necrosis (cont)				
Grade 2	0	0	0	0
Vascular disorders	4 (21.1%)	4 (12.5%)	8 (15.7%)	12 (21.4%)
Grade 1	1 (5.3%)	1 (3.1%)	2 (3.9%)	4 (7.1%)
Grade 2	2 (10.5%)	2 (6.3%)	4 (7.8%)	6 (10.7%)
Grade 3	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Vascular hypotensive disorders	1 (5.3%)	1 (3.1%)	2 (3.9%)	5 (8.9%)
Grade 1	0	1 (3.1%)	1 (2.0%)	2 (3.6%)
Grade 2	0	0	0	2 (3.6%)
Grade 3	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Hypotension	1 (5.3%)	1 (3.1%)	2 (3.9%)	5 (8.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal vascular and ischaemic conditions (cont)				
Renal tubular necrosis (cont)				
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Vascular disorders	10 (22.2%)	12 (23.1%)	22 (22.7%)	31 (27.2%)
Grade 1	4 (8.9%)	4 (7.7%)	8 (8.2%)	13 (11.4%)
Grade 2	3 (6.7%)	5 (9.6%)	8 (8.2%)	9 (7.9%)
Grade 3	3 (6.7%)	3 (5.8%)	6 (6.2%)	9 (7.9%)
Vascular hypotensive disorders	2 (4.4%)	3 (5.8%)	5 (5.2%)	13 (11.4%)
Grade 1	0	0	0	5 (4.4%)
Grade 2	0	3 (5.8%)	3 (3.1%)	4 (3.5%)
Grade 3	2 (4.4%)	0	2 (2.1%)	4 (3.5%)
Hypotension	2 (4.4%)	2 (3.8%)	4 (4.1%)	12 (10.5%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Vascular hypotensive disorders (cont)				
Hypotension (cont)				
Grade 1	0	1 (3.1%)	1 (2.0%)	2 (3.6%)
Grade 2	0	0	0	2 (3.6%)
Grade 3	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Orthostatic hypotension	0	0	0	0
Grade 2	0	0	0	0
Vascular hypertensive disorders NEC	2 (10.5%)	2 (6.3%)	4 (7.8%)	4 (7.1%)
Grade 1	0	0	0	0
Grade 2	2 (10.5%)	1 (3.1%)	3 (5.9%)	3 (5.4%)
Grade 3	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Hypertension	2 (10.5%)	2 (6.3%)	4 (7.8%)	4 (7.1%)
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Vascular hypotensive disorders (cont)				
Hypotension (cont)				
Grade 1	0	0	0	5 (4.4%)
Grade 2	0	2 (3.8%)	2 (2.1%)	3 (2.6%)
Grade 3	2 (4.4%)	0	2 (2.1%)	4 (3.5%)
Orthostatic hypotension	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Vascular hypertensive disorders NEC	3 (6.7%)	4 (7.7%)	7 (7.2%)	8 (7.0%)
Grade 1	0	2 (3.8%)	2 (2.1%)	2 (1.8%)
Grade 2	2 (4.4%)	0	2 (2.1%)	2 (1.8%)
Grade 3	1 (2.2%)	2 (3.8%)	3 (3.1%)	4 (3.5%)
Hypertension	3 (6.7%)	4 (7.7%)	7 (7.2%)	8 (7.0%)
Grade 1	0	2 (3.8%)	2 (2.1%)	2 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Vascular hypertensive disorders NEC (cont)				
Hypertension (cont)				
Grade 2	2 (10.5%)	1 (3.1%)	3 (5.9%)	3 (5.4%)
Grade 3	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Peripheral vascular disorders NEC	1 (5.3%)	1 (3.1%)	2 (3.9%)	4 (7.1%)
Grade 1	1 (5.3%)	1 (3.1%)	2 (3.9%)	4 (7.1%)
Grade 2	0	0	0	0
Flushing	0	0	0	2 (3.6%)
Grade 1	0	0	0	2 (3.6%)
Grade 2	0	0	0	0
Hot flush	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 1	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Vascular hypertensive disorders NEC (cont)				
Hypertension (cont)				
Grade 2	2 (4.4%)	0	2 (2.1%)	2 (1.8%)
Grade 3	1 (2.2%)	2 (3.8%)	3 (3.1%)	4 (3.5%)
Peripheral vascular disorders NEC	0	1 (1.9%)	1 (1.0%)	4 (3.5%)
Grade 1	0	1 (1.9%)	1 (1.0%)	3 (2.6%)
Grade 2	0	0	0	1 (0.9%)
Flushing	0	1 (1.9%)	1 (1.0%)	3 (2.6%)
Grade 1	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Grade 2	0	0	0	1 (0.9%)
Hot flush	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Haemorrhages NEC	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 1	0	0	0	0
Grade 2	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Haematoma	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 1	0	0	0	0
Grade 2	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Aortic necrosis and vascular insufficiency	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Aortic stenosis	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Haemorrhages NEC	2 (4.4%)	1 (1.9%)	3 (3.1%)	4 (3.5%)
Grade 1	2 (4.4%)	1 (1.9%)	3 (3.1%)	4 (3.5%)
Grade 2	0	0	0	0
Haematoma	2 (4.4%)	1 (1.9%)	3 (3.1%)	4 (3.5%)
Grade 1	2 (4.4%)	1 (1.9%)	3 (3.1%)	4 (3.5%)
Grade 2	0	0	0	0
Aortic necrosis and vascular insufficiency	2 (4.4%)	1 (1.9%)	3 (3.1%)	3 (2.6%)
Grade 1	2 (4.4%)	0	2 (2.1%)	2 (1.8%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Aortic stenosis	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Aortic necrosis and vascular insufficiency (cont)				
Aortic arteriosclerosis	0	0	0	0
Grade 1	0	0	0	0
Non-site specific necrosis and vascular insufficiency NEC	0	0	0	0
Grade 1	0	0	0	0
Arteriosclerosis	0	0	0	0
Grade 1	0	0	0	0
Peripheral embolism and thrombosis	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Aortic necrosis and vascular insufficiency (cont)				
Aortic arteriosclerosis	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Non-site specific necrosis and vascular insufficiency NEC	0	2 (3.8%)	2 (2.1%)	2 (1.8%)
Grade 1	0	2 (3.8%)	2 (2.1%)	2 (1.8%)
Arteriosclerosis	0	2 (3.8%)	2 (2.1%)	2 (1.8%)
Grade 1	0	2 (3.8%)	2 (2.1%)	2 (1.8%)
Peripheral embolism and thrombosis	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Peripheral embolism and thrombosis (cont)				
Deep vein thrombosis	0	0	0	0
Grade 3	0	0	0	0
Thrombophlebitis superficial	0	0	0	0
Grade 2	0	0	0	0
Peripheral vasoconstriction, necrosis and vascular insufficiency	0	0	0	1 (1.8%)
Grade 1	0	0	0	1 (1.8%)
Grade 2	0	0	0	0
Peripheral arterial occlusive disease	0	0	0	1 (1.8%)
Grade 1	0	0	0	1 (1.8%)
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Peripheral embolism and thrombosis (cont)				
Deep vein thrombosis	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Thrombophlebitis superficial	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Peripheral vasoconstriction, necrosis and vascular insufficiency	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	0	0	0
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Peripheral arterial occlusive disease	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	0	0	0
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Non-site specific vascular disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Poor venous access	0	0	0	0
Grade 1	0	0	0	0
Phlebitis NEC	0	0	0	0
Grade 1	0	0	0	0
Phlebitis	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Non-site specific vascular disorders NEC	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)
Poor venous access	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)
Phlebitis NEC	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Phlebitis	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders	2 (10.5%)	6 (18.8%)	8 (15.7%)	8 (14.3%)
Grade 1	2 (10.5%)	1 (3.1%)	3 (5.9%)	2 (3.6%)
Grade 2	0	1 (3.1%)	1 (2.0%)	2 (3.6%)
Grade 3	0	3 (9.4%)	3 (5.9%)	3 (5.4%)
Grade 4	0	0	0	0
Grade 5	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Supraventricular arrhythmias	1 (5.3%)	2 (6.3%)	3 (5.9%)	4 (7.1%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 2	0	1 (3.1%)	1 (2.0%)	2 (3.6%)
Grade 3	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Atrial fibrillation	1 (5.3%)	2 (6.3%)	3 (5.9%)	4 (7.1%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 2	0	1 (3.1%)	1 (2.0%)	2 (3.6%)
Grade 3	0	1 (3.1%)	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders	10 (22.2%)	7 (13.5%)	17 (17.5%)	27 (23.7%)
Grade 1	2 (4.4%)	2 (3.8%)	4 (4.1%)	6 (5.3%)
Grade 2	3 (6.7%)	0	3 (3.1%)	5 (4.4%)
Grade 3	4 (8.9%)	5 (9.6%)	9 (9.3%)	14 (12.3%)
Grade 4	0	0	0	1 (0.9%)
Grade 5	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Supraventricular arrhythmias	7 (15.6%)	3 (5.8%)	10 (10.3%)	15 (13.2%)
Grade 1	2 (4.4%)	0	2 (2.1%)	3 (2.6%)
Grade 2	2 (4.4%)	0	2 (2.1%)	4 (3.5%)
Grade 3	3 (6.7%)	3 (5.8%)	6 (6.2%)	8 (7.0%)
Atrial fibrillation	5 (11.1%)	3 (5.8%)	8 (8.2%)	12 (10.5%)
Grade 1	1 (2.2%)	0	1 (1.0%)	2 (1.8%)
Grade 2	2 (4.4%)	0	2 (2.1%)	3 (2.6%)
Grade 3	2 (4.4%)	3 (5.8%)	5 (5.2%)	7 (6.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Supraventricular arrhythmias (cont)				
Atrial flutter	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Sinus bradycardia	0	0	0	0
Grade 3	0	0	0	0
Supraventricular extrasystoles	0	0	0	0
Grade 1	0	0	0	0
Supraventricular tachycardia	0	0	0	0
Grade 2	0	0	0	0
Heart failures NEC	0	2 (6.3%)	2 (3.9%)	2 (3.6%)
Grade 1	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Supraventricular arrhythmias (cont)				
Atrial flutter	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Sinus bradycardia	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Supraventricular extrasystoles	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Supraventricular tachycardia	0	0	0	1 (0.9%)
Grade 2	0	0	0	1 (0.9%)
Heart failures NEC	3 (6.7%)	1 (1.9%)	4 (4.1%)	7 (6.1%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Heart failures NEC (cont)				
(cont)				
Grade 3	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 5	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Cardiac failure	0	2 (6.3%)	2 (3.9%)	2 (3.6%)
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 5	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Cardiac failure congestive	0	0	0	0
Grade 3	0	0	0	0
Ischaemic coronary artery disorders	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Heart failures NEC (cont)				
(cont)				
Grade 3	2 (4.4%)	0	2 (2.1%)	5 (4.4%)
Grade 5	0	0	0	0
Cardiac failure	2 (4.4%)	1 (1.9%)	3 (3.1%)	5 (4.4%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 3	1 (2.2%)	0	1 (1.0%)	3 (2.6%)
Grade 5	0	0	0	0
Cardiac failure congestive	1 (2.2%)	0	1 (1.0%)	2 (1.8%)
Grade 3	1 (2.2%)	0	1 (1.0%)	2 (1.8%)
Ischaemic coronary artery disorders	0	2 (3.8%)	2 (2.1%)	3 (2.6%)
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Ischaemic coronary artery disorders (cont) (cont)				
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Angina pectoris	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 3	0	0	0	0
Acute myocardial infarction	0	0	0	0
Grade 4	0	0	0	0
Myocardial infarction	0	0	0	0
Grade 3	0	0	0	0
Cardiac signs and symptoms NEC	1 (5.3%)	0	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Ischaemic coronary artery disorders (cont) (cont)				
Grade 3	0	2 (3.8%)	2 (2.1%)	2 (1.8%)
Grade 4	0	0	0	1 (0.9%)
Angina pectoris	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Grade 1	0	0	0	0
Grade 3	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Acute myocardial infarction	0	0	0	1 (0.9%)
Grade 4	0	0	0	1 (0.9%)
Myocardial infarction	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Cardiac signs and symptoms NEC	0	1 (1.9%)	1 (1.0%)	2 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Cardiac signs and symptoms NEC (cont) (cont)				
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Palpitations	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Rate and rhythm disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Tachycardia	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Cardiac signs and symptoms NEC (cont)				
(cont)				
Grade 1	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Palpitations	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Grade 1	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Rate and rhythm disorders NEC	1 (2.2%)	0	1 (1.0%)	3 (2.6%)
Grade 1	0	0	0	1 (0.9%)
Grade 2	0	0	0	1 (0.9%)
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Tachycardia	1 (2.2%)	0	1 (1.0%)	2 (1.8%)
Grade 2	0	0	0	1 (0.9%)
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Rate and rhythm disorders NEC (cont)				
Bradycardia	0	0	0	0
Grade 1	0	0	0	0
Extrasystoles	0	0	0	0
Grade 1	0	0	0	0
Cardiac conduction disorders	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Atrioventricular block complete	0	0	0	0
Grade 3	0	0	0	0
Atrioventricular block first degree	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Rate and rhythm disorders NEC (cont)				
Bradycardia	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Extrasystoles	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)
Cardiac conduction disorders	1 (2.2%)	0	1 (1.0%)	2 (1.8%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 3	0	0	0	1 (0.9%)
Atrioventricular block complete	0	0	0	1 (0.9%)
Grade 3	0	0	0	1 (0.9%)
Atrioventricular block first degree	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Mitral valvular disorders	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	0	0	0
Grade 3	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Mitral valve incompetence	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	0	0	0
Grade 3	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Cardiac valve disorders NEC	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Cardiac valve disease	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Cardiomyopathies	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Mitral valvular disorders	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 3	0	0	0	0
Mitral valve incompetence	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 3	0	0	0	0
Cardiac valve disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Cardiac valve disease	0	0	0	0
Grade 1	0	0	0	0
Cardiomyopathies	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Cardiomyopathies (cont)				
Cardiomyopathy	0	0	0	0
Grade 3	0	0	0	0
Myocardial disorders NEC	0	0	0	0
Grade 2	0	0	0	0
Cardiomegaly	0	0	0	0
Grade 2	0	0	0	0
Pericardial disorders NEC	0	0	0	0
Grade 3	0	0	0	0
Pericardial effusion	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Cardiomyopathies (cont)				
Cardiomyopathy	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Myocardial disorders NEC	0	0	0	1 (0.9%)
Grade 2	0	0	0	1 (0.9%)
Cardiomegaly	0	0	0	1 (0.9%)
Grade 2	0	0	0	1 (0.9%)
Pericardial disorders NEC	0	0	0	1 (0.9%)
Grade 3	0	0	0	1 (0.9%)
Pericardial effusion	0	0	0	1 (0.9%)
Grade 3	0	0	0	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Ventricular arrhythmias and cardiac arrest	0	0	0	0
Grade 5	0	0	0	0
Cardiac arrest	0	0	0	0
Grade 5	0	0	0	0
Injury, poisoning and procedural complications	5 (26.3%)	2 (6.3%)	7 (13.7%)	9 (16.1%)
Grade 1	4 (21.1%)	0	4 (7.8%)	5 (8.9%)
Grade 2	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 3	0	2 (6.3%)	2 (3.9%)	3 (5.4%)
Grade 5	0	0	0	0
Skin injuries NEC	2 (10.5%)	0	2 (3.9%)	3 (5.4%)
Grade 1	2 (10.5%)	0	2 (3.9%)	3 (5.4%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Ventricular arrhythmias and cardiac arrest	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 5	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Cardiac arrest	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 5	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Injury, poisoning and procedural complications	8 (17.8%)	10 (19.2%)	18 (18.6%)	25 (21.9%)
Grade 1	5 (11.1%)	3 (5.8%)	8 (8.2%)	12 (10.5%)
Grade 2	1 (2.2%)	5 (9.6%)	6 (6.2%)	9 (7.9%)
Grade 3	2 (4.4%)	1 (1.9%)	3 (3.1%)	3 (2.6%)
Grade 5	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Skin injuries NEC	3 (6.7%)	4 (7.7%)	7 (7.2%)	14 (12.3%)
Grade 1	2 (4.4%)	3 (5.8%)	5 (5.2%)	11 (9.6%)
Grade 2	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Skin injuries NEC (cont)				
Contusion	2 (10.5%)	0	2 (3.9%)	3 (5.4%)
Grade 1	2 (10.5%)	0	2 (3.9%)	3 (5.4%)
Grade 2	0	0	0	0
Skin abrasion	0	0	0	0
Grade 1	0	0	0	0
Skin injury	0	0	0	0
Grade 3	0	0	0	0
Skin laceration	0	0	0	0
Grade 2	0	0	0	0
Subcutaneous haematoma	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Skin injuries NEC (cont)				
Contusion	2 (4.4%)	2 (3.8%)	4 (4.1%)	10 (8.8%)
Grade 1	2 (4.4%)	2 (3.8%)	4 (4.1%)	9 (7.9%)
Grade 2	0	0	0	1 (0.9%)
Skin abrasion	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)
Skin injury	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Skin laceration	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Subcutaneous haematoma	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Skin injuries NEC (cont)				
Subcutaneous haematoma (cont)				
Grade 1	0	0	0	0
Non-site specific injuries NEC	1 (5.3%)	2 (6.3%)	3 (5.9%)	4 (7.1%)
Grade 1	1 (5.3%)	1 (3.1%)	2 (3.9%)	3 (5.4%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 5	0	0	0	0
Fall	0	2 (6.3%)	2 (3.9%)	3 (5.4%)
Grade 1	0	1 (3.1%)	1 (2.0%)	2 (3.6%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 5	0	0	0	0
Wound	1 (5.3%)	0	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Skin injuries NEC (cont)				
Subcutaneous haematoma (cont)				
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Non-site specific injuries NEC	3 (6.7%)	4 (7.7%)	7 (7.2%)	10 (8.8%)
Grade 1	2 (4.4%)	1 (1.9%)	3 (3.1%)	6 (5.3%)
Grade 2	1 (2.2%)	2 (3.8%)	3 (3.1%)	3 (2.6%)
Grade 5	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Fall	3 (6.7%)	4 (7.7%)	7 (7.2%)	10 (8.8%)
Grade 1	2 (4.4%)	1 (1.9%)	3 (3.1%)	6 (5.3%)
Grade 2	1 (2.2%)	2 (3.8%)	3 (3.1%)	3 (2.6%)
Grade 5	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Wound	0	0	0	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Non-site specific injuries NEC (cont)				
Wound (cont)				
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Site specific injuries NEC	0	0	0	1 (1.8%)
Grade 1	0	0	0	1 (1.8%)
Grade 2	0	0	0	0
Limb injury	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Head injury	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Non-site specific injuries NEC (cont)				
Wound (cont)				
Grade 1	0	0	0	1 (0.9%)
Site specific injuries NEC	2 (4.4%)	2 (3.8%)	4 (4.1%)	6 (5.3%)
Grade 1	1 (2.2%)	1 (1.9%)	2 (2.1%)	3 (2.6%)
Grade 2	1 (2.2%)	1 (1.9%)	2 (2.1%)	3 (2.6%)
Limb injury	2 (4.4%)	1 (1.9%)	3 (3.1%)	5 (4.4%)
Grade 1	1 (2.2%)	0	1 (1.0%)	2 (1.8%)
Grade 2	1 (2.2%)	1 (1.9%)	2 (2.1%)	3 (2.6%)
Head injury	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Site specific injuries NEC (cont)				
Limb crushing injury	0	0	0	1 (1.8%)
Grade 1	0	0	0	1 (1.8%)
Non-site specific procedural complications	1 (5.3%)	1 (3.1%)	2 (3.9%)	3 (5.4%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 2	0	0	0	0
Grade 3	0	1 (3.1%)	1 (2.0%)	2 (3.6%)
Post procedural haemorrhage	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 3	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Procedural pain	0	1 (3.1%)	1 (2.0%)	2 (3.6%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Site specific injuries NEC (cont)				
Limb crushing injury	0	0	0	0
Grade 1	0	0	0	0
Non-site specific procedural complications	0	1 (1.9%)	1 (1.0%)	3 (2.6%)
Grade 1	0	0	0	1 (0.9%)
Grade 2	0	0	0	1 (0.9%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Post procedural haemorrhage	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Procedural pain	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Non-site specific procedural complications (cont)				
Procedural pain (cont)				
Grade 3	0	0	0	1 (1.8%)
Post procedural complication	0	0	0	0
Grade 2	0	0	0	0
Post procedural contusion	0	0	0	0
Grade 1	0	0	0	0
Post procedural inflammation	0	0	0	0
Grade 3	0	0	0	0
Spinal fractures and dislocations	1 (5.3%)	0	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Non-site specific procedural complications (cont)				
Procedural pain (cont)				
Grade 3	0	0	0	0
Post procedural complication	0	0	0	1 (0.9%)
Grade 2	0	0	0	1 (0.9%)
Post procedural contusion	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)
Post procedural inflammation	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Spinal fractures and dislocations	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Spinal fractures and dislocations (cont) (cont)				
Grade 2	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 3	0	0	0	0
Spinal compression fracture	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Spinal fracture	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 2	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Gastrointestinal and hepatobiliary procedural complications	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Spinal fractures and dislocations (cont) (cont)				
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Spinal compression fracture	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Spinal fracture	0	0	0	0
Grade 2	0	0	0	0
Gastrointestinal and hepatobiliary procedural complications	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Gastrointestinal and hepatobiliary procedural complications (cont) (cont)				
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Dental restoration failure	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Procedural nausea	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Cerebral injuries NEC	0	0	0	0
Grade 1	0	0	0	0
Subdural haemorrhage	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Gastrointestinal and hepatobiliary procedural complications (cont) (cont)				
Grade 2	0	0	0	0
Dental restoration failure	0	0	0	0
Grade 1	0	0	0	0
Procedural nausea	0	0	0	0
Grade 2	0	0	0	0
Cerebral injuries NEC	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Subdural haemorrhage	1 (2.2%)	0	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Cerebral injuries NEC (cont)				
Subdural haemorrhage (cont)				
Grade 1	0	0	0	0
Chest and respiratory tract injuries NEC	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 3	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Traumatic haemothorax	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 3	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Limb fractures and dislocations	0	0	0	0
Grade 2	0	0	0	0
Patella fracture	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Cerebral injuries NEC (cont)				
Subdural haemorrhage (cont)				
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Chest and respiratory tract injuries NEC	0	0	0	0
Grade 3	0	0	0	0
Traumatic haemothorax	0	0	0	0
Grade 3	0	0	0	0
Limb fractures and dislocations	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Patella fracture	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Muscle, tendon and ligament injuries	0	0	0	0
Grade 2	0	0	0	0
Muscle strain	0	0	0	0
Grade 2	0	0	0	0
Skull fractures, facial bone fractures and dislocations	0	0	0	0
Grade 1	0	0	0	0
Facial bones fracture	0	0	0	0
Grade 1	0	0	0	0
Transfusion related complications	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Muscle, tendon and ligament injuries	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Muscle strain	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Skull fractures, facial bone fractures and dislocations	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Facial bones fracture	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Transfusion related complications	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Transfusion related complications (cont)				
Febrile nonhaemolytic transfusion reaction	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Eye disorders	8 (42.1%)	6 (18.8%)	14 (27.5%)	17 (30.4%)
Grade 1	6 (31.6%)	5 (15.6%)	11 (21.6%)	14 (25.0%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 3	2 (10.5%)	0	2 (3.9%)	2 (3.6%)
Grade 4	0	0	0	0
Cataract conditions	4 (21.1%)	2 (6.3%)	6 (11.8%)	6 (10.7%)
Grade 1	3 (15.8%)	2 (6.3%)	5 (9.8%)	5 (8.9%)
Grade 2	0	0	0	0
Grade 3	1 (5.3%)	0	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Transfusion related complications (cont)				
Febrile nonhaemolytic transfusion reaction	0	0	0	0
Grade 1	0	0	0	0
Eye disorders	6 (13.3%)	3 (5.8%)	9 (9.3%)	14 (12.3%)
Grade 1	4 (8.9%)	2 (3.8%)	6 (6.2%)	10 (8.8%)
Grade 2	0	0	0	1 (0.9%)
Grade 3	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)
Grade 4	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Cataract conditions	2 (4.4%)	1 (1.9%)	3 (3.1%)	5 (4.4%)
Grade 1	1 (2.2%)	0	1 (1.0%)	2 (1.8%)
Grade 2	0	0	0	1 (0.9%)
Grade 3	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Cataract conditions (cont)				
Cataract cortical	2 (10.5%)	2 (6.3%)	4 (7.8%)	4 (7.1%)
Grade 1	1 (5.3%)	2 (6.3%)	3 (5.9%)	3 (5.4%)
Grade 2	0	0	0	0
Grade 3	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Cataract nuclear	3 (15.8%)	0	3 (5.9%)	3 (5.4%)
Grade 1	2 (10.5%)	0	2 (3.9%)	2 (3.6%)
Grade 2	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 3	0	0	0	0
Cataract	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Cataract subcapsular	1 (5.3%)	0	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Cataract conditions (cont)				
Cataract cortical	0	0	0	1 (0.9%)
Grade 1	0	0	0	0
Grade 2	0	0	0	1 (0.9%)
Grade 3	0	0	0	0
Cataract nuclear	2 (4.4%)	0	2 (2.1%)	2 (1.8%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	0	0	0	0
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Cataract	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Grade 1	0	0	0	1 (0.9%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Cataract subcapsular	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
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	<65 Years			
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Cataract conditions (cont)				
Cataract subcapsular (cont)				
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Visual disorders NEC	0	1 (3.1%)	1 (2.0%)	2 (3.6%)
Grade 1	0	1 (3.1%)	1 (2.0%)	2 (3.6%)
Grade 3	0	0	0	0
Vision blurred	0	1 (3.1%)	1 (2.0%)	2 (3.6%)
Grade 1	0	1 (3.1%)	1 (2.0%)	2 (3.6%)
Grade 3	0	0	0	0
Diplopia	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Cataract conditions (cont)				
Cataract subcapsular (cont)				
Grade 1	0	0	0	0
Visual disorders NEC	1 (2.2%)	1 (1.9%)	2 (2.1%)	4 (3.5%)
Grade 1	0	1 (1.9%)	1 (1.0%)	3 (2.6%)
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Vision blurred	1 (2.2%)	0	1 (1.0%)	3 (2.6%)
Grade 1	0	0	0	2 (1.8%)
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Diplopia	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Conjunctival and corneal bleeding and vascular disorders	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Conjunctival haemorrhage	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Lacrimation disorders	1 (5.3%)	0	1 (2.0%)	2 (3.6%)
Grade 1	1 (5.3%)	0	1 (2.0%)	2 (3.6%)
Dry eye	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Lacrimation increased	0	0	0	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Conjunctival and corneal bleeding and vascular disorders	2 (4.4%)	0	2 (2.1%)	2 (1.8%)
Grade 1	2 (4.4%)	0	2 (2.1%)	2 (1.8%)
Grade 2	0	0	0	0
Conjunctival haemorrhage	2 (4.4%)	0	2 (2.1%)	2 (1.8%)
Grade 1	2 (4.4%)	0	2 (2.1%)	2 (1.8%)
Grade 2	0	0	0	0
Lacrimation disorders	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Grade 1	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Dry eye	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Lacrimation increased	0	0	0	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Lacrimation disorders (cont)				
Lacrimation increased (cont)				
Grade 1	0	0	0	1 (1.8%)
Retinal bleeding and vascular disorders (excl retinopathy)	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Retinal haemorrhage	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Choroid and vitreous structural change, deposit and degeneration	1 (5.3%)	0	1 (2.0%)	2 (3.6%)
Grade 1	1 (5.3%)	0	1 (2.0%)	2 (3.6%)
Hyalosis asteroid	0	0	0	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Lacrimation disorders (cont)				
Lacrimation increased (cont)				
Grade 1	0	0	0	1 (0.9%)
Retinal bleeding and vascular disorders (excl retinopathy)	1 (2.2%)	0	1 (1.0%)	2 (1.8%)
Grade 1	1 (2.2%)	0	1 (1.0%)	2 (1.8%)
Retinal haemorrhage	1 (2.2%)	0	1 (1.0%)	2 (1.8%)
Grade 1	1 (2.2%)	0	1 (1.0%)	2 (1.8%)
Choroid and vitreous structural change, deposit and degeneration	0	0	0	0
Grade 1	0	0	0	0
Hyalosis asteroid	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Choroid and vitreous structural change, deposit and degeneration (cont)				
Hyalosis asteroid (cont)				
Grade 1	0	0	0	1 (1.8%)
Vitreous floaters	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Corneal infections, oedemas and inflammations	0	1 (3.1%)	1 (2.0%)	2 (3.6%)
Grade 1	0	0	0	1 (1.8%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Keratitis	0	1 (3.1%)	1 (2.0%)	2 (3.6%)
Grade 1	0	0	0	1 (1.8%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Choroid and vitreous structural change, deposit and degeneration (cont)				
Hyalosis asteroid (cont)				
Grade 1	0	0	0	0
Vitreous floaters	0	0	0	0
Grade 1	0	0	0	0
Corneal infections, oedemas and inflammations	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Keratitis	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Lid, lash and lacrimal infections, irritations and inflammations	0	2 (6.3%)	2 (3.9%)	2 (3.6%)
Grade 1	0	2 (6.3%)	2 (3.9%)	2 (3.6%)
Erythema of eyelid	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Eyelid oedema	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Ocular bleeding and vascular disorders NEC	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 4	0	0	0	0
Eye haemorrhage	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Lid, lash and lacrimal infections, irritations and inflammations	0	0	0	0
Grade 1	0	0	0	0
Erythema of eyelid	0	0	0	0
Grade 1	0	0	0	0
Eyelid oedema	0	0	0	0
Grade 1	0	0	0	0
Ocular bleeding and vascular disorders NEC	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	0	0	0	0
Grade 4	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Eye haemorrhage	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Ocular bleeding and vascular disorders NEC (cont)				
Eye haemorrhage (cont)				
Grade 4	0	0	0	0
Ocular disorders NEC	0	0	0	1 (1.8%)
Grade 1	0	0	0	1 (1.8%)
Grade 3	0	0	0	0
Eye pain	0	0	0	0
Grade 3	0	0	0	0
Periorbital oedema	0	0	0	1 (1.8%)
Grade 1	0	0	0	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Ocular bleeding and vascular disorders NEC (cont)				
Eye haemorrhage (cont)				
Grade 4	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Ocular disorders NEC	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	0	0	0	0
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Eye pain	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Periorbital oedema	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Retinal structural change, deposit and degeneration	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	0	0	0	0
Grade 3	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Macular degeneration	0	0	0	0
Grade 1	0	0	0	0
Retinal detachment	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 3	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Visual impairment and blindness (excl colour blindness)	1 (5.3%)	0	1 (2.0%)	2 (3.6%)
Grade 1	1 (5.3%)	0	1 (2.0%)	2 (3.6%)
Visual acuity reduced	0	0	0	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Retinal structural change, deposit and degeneration	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)
Grade 3	0	0	0	0
Macular degeneration	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)
Retinal detachment	0	0	0	0
Grade 3	0	0	0	0
Visual impairment and blindness (excl colour blindness)	0	0	0	0
Grade 1	0	0	0	0
Visual acuity reduced	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Visual impairment and blindness (excl colour blindness) (cont)				
Visual acuity reduced (cont)				
Grade 1	0	0	0	1 (1.8%)
Visual impairment	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Eyelid movement disorders	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Eyelid ptosis	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Visual impairment and blindness (excl colour blindness) (cont)				
Visual acuity reduced (cont)				
Grade 1	0	0	0	0
Visual impairment	0	0	0	0
Grade 1	0	0	0	0
Eyelid movement disorders	0	0	0	0
Grade 1	0	0	0	0
Eyelid ptosis	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4 (21.1%)	3 (9.4%)	7 (13.7%)	9 (16.1%)
Grade 1	2 (10.5%)	1 (3.1%)	3 (5.9%)	3 (5.4%)
Grade 2	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 3	1 (5.3%)	1 (3.1%)	2 (3.9%)	3 (5.4%)
Grade 4	0	0	0	1 (1.8%)
Grade 5	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Leukaemias acute myeloid	1 (5.3%)	0	1 (2.0%)	2 (3.6%)
Grade 3	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 4	0	0	0	1 (1.8%)
Acute myeloid leukaemia	0	0	0	1 (1.8%)
Grade 3	0	0	0	0
Grade 4	0	0	0	1 (1.8%)
Transformation to acute myeloid leukaemia	1 (5.3%)	0	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10 (22.2%)	8 (15.4%)	18 (18.6%)	19 (16.7%)
Grade 1	1 (2.2%)	3 (5.8%)	4 (4.1%)	4 (3.5%)
Grade 2	2 (4.4%)	2 (3.8%)	4 (4.1%)	4 (3.5%)
Grade 3	6 (13.3%)	3 (5.8%)	9 (9.3%)	9 (7.9%)
Grade 4	0	0	0	1 (0.9%)
Grade 5	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Leukaemias acute myeloid	3 (6.7%)	1 (1.9%)	4 (4.1%)	4 (3.5%)
Grade 3	3 (6.7%)	1 (1.9%)	4 (4.1%)	4 (3.5%)
Grade 4	0	0	0	0
Acute myeloid leukaemia	3 (6.7%)	1 (1.9%)	4 (4.1%)	4 (3.5%)
Grade 3	3 (6.7%)	1 (1.9%)	4 (4.1%)	4 (3.5%)
Grade 4	0	0	0	0
Transformation to acute myeloid leukaemia	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Leukaemias acute myeloid (cont)				
Transformation to acute myeloid leukaemia (cont)				
Grade 3	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Skin neoplasms malignant and unspecified (excl melanoma)	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Basal cell carcinoma	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 2	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Squamous cell carcinoma of skin	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Leukaemias acute myeloid (cont)				
Transformation to acute myeloid leukaemia (cont)				
Grade 3	0	0	0	0
Skin neoplasms malignant and unspecified (excl melanoma)	2 (4.4%)	2 (3.8%)	4 (4.1%)	4 (3.5%)
Grade 1	0	0	0	0
Grade 2	2 (4.4%)	2 (3.8%)	4 (4.1%)	4 (3.5%)
Basal cell carcinoma	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)
Grade 2	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)
Squamous cell carcinoma of skin	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Skin neoplasms malignant and unspecified (excl melanoma) (cont)				
Squamous cell carcinoma of skin (cont)				
Grade 2	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Bowen's disease	0	0	0	0
Grade 2	0	0	0	0
Skin neoplasms benign	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Seborrhoeic keratosis	0	0	0	0
Grade 1	0	0	0	0
Skin papilloma	1 (5.3%)	0	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Skin neoplasms malignant and unspecified (excl melanoma) (cont)				
Squamous cell carcinoma of skin (cont)				
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Bowen's disease	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Skin neoplasms benign	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Seborrhoeic keratosis	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Skin papilloma	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Skin neoplasms benign (cont)				
Skin papilloma (cont)				
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Uterine neoplasms malignant NEC	0	0	0	1 (1.8%)
Grade 3	0	0	0	1 (1.8%)
Grade 5	0	0	0	0
Uterine cancer	0	0	0	1 (1.8%)
Grade 3	0	0	0	1 (1.8%)
Grade 5	0	0	0	0
Bone neoplasms benign (excl cysts)	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Skin neoplasms benign (cont)				
Skin papilloma (cont)				
Grade 1	0	0	0	0
Uterine neoplasms malignant NEC	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 3	0	0	0	0
Grade 5	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Uterine cancer	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 3	0	0	0	0
Grade 5	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Bone neoplasms benign (excl cysts)	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Bone neoplasms benign (excl cysts) (cont)				
Haemangioma of bone	0	0	0	0
Grade 1	0	0	0	0
Colorectal neoplasms malignant	0	0	0	0
Grade 3	0	0	0	0
Rectal cancer	0	0	0	0
Grade 3	0	0	0	0
Histiocytoses	0	0	0	0
Grade 3	0	0	0	0
Langerhans cell sarcoma	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Bone neoplasms benign (excl cysts) (cont)				
Haemangioma of bone	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Colorectal neoplasms malignant	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Rectal cancer	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Histiocytoses	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Langerhans cell sarcoma	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Leukaemias chronic myeloid	0	0	0	0
Grade 3	0	0	0	0
Chronic myeloid leukaemia	0	0	0	0
Grade 3	0	0	0	0
Myeloproliferative disorders (excl leukaemias)	0	0	0	0
Grade 3	0	0	0	0
Leukoerythroblastosis	0	0	0	0
Grade 3	0	0	0	0
Nasal and paranasal sinus neoplasms benign	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 3	0	1 (3.1%)	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Leukaemias chronic myeloid	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Chronic myeloid leukaemia	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Myeloproliferative disorders (excl leukaemias)	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Leukoerythroblastosis	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Nasal and paranasal sinus neoplasms benign	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Nasal and paranasal sinus neoplasms benign (cont)				
Sinonasal papilloma	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 3	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Neoplasms malignant site unspecified NEC	0	0	0	0
Grade 1	0	0	0	0
Metastatic squamous cell carcinoma	0	0	0	0
Grade 1	0	0	0	0
Ocular neoplasms malignancy unspecified	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Eyelid tumour	0	1 (3.1%)	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Nasal and paranasal sinus neoplasms benign (cont)				
Sinonasal papilloma	0	0	0	0
Grade 3	0	0	0	0
Neoplasms malignant site unspecified NEC	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Metastatic squamous cell carcinoma	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Ocular neoplasms malignancy unspecified	0	0	0	0
Grade 1	0	0	0	0
Eyelid tumour	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Data Extracted: CRF data: 01JUL2019
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Ocular neoplasms malignancy unspecified (cont)				
Eyelid tumour (cont)				
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Oncologic complications and emergencies	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Tumour associated fever	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Ovarian neoplasms malignant (excl germ cell)	0	0	0	1 (1.8%)
Grade 3	0	0	0	1 (1.8%)
Ovarian clear cell carcinoma	0	0	0	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Ocular neoplasms malignancy unspecified (cont)				
Eyelid tumour (cont)				
Grade 1	0	0	0	0
Oncologic complications and emergencies	0	0	0	0
Grade 1	0	0	0	0
Tumour associated fever	0	0	0	0
Grade 1	0	0	0	0
Ovarian neoplasms malignant (excl germ cell)	0	0	0	0
Grade 3	0	0	0	0
Ovarian clear cell carcinoma	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Ovarian neoplasms malignant (excl germ cell) (cont)				
Ovarian clear cell carcinoma (cont)				
Grade 3	0	0	0	1 (1.8%)
Skin melanomas (excl ocular)	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 5	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Malignant melanoma	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 5	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Soft tissue neoplasms benign NEC	0	0	0	0
Grade 1	0	0	0	0
Angiomyolipoma	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Ovarian neoplasms malignant (excl germ cell) (cont)				
Ovarian clear cell carcinoma (cont)				
Grade 3	0	0	0	0
Skin melanomas (excl ocular)	0	0	0	0
Grade 5	0	0	0	0
Malignant melanoma	0	0	0	0
Grade 5	0	0	0	0
Soft tissue neoplasms benign NEC	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Angiomyolipoma	1 (2.2%)	0	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Soft tissue neoplasms benign NEC (cont)				
Angiomyolipoma (cont)				
Grade 1	0	0	0	0
Splenic marginal zone lymphomas	0	0	0	0
Grade 4	0	0	0	0
Splenic marginal zone lymphoma	0	0	0	0
Grade 4	0	0	0	0
Testicular neoplasms malignant	0	0	0	0
Grade 3	0	0	0	0
Seminoma	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Soft tissue neoplasms benign NEC (cont)				
Angiomyolipoma (cont)				
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Splenic marginal zone lymphomas	0	0	0	1 (0.9%)
Grade 4	0	0	0	1 (0.9%)
Splenic marginal zone lymphoma	0	0	0	1 (0.9%)
Grade 4	0	0	0	1 (0.9%)
Testicular neoplasms malignant	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Seminoma	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Uterine neoplasms benign	0	0	0	0
Grade 1	0	0	0	0
Uterine leiomyoma	0	0	0	0
Grade 1	0	0	0	0
Psychiatric disorders	4 (21.1%)	1 (3.1%)	5 (9.8%)	6 (10.7%)
Grade 1	1 (5.3%)	1 (3.1%)	2 (3.9%)	3 (5.4%)
Grade 2	3 (15.8%)	0	3 (5.9%)	3 (5.4%)
Grade 3	0	0	0	0
Disturbances in initiating and maintaining sleep	2 (10.5%)	1 (3.1%)	3 (5.9%)	3 (5.4%)
Grade 1	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 2	1 (5.3%)	0	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Uterine neoplasms benign	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Uterine leiomyoma	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Psychiatric disorders	10 (22.2%)	8 (15.4%)	18 (18.6%)	21 (18.4%)
Grade 1	5 (11.1%)	3 (5.8%)	8 (8.2%)	9 (7.9%)
Grade 2	4 (8.9%)	5 (9.6%)	9 (9.3%)	11 (9.6%)
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Disturbances in initiating and maintaining sleep	5 (11.1%)	3 (5.8%)	8 (8.2%)	9 (7.9%)
Grade 1	3 (6.7%)	1 (1.9%)	4 (4.1%)	5 (4.4%)
Grade 2	2 (4.4%)	2 (3.8%)	4 (4.1%)	4 (3.5%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Disturbances in initiating and maintaining sleep (cont)				
Insomnia	2 (10.5%)	1 (3.1%)	3 (5.9%)	3 (5.4%)
Grade 1	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 2	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Depressive disorders	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Depression	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Disturbances in initiating and maintaining sleep (cont)				
Insomnia	5 (11.1%)	3 (5.8%)	8 (8.2%)	9 (7.9%)
Grade 1	3 (6.7%)	1 (1.9%)	4 (4.1%)	5 (4.4%)
Grade 2	2 (4.4%)	2 (3.8%)	4 (4.1%)	4 (3.5%)
Depressive disorders	5 (11.1%)	1 (1.9%)	6 (6.2%)	7 (6.1%)
Grade 1	2 (4.4%)	0	2 (2.1%)	2 (1.8%)
Grade 2	2 (4.4%)	1 (1.9%)	3 (3.1%)	4 (3.5%)
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Depression	5 (11.1%)	1 (1.9%)	6 (6.2%)	7 (6.1%)
Grade 1	2 (4.4%)	0	2 (2.1%)	2 (1.8%)
Grade 2	2 (4.4%)	1 (1.9%)	3 (3.1%)	4 (3.5%)
Grade 3	1 (2.2%)	0	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Anxiety symptoms	2 (10.5%)	0	2 (3.9%)	4 (7.1%)
Grade 1	1 (5.3%)	0	1 (2.0%)	2 (3.6%)
Grade 2	1 (5.3%)	0	1 (2.0%)	2 (3.6%)
Anxiety	2 (10.5%)	0	2 (3.9%)	4 (7.1%)
Grade 1	1 (5.3%)	0	1 (2.0%)	2 (3.6%)
Grade 2	1 (5.3%)	0	1 (2.0%)	2 (3.6%)
Confusion and disorientation	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 2	0	0	0	0
Confusional state	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Anxiety symptoms	1 (2.2%)	0	1 (1.0%)	2 (1.8%)
Grade 1	0	0	0	0
Grade 2	1 (2.2%)	0	1 (1.0%)	2 (1.8%)
Anxiety	1 (2.2%)	0	1 (1.0%)	2 (1.8%)
Grade 1	0	0	0	0
Grade 2	1 (2.2%)	0	1 (1.0%)	2 (1.8%)
Confusion and disorientation	1 (2.2%)	2 (3.8%)	3 (3.1%)	4 (3.5%)
Grade 1	1 (2.2%)	1 (1.9%)	2 (2.1%)	3 (2.6%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Confusional state	1 (2.2%)	1 (1.9%)	2 (2.1%)	3 (2.6%)
Grade 1	1 (2.2%)	0	1 (1.0%)	2 (1.8%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
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Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Confusion and disorientation (cont)				
Disorientation	0	0	0	0
Grade 1	0	0	0	0
Sexual desire disorders	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 2	0	0	0	0
Libido decreased	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 2	0	0	0	0
Delusional symptoms	0	0	0	0
Grade 1	0	0	0	0
Delusion	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Confusion and disorientation (cont)				
Disorientation	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Sexual desire disorders	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	0	0	0
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Libido decreased	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	0	0	0
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Delusional symptoms	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Delusion	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Delusional symptoms (cont)				
Delusion (cont)				
Grade 1	0	0	0	0
Hallucinations (excl sleep-related)	0	0	0	0
Grade 1	0	0	0	0
Hallucination	0	0	0	0
Grade 1	0	0	0	0
Mental disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Mental status changes	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Delusional symptoms (cont)				
Delusion (cont)				
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Hallucinations (excl sleep-related)	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)
Hallucination	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)
Mental disorders NEC	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)
Mental status changes	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Sleep disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Sleep disorder	0	0	0	0
Grade 1	0	0	0	0
Suicidal and self-injurious behaviour	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 2	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Suicidal ideation	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 2	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Ear and labyrinth disorders	0	2 (6.3%)	2 (3.9%)	3 (5.4%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	1 (3.1%)	1 (2.0%)	2 (3.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Sleep disorders NEC	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Sleep disorder	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Suicidal and self-injurious behaviour	0	0	0	0
Grade 2	0	0	0	0
Suicidal ideation	0	0	0	0
Grade 2	0	0	0	0
Ear and labyrinth disorders	4 (8.9%)	4 (7.7%)	8 (8.2%)	11 (9.6%)
Grade 1	2 (4.4%)	2 (3.8%)	4 (4.1%)	6 (5.3%)
Grade 2	2 (4.4%)	2 (3.8%)	4 (4.1%)	5 (4.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Ear and labyrinth disorders (cont)				
Inner ear signs and symptoms	0	2 (6.3%)	2 (3.9%)	2 (3.6%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Vertigo	0	2 (6.3%)	2 (3.9%)	2 (3.6%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Motion sickness	0	0	0	0
Grade 1	0	0	0	0
Hearing losses	0	0	0	1 (1.8%)
Grade 1	0	0	0	0
Grade 2	0	0	0	1 (1.8%)
Hypoacusis	0	0	0	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Ear and labyrinth disorders (cont)				
Inner ear signs and symptoms	2 (4.4%)	2 (3.8%)	4 (4.1%)	7 (6.1%)
Grade 1	2 (4.4%)	1 (1.9%)	3 (3.1%)	5 (4.4%)
Grade 2	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Vertigo	1 (2.2%)	2 (3.8%)	3 (3.1%)	6 (5.3%)
Grade 1	1 (2.2%)	1 (1.9%)	2 (2.1%)	4 (3.5%)
Grade 2	0	1 (1.9%)	1 (1.0%)	2 (1.8%)
Motion sickness	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Hearing losses	2 (4.4%)	2 (3.8%)	4 (4.1%)	4 (3.5%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	2 (4.4%)	1 (1.9%)	3 (3.1%)	3 (2.6%)
Hypoacusis	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Ear and labyrinth disorders (cont)				
Hearing losses (cont)				
Hypoacusis (cont)				
Grade 1	0	0	0	0
Grade 2	0	0	0	1 (1.8%)
Deafness	0	0	0	0
Grade 2	0	0	0	0
Deafness unilateral	0	0	0	0
Grade 2	0	0	0	0
Sudden hearing loss	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Ear and labyrinth disorders (cont)				
Hearing losses (cont)				
Hypoacusis (cont)				
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	0	0	0
Deafness	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Deafness unilateral	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Sudden hearing loss	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	1 (2.2%)	0	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Hepatobiliary disorders	3 (15.8%)	3 (9.4%)	6 (11.8%)	6 (10.7%)
Grade 1	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 2	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 3	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Cholecystitis and cholelithiasis	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Cholelithiasis	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 1	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Cholestasis and jaundice	0	0	0	0
Grade 1	0	0	0	0
Ocular icterus	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Hepatobiliary disorders	2 (4.4%)	2 (3.8%)	4 (4.1%)	4 (3.5%)
Grade 1	2 (4.4%)	2 (3.8%)	4 (4.1%)	4 (3.5%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Cholecystitis and cholelithiasis	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	0	0	0	0
Cholelithiasis	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	0	0	0	0
Cholestasis and jaundice	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)
Grade 1	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)
Ocular icterus	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Hepatobiliary disorders (cont)				
Cholestasis and jaundice (cont)				
Ocular icterus (cont)				
Grade 1	0	0	0	0
Hepatic and hepatobiliary disorders NEC	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	0	0	0	0
Grade 3	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Liver disorder	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	0	0	0	0
Grade 3	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Hepatic vascular disorders	0	2 (6.3%)	2 (3.9%)	2 (3.6%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 3	0	1 (3.1%)	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Hepatobiliary disorders (cont)				
Cholestasis and jaundice (cont)				
Ocular icterus (cont)				
Grade 1	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)
Hepatic and hepatobiliary disorders NEC	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 3	0	0	0	0
Liver disorder	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 3	0	0	0	0
Hepatic vascular disorders	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Hepatobiliary disorders (cont)				
Hepatic vascular disorders (cont)				
Portal hypertension	0	2 (6.3%)	2 (3.9%)	2 (3.6%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 3	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Hepatic enzymes and function abnormalities	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Hepatic function abnormal	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Hepatocellular damage and hepatitis NEC	0	0	0	0
Grade 1	0	0	0	0
Hepatic steatosis	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Hepatobiliary disorders (cont)				
Hepatic vascular disorders (cont)				
Portal hypertension	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Hepatic enzymes and function abnormalities	0	0	0	0
Grade 1	0	0	0	0
Hepatic function abnormal	0	0	0	0
Grade 1	0	0	0	0
Hepatocellular damage and hepatitis NEC	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Hepatic steatosis	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Reproductive system and breast disorders	2 (10.5%)	1 (3.1%)	3 (5.9%)	5 (8.9%)
Grade 1	1 (5.3%)	0	1 (2.0%)	3 (5.4%)
Grade 2	1 (5.3%)	1 (3.1%)	2 (3.9%)	2 (3.6%)
Grade 3	0	0	0	0
Prostatic neoplasms and hypertrophy	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	0	0	0	0
Grade 2	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 3	0	0	0	0
Benign prostatic hyperplasia	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	0	0	0	0
Grade 2	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 3	0	0	0	0
Menopausal effects on the genitourinary tract	0	1 (3.1%)	1 (2.0%)	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Reproductive system and breast disorders	1 (2.2%)	3 (5.8%)	4 (4.1%)	5 (4.4%)
Grade 1	0	0	0	1 (0.9%)
Grade 2	1 (2.2%)	2 (3.8%)	3 (3.1%)	3 (2.6%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Prostatic neoplasms and hypertrophy	1 (2.2%)	3 (5.8%)	4 (4.1%)	5 (4.4%)
Grade 1	0	0	0	1 (0.9%)
Grade 2	1 (2.2%)	2 (3.8%)	3 (3.1%)	3 (2.6%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Benign prostatic hyperplasia	1 (2.2%)	3 (5.8%)	4 (4.1%)	5 (4.4%)
Grade 1	0	0	0	1 (0.9%)
Grade 2	1 (2.2%)	2 (3.8%)	3 (3.1%)	3 (2.6%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Menopausal effects on the genitourinary tract	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-ol.pdf 29AUG2023: 9:42

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Reproductive system and breast disorders (cont)				
Menopausal effects on the genitourinary tract (cont) (cont)				
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Postmenopausal haemorrhage	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Grade 2	0	1 (3.1%)	1 (2.0%)	1 (1.8%)
Uterine disorders NEC	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Uterine haemorrhage	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Grade 1	1 (5.3%)	0	1 (2.0%)	1 (1.8%)
Vulvovaginal disorders NEC	0	0	0	1 (1.8%)
Grade 1	0	0	0	1 (1.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Reproductive system and breast disorders (cont)				
Menopausal effects on the genitourinary tract (cont) (cont)				
Grade 2	0	0	0	0
Postmenopausal haemorrhage	0	0	0	0
Grade 2	0	0	0	0
Uterine disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Uterine haemorrhage	0	0	0	0
Grade 1	0	0	0	0
Vulvovaginal disorders NEC	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Reproductive system and breast disorders (cont)				
Vulvovaginal disorders NEC (cont)				
Vaginal haemorrhage	0	0	0	1 (1.8%)
Grade 1	0	0	0	1 (1.8%)
Vulvovaginal signs and symptoms	0	0	0	1 (1.8%)
Grade 1	0	0	0	1 (1.8%)
Vulvovaginal pain	0	0	0	1 (1.8%)
Grade 1	0	0	0	1 (1.8%)
Endocrine disorders	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Acute and chronic thyroiditis	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Reproductive system and breast disorders (cont)				
Vulvovaginal disorders NEC (cont)				
Vaginal haemorrhage	0	0	0	0
Grade 1	0	0	0	0
Vulvovaginal signs and symptoms	0	0	0	0
Grade 1	0	0	0	0
Vulvovaginal pain	0	0	0	0
Grade 1	0	0	0	0
Endocrine disorders	0	3 (5.8%)	3 (3.1%)	3 (2.6%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Acute and chronic thyroiditis	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Endocrine disorders (cont)				
Acute and chronic thyroiditis (cont)				
(cont)				
Grade 3	0	0	0	0
Thyroiditis	0	0	0	0
Grade 3	0	0	0	0
Thyroid disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Goitre	0	0	0	0
Grade 1	0	0	0	0
Thyroid hypofunction disorders	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Endocrine disorders (cont)				
Acute and chronic thyroiditis (cont)				
(cont)				
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Thyroiditis	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 3	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Thyroid disorders NEC	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Goitre	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 1	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Thyroid hypofunction disorders	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Endocrine disorders (cont)				
Thyroid hypofunction disorders (cont)				
Hypothyroidism	0	0	0	0
Grade 2	0	0	0	0
Immune system disorders	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Allergies to foods, food additives, drugs and other chemicals	0	0	0	0
Grade 1	0	0	0	0
Drug hypersensitivity	0	0	0	0
Grade 1	0	0	0	0
Atopic disorders	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Endocrine disorders (cont)				
Thyroid hypofunction disorders (cont)				
Hypothyroidism	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Immune system disorders	1 (2.2%)	1 (1.9%)	2 (2.1%)	2 (1.8%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Allergies to foods, food additives, drugs and other chemicals	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Drug hypersensitivity	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Grade 1	1 (2.2%)	0	1 (1.0%)	1 (0.9%)
Atopic disorders	0	1 (1.9%)	1 (1.0%)	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	<65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=19)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=32)	OL Phase (Week 24 Onward) Total (N=51)	Overall Exposed to MMB Total (N=56)
Number of Subjects with Any Treatment-Emergent AE	18 (94.7%)	32 (100.0%)	50 (98.0%)	55 (98.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Immune system disorders (cont)				
Atopic disorders (cont)				
(cont)				
Grade 2	0	0	0	0
Seasonal allergy	0	0	0	0
Grade 2	0	0	0	0
Surgical and medical procedures	0	0	0	0
Grade 1	0	0	0	0
Dental and gingival therapeutic procedures	0	0	0	0
Grade 1	0	0	0	0
Tooth extraction	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0804: TEAEs by SOC, High-Level Term, and PT by Age Group and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=45)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=52)	OL Phase (Week 24 Onward) Total (N=97)	Overall Exposed to MMB Total (N=114)
Number of Subjects with Any Treatment-Emergent AE	41 (91.1%)	51 (98.1%)	92 (94.8%)	111 (97.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Immune system disorders (cont)				
Atopic disorders (cont)				
(cont)				
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Seasonal allergy	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Grade 2	0	1 (1.9%)	1 (1.0%)	1 (0.9%)
Surgical and medical procedures	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)
Dental and gingival therapeutic procedures	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)
Tooth extraction	0	0	0	1 (0.9%)
Grade 1	0	0	0	1 (0.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders	38 (55.1%)	27 (35.5%)	65 (44.8%)	11 (22.0%)	33 (47.8%)	44 (37.0%)
Grade 1	22 (31.9%)	14 (18.4%)	36 (24.8%)	8 (16.0%)	14 (20.3%)	22 (18.5%)
Grade 2	11 (15.9%)	9 (11.8%)	20 (13.8%)	3 (6.0%)	13 (18.8%)	16 (13.4%)
Grade 3	5 (7.2%)	3 (3.9%)	8 (5.5%)	0	6 (8.7%)	6 (5.0%)
Grade 4	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 5	0	0	0	0	0	0
Nausea and vomiting symptoms	17 (24.6%)	6 (7.9%)	23 (15.9%)	3 (6.0%)	8 (11.6%)	11 (9.2%)
Grade 1	11 (15.9%)	2 (2.6%)	13 (9.0%)	2 (4.0%)	5 (7.2%)	7 (5.9%)
Grade 2	5 (7.2%)	3 (3.9%)	8 (5.5%)	1 (2.0%)	2 (2.9%)	3 (2.5%)
Grade 3	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	1 (1.4%)	1 (0.8%)
Nausea	15 (21.7%)	3 (3.9%)	18 (12.4%)	1 (2.0%)	5 (7.2%)	6 (5.0%)
Grade 1	12 (17.4%)	0	12 (8.3%)	1 (2.0%)	4 (5.8%)	5 (4.2%)
Grade 2	2 (2.9%)	2 (2.6%)	4 (2.8%)	0	1 (1.4%)	1 (0.8%)
Grade 3	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders	8 (47.1%)	10 (55.6%)	18 (51.4%)	5 (35.7%)	10 (66.7%)	15 (51.7%)
Grade 1	6 (35.3%)	6 (33.3%)	12 (34.3%)	3 (21.4%)	6 (40.0%)	9 (31.0%)
Grade 2	1 (5.9%)	4 (22.2%)	5 (14.3%)	2 (14.3%)	4 (26.7%)	6 (20.7%)
Grade 3	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Grade 5	1 (5.9%)	0	1 (2.9%)	0	0	0
Nausea and vomiting symptoms	4 (23.5%)	2 (11.1%)	6 (17.1%)	1 (7.1%)	3 (20.0%)	4 (13.8%)
Grade 1	3 (17.6%)	1 (5.6%)	4 (11.4%)	1 (7.1%)	2 (13.3%)	3 (10.3%)
Grade 2	0	1 (5.6%)	1 (2.9%)	0	1 (6.7%)	1 (3.4%)
Grade 3	1 (5.9%)	0	1 (2.9%)	0	0	0
Nausea	4 (23.5%)	0	4 (11.4%)	1 (7.1%)	2 (13.3%)	3 (10.3%)
Grade 1	3 (17.6%)	0	3 (8.6%)	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 2	1 (5.9%)	0	1 (2.9%)	0	1 (6.7%)	1 (3.4%)
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Nausea and vomiting symptoms (cont)						
Vomiting	7 (10.1%)	3 (3.9%)	10 (6.9%)	3 (6.0%)	4 (5.8%)	7 (5.9%)
Grade 1	4 (5.8%)	2 (2.6%)	6 (4.1%)	2 (4.0%)	1 (1.4%)	3 (2.5%)
Grade 2	3 (4.3%)	1 (1.3%)	4 (2.8%)	1 (2.0%)	2 (2.9%)	3 (2.5%)
Grade 3	0	0	0	0	1 (1.4%)	1 (0.8%)
Retching	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Diarrhoea (excl infective)	15 (21.7%)	13 (17.1%)	28 (19.3%)	5 (10.0%)	10 (14.5%)	15 (12.6%)
Grade 1	8 (11.6%)	10 (13.2%)	18 (12.4%)	4 (8.0%)	5 (7.2%)	9 (7.6%)
Grade 2	6 (8.7%)	2 (2.6%)	8 (5.5%)	1 (2.0%)	2 (2.9%)	3 (2.5%)
Grade 3	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	3 (4.3%)	3 (2.5%)
Diarrhoea	15 (21.7%)	13 (17.1%)	28 (19.3%)	5 (10.0%)	10 (14.5%)	15 (12.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Nausea and vomiting symptoms (cont)						
Vomiting	1 (5.9%)	2 (11.1%)	3 (8.6%)	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 1	0	1 (5.6%)	1 (2.9%)	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 2	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 3	1 (5.9%)	0	1 (2.9%)	0	0	0
Retching	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Diarrhoea (excl infective)	4 (23.5%)	6 (33.3%)	10 (28.6%)	3 (21.4%)	6 (40.0%)	9 (31.0%)
Grade 1	2 (11.8%)	4 (22.2%)	6 (17.1%)	3 (21.4%)	5 (33.3%)	8 (27.6%)
Grade 2	1 (5.9%)	2 (11.1%)	3 (8.6%)	0	1 (6.7%)	1 (3.4%)
Grade 3	1 (5.9%)	0	1 (2.9%)	0	0	0
Diarrhoea	4 (23.5%)	6 (33.3%)	10 (28.6%)	3 (21.4%)	6 (40.0%)	9 (31.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Diarrhoea (excl infective) (cont)						
Diarrhoea (cont)						
Grade 1	8 (11.6%)	10 (13.2%)	18 (12.4%)	4 (8.0%)	5 (7.2%)	9 (7.6%)
Grade 2	6 (8.7%)	2 (2.6%)	8 (5.5%)	1 (2.0%)	2 (2.9%)	3 (2.5%)
Grade 3	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	3 (4.3%)	3 (2.5%)
Gastrointestinal atonic and hypomotility disorders NEC	12 (17.4%)	7 (9.2%)	19 (13.1%)	1 (2.0%)	7 (10.1%)	8 (6.7%)
Grade 1	10 (14.5%)	5 (6.6%)	15 (10.3%)	1 (2.0%)	5 (7.2%)	6 (5.0%)
Grade 2	2 (2.9%)	2 (2.6%)	4 (2.8%)	0	1 (1.4%)	1 (0.8%)
Grade 3	0	0	0	0	1 (1.4%)	1 (0.8%)
Constipation	9 (13.0%)	6 (7.9%)	15 (10.3%)	1 (2.0%)	2 (2.9%)	3 (2.5%)
Grade 1	9 (13.0%)	4 (5.3%)	13 (9.0%)	1 (2.0%)	1 (1.4%)	2 (1.7%)
Grade 2	0	2 (2.6%)	2 (1.4%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Diarrhoea (excl infective) (cont)						
Diarrhoea (cont)						
Grade 1	2 (11.8%)	4 (22.2%)	6 (17.1%)	3 (21.4%)	5 (33.3%)	8 (27.6%)
Grade 2	1 (5.9%)	2 (11.1%)	3 (8.6%)	0	1 (6.7%)	1 (3.4%)
Grade 3	1 (5.9%)	0	1 (2.9%)	0	0	0
Gastrointestinal atonic and hypomotility disorders NEC	2 (11.8%)	0	2 (5.7%)	0	3 (20.0%)	3 (10.3%)
Grade 1	2 (11.8%)	0	2 (5.7%)	0	1 (6.7%)	1 (3.4%)
Grade 2	0	0	0	0	2 (13.3%)	2 (6.9%)
Grade 3	0	0	0	0	0	0
Constipation	2 (11.8%)	0	2 (5.7%)	0	3 (20.0%)	3 (10.3%)
Grade 1	2 (11.8%)	0	2 (5.7%)	0	1 (6.7%)	1 (3.4%)
Grade 2	0	0	0	0	2 (13.3%)	2 (6.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal atonic and hypomotility disorders NEC (cont)						
Constipation (cont)						
Grade 3	0	0	0	0	1 (1.4%)	1 (0.8%)
Gastrooesophageal reflux disease	4 (5.8%)	1 (1.3%)	5 (3.4%)	0	5 (7.2%)	5 (4.2%)
Grade 1	2 (2.9%)	1 (1.3%)	3 (2.1%)	0	4 (5.8%)	4 (3.4%)
Grade 2	2 (2.9%)	0	2 (1.4%)	0	1 (1.4%)	1 (0.8%)
Gastrointestinal and abdominal pains (excl oral and throat)	9 (13.0%)	9 (11.8%)	18 (12.4%)	2 (4.0%)	8 (11.6%)	10 (8.4%)
Grade 1	6 (8.7%)	4 (5.3%)	10 (6.9%)	1 (2.0%)	5 (7.2%)	6 (5.0%)
Grade 2	2 (2.9%)	4 (5.3%)	6 (4.1%)	1 (2.0%)	3 (4.3%)	4 (3.4%)
Grade 3	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal atonic and hypomotility disorders NEC (cont)						
Constipation (cont)						
Grade 3	0	0	0	0	0	0
Gastrooesophageal reflux disease	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Gastrointestinal and abdominal pains (excl oral and throat)	4 (23.5%)	3 (16.7%)	7 (20.0%)	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 1	2 (11.8%)	3 (16.7%)	5 (14.3%)	1 (7.1%)	0	1 (3.4%)
Grade 2	1 (5.9%)	0	1 (2.9%)	0	1 (6.7%)	1 (3.4%)
Grade 3	1 (5.9%)	0	1 (2.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal and abdominal pains (excl oral and throat) (cont)						
Abdominal pain	7 (10.1%)	8 (10.5%)	15 (10.3%)	0	5 (7.2%)	5 (4.2%)
Grade 1	4 (5.8%)	4 (5.3%)	8 (5.5%)	0	3 (4.3%)	3 (2.5%)
Grade 2	2 (2.9%)	3 (3.9%)	5 (3.4%)	0	2 (2.9%)	2 (1.7%)
Grade 3	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0
Abdominal pain upper	3 (4.3%)	2 (2.6%)	5 (3.4%)	2 (4.0%)	3 (4.3%)	5 (4.2%)
Grade 1	3 (4.3%)	1 (1.3%)	4 (2.8%)	1 (2.0%)	2 (2.9%)	3 (2.5%)
Grade 2	0	1 (1.3%)	1 (0.7%)	1 (2.0%)	1 (1.4%)	2 (1.7%)
Abdominal rigidity	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Oesophageal pain	0	1 (1.3%)	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal and abdominal pains (excl oral and throat) (cont)						
Abdominal pain	4 (23.5%)	3 (16.7%)	7 (20.0%)	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 1	2 (11.8%)	3 (16.7%)	5 (14.3%)	1 (7.1%)	0	1 (3.4%)
Grade 2	1 (5.9%)	0	1 (2.9%)	0	1 (6.7%)	1 (3.4%)
Grade 3	1 (5.9%)	0	1 (2.9%)	0	0	0
Abdominal pain upper	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Abdominal rigidity	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Oesophageal pain	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal and abdominal pains (excl oral and throat) (cont)						
Oesophageal pain (cont)						
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0
Flatulence, bloating and distension	4 (5.8%)	6 (7.9%)	10 (6.9%)	0	2 (2.9%)	2 (1.7%)
Grade 1	2 (2.9%)	6 (7.9%)	8 (5.5%)	0	1 (1.4%)	1 (0.8%)
Grade 2	2 (2.9%)	0	2 (1.4%)	0	1 (1.4%)	1 (0.8%)
Abdominal distension	3 (4.3%)	2 (2.6%)	5 (3.4%)	0	1 (1.4%)	1 (0.8%)
Grade 1	1 (1.4%)	2 (2.6%)	3 (2.1%)	0	1 (1.4%)	1 (0.8%)
Grade 2	2 (2.9%)	0	2 (1.4%)	0	0	0
Flatulence	2 (2.9%)	5 (6.6%)	7 (4.8%)	0	1 (1.4%)	1 (0.8%)
Grade 1	2 (2.9%)	5 (6.6%)	7 (4.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal and abdominal pains (excl oral and throat) (cont)						
Oesophageal pain (cont)						
Grade 2	0	0	0	0	0	0
Flatulence, bloating and distension	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 1	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Abdominal distension	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Flatulence	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 1	1 (5.9%)	0	1 (2.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Flatulence, bloating and distension (cont)						
Flatulence (cont)						
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Gastrointestinal signs and symptoms NEC	4 (5.8%)	1 (1.3%)	5 (3.4%)	0	4 (5.8%)	4 (3.4%)
Grade 1	4 (5.8%)	0	4 (2.8%)	0	3 (4.3%)	3 (2.5%)
Grade 2	0	1 (1.3%)	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Abdominal discomfort	3 (4.3%)	1 (1.3%)	4 (2.8%)	0	2 (2.9%)	2 (1.7%)
Grade 1	3 (4.3%)	0	3 (2.1%)	0	2 (2.9%)	2 (1.7%)
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0
Dysphagia	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Flatulence, bloating and distension (cont)						
Flatulence (cont)						
Grade 2	0	0	0	0	0	0
Gastrointestinal signs and symptoms NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Abdominal discomfort	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Dysphagia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal signs and symptoms NEC (cont)						
Anal incontinence	0	0	0	0	2 (2.9%)	2 (1.7%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Haemorrhoids and gastrointestinal varices (excl oesophageal)	3 (4.3%)	0	3 (2.1%)	0	2 (2.9%)	2 (1.7%)
Grade 1	2 (2.9%)	0	2 (1.4%)	0	1 (1.4%)	1 (0.8%)
Grade 2	1 (1.4%)	0	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Haemorrhoids	2 (2.9%)	0	2 (1.4%)	0	2 (2.9%)	2 (1.7%)
Grade 1	1 (1.4%)	0	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Grade 2	1 (1.4%)	0	1 (0.7%)	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal signs and symptoms NEC (cont)						
Anal incontinence	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Haemorrhoids and gastrointestinal varices (excl oesophageal)	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Haemorrhoids	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Haemorrhoids and gastrointestinal varices (excl oesophageal) (cont)						
Haemorrhoidal haemorrhage	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Anal and rectal pains	2 (2.9%)	0	2 (1.4%)	0	0	0
Grade 2	2 (2.9%)	0	2 (1.4%)	0	0	0
Proctalgia	2 (2.9%)	0	2 (1.4%)	0	0	0
Grade 2	2 (2.9%)	0	2 (1.4%)	0	0	0
Intestinal haemorrhages	2 (2.9%)	1 (1.3%)	3 (2.1%)	0	3 (4.3%)	3 (2.5%)
Grade 1	0	1 (1.3%)	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Grade 2	1 (1.4%)	0	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Grade 3	1 (1.4%)	0	1 (0.7%)	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Haemorrhoids and gastrointestinal varices (excl oesophageal) (cont)						
Haemorrhoidal haemorrhage	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Anal and rectal pains	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Proctalgia	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Intestinal haemorrhages	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 1	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Intestinal haemorrhages (cont)						
Rectal haemorrhage	2 (2.9%)	0	2 (1.4%)	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 2	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 3	1 (1.4%)	0	1 (0.7%)	0	0	0
Anal haemorrhage	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Lower gastrointestinal haemorrhage	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Small intestinal haemorrhage	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 3	0	0	0	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Intestinal haemorrhages (cont)						
Rectal haemorrhage	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 1	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Anal haemorrhage	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Lower gastrointestinal haemorrhage	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Small intestinal haemorrhage	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Oral dryness and saliva altered	2 (2.9%)	0	2 (1.4%)	1 (2.0%)	2 (2.9%)	3 (2.5%)
Grade 1	2 (2.9%)	0	2 (1.4%)	1 (2.0%)	0	1 (0.8%)
Grade 2	0	0	0	0	2 (2.9%)	2 (1.7%)
Dry mouth	2 (2.9%)	0	2 (1.4%)	1 (2.0%)	2 (2.9%)	3 (2.5%)
Grade 1	2 (2.9%)	0	2 (1.4%)	1 (2.0%)	0	1 (0.8%)
Grade 2	0	0	0	0	2 (2.9%)	2 (1.7%)
Oral soft tissue pain and paraesthesia	2 (2.9%)	0	2 (1.4%)	0	1 (1.4%)	1 (0.8%)
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 3	1 (1.4%)	0	1 (0.7%)	0	0	0
Lip pain	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
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Data Extracted: CRF data: 01JUL2019
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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Oral dryness and saliva altered	0	0	0	1 (7.1%)	0	1 (3.4%)
Grade 1	0	0	0	1 (7.1%)	0	1 (3.4%)
Grade 2	0	0	0	0	0	0
Dry mouth	0	0	0	1 (7.1%)	0	1 (3.4%)
Grade 1	0	0	0	1 (7.1%)	0	1 (3.4%)
Grade 2	0	0	0	0	0	0
Oral soft tissue pain and paraesthesia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Lip pain	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Oral soft tissue pain and paraesthesia (cont)						
Odynophagia	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 3	1 (1.4%)	0	1 (0.7%)	0	0	0
Oral pain	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Dental pain and sensation disorders	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Toothache	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Dyspeptic signs and symptoms	1 (1.4%)	2 (2.6%)	3 (2.1%)	1 (2.0%)	1 (1.4%)	2 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Oral soft tissue pain and paraesthesia (cont)						
Odynophagia	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Oral pain	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Dental pain and sensation disorders	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 1	0	0	0	0	1 (6.7%)	1 (3.4%)
Toothache	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 1	0	0	0	0	1 (6.7%)	1 (3.4%)
Dyspeptic signs and symptoms	0	0	0	1 (7.1%)	2 (13.3%)	3 (10.3%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Dyspeptic signs and symptoms (cont)						
(cont)						
Grade 1	1 (1.4%)	2 (2.6%)	3 (2.1%)	1 (2.0%)	1 (1.4%)	2 (1.7%)
Dyspepsia	1 (1.4%)	2 (2.6%)	3 (2.1%)	1 (2.0%)	1 (1.4%)	2 (1.7%)
Grade 1	1 (1.4%)	2 (2.6%)	3 (2.1%)	1 (2.0%)	1 (1.4%)	2 (1.7%)
Epigastric discomfort	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Gastric ulcers and perforation	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Gastric ulcer	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Dyspeptic signs and symptoms (cont)						
(cont)						
Grade 1	0	0	0	1 (7.1%)	2 (13.3%)	3 (10.3%)
Dyspepsia	0	0	0	1 (7.1%)	2 (13.3%)	3 (10.3%)
Grade 1	0	0	0	1 (7.1%)	2 (13.3%)	3 (10.3%)
Epigastric discomfort	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 1	0	0	0	0	1 (6.7%)	1 (3.4%)
Gastric ulcers and perforation	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 2	1 (5.9%)	0	1 (2.9%)	0	0	0
Gastric ulcer	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 2	1 (5.9%)	0	1 (2.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal vascular occlusion and infarction	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Mesenteric vein thrombosis	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Oral soft tissue disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Cheilitis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal vascular occlusion and infarction	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 5	1 (5.9%)	0	1 (2.9%)	0	0	0
Mesenteric vein thrombosis	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 5	1 (5.9%)	0	1 (2.9%)	0	0	0
Oral soft tissue disorders NEC	1 (5.9%)	1 (5.6%)	2 (5.7%)	0	1 (6.7%)	1 (3.4%)
Grade 1	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 2	0	1 (5.6%)	1 (2.9%)	0	1 (6.7%)	1 (3.4%)
Cheilitis	1 (5.9%)	1 (5.6%)	2 (5.7%)	0	1 (6.7%)	1 (3.4%)
Grade 1	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 2	0	1 (5.6%)	1 (2.9%)	0	1 (6.7%)	1 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Peritoneal and retroperitoneal disorders	0	1 (1.3%)	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 3	0	1 (1.3%)	1 (0.7%)	0	0	0
Ascites	0	1 (1.3%)	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 3	0	1 (1.3%)	1 (0.7%)	0	0	0
Stomatitis and ulceration	1 (1.4%)	3 (3.9%)	4 (2.8%)	0	0	0
Grade 1	1 (1.4%)	2 (2.6%)	3 (2.1%)	0	0	0
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0
Mouth ulceration	1 (1.4%)	2 (2.6%)	3 (2.1%)	0	0	0
Grade 1	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Peritoneal and retroperitoneal disorders	1 (5.9%)	0	1 (2.9%)	1 (7.1%)	0	1 (3.4%)
Grade 2	0	0	0	1 (7.1%)	0	1 (3.4%)
Grade 3	1 (5.9%)	0	1 (2.9%)	0	0	0
Ascites	1 (5.9%)	0	1 (2.9%)	1 (7.1%)	0	1 (3.4%)
Grade 2	0	0	0	1 (7.1%)	0	1 (3.4%)
Grade 3	1 (5.9%)	0	1 (2.9%)	0	0	0
Stomatitis and ulceration	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Mouth ulceration	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Stomatitis and ulceration (cont)						
Mouth ulceration (cont)						
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0
Stomatitis	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Dental and periodontal infections and inflammations	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dental caries	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dental disorders NEC	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Stomatitis and ulceration (cont)						
Mouth ulceration (cont)						
Grade 2	0	0	0	0	0	0
Stomatitis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dental and periodontal infections and inflammations	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 1	0	0	0	0	1 (6.7%)	1 (3.4%)
Dental caries	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 1	0	0	0	0	1 (6.7%)	1 (3.4%)
Dental disorders NEC	0	0	0	0	1 (6.7%)	1 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Dental disorders NEC (cont)						
(cont)						
Grade 1	0	0	0	0	0	0
Periodontal disease	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Gastric and oesophageal haemorrhages	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 3	0	0	0	0	1 (1.4%)	1 (0.8%)
Gastric haemorrhage	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 3	0	0	0	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Dental disorders NEC (cont)						
(cont)						
Grade 1	0	0	0	0	1 (6.7%)	1 (3.4%)
Periodontal disease	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 1	0	0	0	0	1 (6.7%)	1 (3.4%)
Gastric and oesophageal haemorrhages	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Gastric haemorrhage	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal inflammatory disorders NEC	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 2	0	0	0	0	0	0
Enteritis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Enterocolitis	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Gastrointestinal spastic and hypermotility disorders	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal inflammatory disorders NEC	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (5.6%)	1 (2.9%)	0	0	0
Enteritis	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 2	0	1 (5.6%)	1 (2.9%)	0	0	0
Enterocolitis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Gastrointestinal spastic and hypermotility disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal spastic and hypermotility disorders (cont)						
Defaecation urgency	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Gastrointestinal stenosis and obstruction NEC	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 4	0	1 (1.3%)	1 (0.7%)	0	0	0
Ileus	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 4	0	1 (1.3%)	1 (0.7%)	0	0	0
Subileus	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 4	0	1 (1.3%)	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal spastic and hypermotility disorders (cont)						
Defaecation urgency	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Gastrointestinal stenosis and obstruction NEC	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Ileus	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Subileus	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gingival haemorrhages	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Gingival bleeding	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Non-site specific gastrointestinal haemorrhages	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 3	0	0	0	0	1 (1.4%)	1 (0.8%)
Gastrointestinal haemorrhage	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 3	0	0	0	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gingival haemorrhages	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 1	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Gingival bleeding	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 1	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Non-site specific gastrointestinal haemorrhages	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Gastrointestinal haemorrhage	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Oesophageal varices	0	0	0	1 (2.0%)	1 (1.4%)	2 (1.7%)
Grade 1	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Varices oesophageal	0	0	0	1 (2.0%)	1 (1.4%)	2 (1.7%)
Grade 1	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Oral soft tissue haemorrhages	0	0	0	1 (2.0%)	1 (1.4%)	2 (1.7%)
Grade 1	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Mouth haemorrhage	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Oesophageal varices	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Varices oesophageal	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Oral soft tissue haemorrhages	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Mouth haemorrhage	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Oral soft tissue haemorrhages (cont)						
Oral mucosa haematoma	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 1	0	0	0	1 (2.0%)	0	1 (0.8%)
Oral soft tissue infections	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 2	0	0	0	1 (2.0%)	0	1 (0.8%)
Angular cheilitis	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 2	0	0	0	1 (2.0%)	0	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Oral soft tissue haemorrhages (cont)						
Oral mucosa haematoma	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Oral soft tissue infections	0	0	0	1 (7.1%)	0	1 (3.4%)
Grade 2	0	0	0	1 (7.1%)	0	1 (3.4%)
Angular cheilitis	0	0	0	1 (7.1%)	0	1 (3.4%)
Grade 2	0	0	0	1 (7.1%)	0	1 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions	29 (42.0%)	34 (44.7%)	63 (43.4%)	12 (24.0%)	18 (26.1%)	30 (25.2%)
Grade 1	20 (29.0%)	19 (25.0%)	39 (26.9%)	9 (18.0%)	7 (10.1%)	16 (13.4%)
Grade 2	6 (8.7%)	14 (18.4%)	20 (13.8%)	3 (6.0%)	9 (13.0%)	12 (10.1%)
Grade 3	2 (2.9%)	1 (1.3%)	3 (2.1%)	0	2 (2.9%)	2 (1.7%)
Grade 5	1 (1.4%)	0	1 (0.7%)	0	0	0
Asthenic conditions	14 (20.3%)	19 (25.0%)	33 (22.8%)	3 (6.0%)	10 (14.5%)	13 (10.9%)
Grade 1	12 (17.4%)	10 (13.2%)	22 (15.2%)	2 (4.0%)	2 (2.9%)	4 (3.4%)
Grade 2	2 (2.9%)	8 (10.5%)	10 (6.9%)	1 (2.0%)	6 (8.7%)	7 (5.9%)
Grade 3	0	1 (1.3%)	1 (0.7%)	0	2 (2.9%)	2 (1.7%)
Fatigue	9 (13.0%)	9 (11.8%)	18 (12.4%)	2 (4.0%)	6 (8.7%)	8 (6.7%)
Grade 1	7 (10.1%)	6 (7.9%)	13 (9.0%)	1 (2.0%)	2 (2.9%)	3 (2.5%)
Grade 2	2 (2.9%)	3 (3.9%)	5 (3.4%)	1 (2.0%)	4 (5.8%)	5 (4.2%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions	9 (52.9%)	11 (61.1%)	20 (57.1%)	5 (35.7%)	3 (20.0%)	8 (27.6%)
Grade 1	6 (35.3%)	9 (50.0%)	15 (42.9%)	2 (14.3%)	2 (13.3%)	4 (13.8%)
Grade 2	3 (17.6%)	2 (11.1%)	5 (14.3%)	3 (21.4%)	1 (6.7%)	4 (13.8%)
Grade 3	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Asthenic conditions	5 (29.4%)	4 (22.2%)	9 (25.7%)	2 (14.3%)	1 (6.7%)	3 (10.3%)
Grade 1	4 (23.5%)	2 (11.1%)	6 (17.1%)	0	1 (6.7%)	1 (3.4%)
Grade 2	1 (5.9%)	2 (11.1%)	3 (8.6%)	2 (14.3%)	0	2 (6.9%)
Grade 3	0	0	0	0	0	0
Fatigue	4 (23.5%)	2 (11.1%)	6 (17.1%)	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 1	4 (23.5%)	1 (5.6%)	5 (14.3%)	0	1 (6.7%)	1 (3.4%)
Grade 2	0	1 (5.6%)	1 (2.9%)	1 (7.1%)	0	1 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Asthenic conditions (cont)						
Asthenia	3 (4.3%)	7 (9.2%)	10 (6.9%)	1 (2.0%)	3 (4.3%)	4 (3.4%)
Grade 1	3 (4.3%)	3 (3.9%)	6 (4.1%)	1 (2.0%)	0	1 (0.8%)
Grade 2	0	3 (3.9%)	3 (2.1%)	0	2 (2.9%)	2 (1.7%)
Grade 3	0	1 (1.3%)	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Malaise	2 (2.9%)	3 (3.9%)	5 (3.4%)	0	2 (2.9%)	2 (1.7%)
Grade 1	2 (2.9%)	1 (1.3%)	3 (2.1%)	0	0	0
Grade 2	0	2 (2.6%)	2 (1.4%)	0	1 (1.4%)	1 (0.8%)
Grade 3	0	0	0	0	1 (1.4%)	1 (0.8%)
Febrile disorders	8 (11.6%)	7 (9.2%)	15 (10.3%)	1 (2.0%)	2 (2.9%)	3 (2.5%)
Grade 1	6 (8.7%)	6 (7.9%)	12 (8.3%)	1 (2.0%)	2 (2.9%)	3 (2.5%)
Grade 2	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Asthenic conditions (cont)						
Asthenia	1 (5.9%)	2 (11.1%)	3 (8.6%)	1 (7.1%)	0	1 (3.4%)
Grade 1	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 2	1 (5.9%)	1 (5.6%)	2 (5.7%)	1 (7.1%)	0	1 (3.4%)
Grade 3	0	0	0	0	0	0
Malaise	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Febrile disorders	2 (11.8%)	3 (16.7%)	5 (14.3%)	3 (21.4%)	1 (6.7%)	4 (13.8%)
Grade 1	1 (5.9%)	3 (16.7%)	4 (11.4%)	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 2	1 (5.9%)	0	1 (2.9%)	2 (14.3%)	0	2 (6.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Febrile disorders (cont)						
(cont)						
Grade 3	1 (1.4%)	0	1 (0.7%)	0	0	0
Pyrexia	8 (11.6%)	7 (9.2%)	15 (10.3%)	1 (2.0%)	2 (2.9%)	3 (2.5%)
Grade 1	6 (8.7%)	6 (7.9%)	12 (8.3%)	1 (2.0%)	2 (2.9%)	3 (2.5%)
Grade 2	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0
Grade 3	1 (1.4%)	0	1 (0.7%)	0	0	0
Oedema NEC	4 (5.8%)	7 (9.2%)	11 (7.6%)	3 (6.0%)	2 (2.9%)	5 (4.2%)
Grade 1	2 (2.9%)	5 (6.6%)	7 (4.8%)	2 (4.0%)	2 (2.9%)	4 (3.4%)
Grade 2	2 (2.9%)	2 (2.6%)	4 (2.8%)	1 (2.0%)	0	1 (0.8%)
Oedema peripheral	4 (5.8%)	5 (6.6%)	9 (6.2%)	3 (6.0%)	1 (1.4%)	4 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Febrile disorders (cont)						
(cont)						
Grade 3	0	0	0	0	0	0
Pyrexia	2 (11.8%)	3 (16.7%)	5 (14.3%)	3 (21.4%)	1 (6.7%)	4 (13.8%)
Grade 1	1 (5.9%)	3 (16.7%)	4 (11.4%)	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 2	1 (5.9%)	0	1 (2.9%)	2 (14.3%)	0	2 (6.9%)
Grade 3	0	0	0	0	0	0
Oedema NEC	3 (17.6%)	3 (16.7%)	6 (17.1%)	1 (7.1%)	0	1 (3.4%)
Grade 1	2 (11.8%)	3 (16.7%)	5 (14.3%)	1 (7.1%)	0	1 (3.4%)
Grade 2	1 (5.9%)	0	1 (2.9%)	0	0	0
Oedema peripheral	2 (11.8%)	3 (16.7%)	5 (14.3%)	1 (7.1%)	0	1 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Oedema NEC (cont)						
Oedema peripheral (cont)						
Grade 1	3 (4.3%)	4 (5.3%)	7 (4.8%)	2 (4.0%)	1 (1.4%)	3 (2.5%)
Grade 2	1 (1.4%)	1 (1.3%)	2 (1.4%)	1 (2.0%)	0	1 (0.8%)
Generalised oedema	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 2	1 (1.4%)	0	1 (0.7%)	0	0	0
Oedema	0	2 (2.6%)	2 (1.4%)	0	1 (1.4%)	1 (0.8%)
Grade 1	0	1 (1.3%)	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0
Pain and discomfort NEC	6 (8.7%)	2 (2.6%)	8 (5.5%)	1 (2.0%)	0	1 (0.8%)
Grade 1	4 (5.8%)	2 (2.6%)	6 (4.1%)	1 (2.0%)	0	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Oedema NEC (cont)						
Oedema peripheral (cont)						
Grade 1	1 (5.9%)	3 (16.7%)	4 (11.4%)	1 (7.1%)	0	1 (3.4%)
Grade 2	1 (5.9%)	0	1 (2.9%)	0	0	0
Generalised oedema	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Oedema	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 1	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Pain and discomfort NEC	1 (5.9%)	3 (16.7%)	4 (11.4%)	0	1 (6.7%)	1 (3.4%)
Grade 1	1 (5.9%)	3 (16.7%)	4 (11.4%)	0	1 (6.7%)	1 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Pain and discomfort NEC (cont)						
(cont)						
Grade 2	2 (2.9%)	0	2 (1.4%)	0	0	0
Chest pain	3 (4.3%)	2 (2.6%)	5 (3.4%)	1 (2.0%)	0	1 (0.8%)
Grade 1	3 (4.3%)	2 (2.6%)	5 (3.4%)	1 (2.0%)	0	1 (0.8%)
Pain	2 (2.9%)	0	2 (1.4%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 2	1 (1.4%)	0	1 (0.7%)	0	0	0
Facial pain	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	1 (1.4%)	0	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Pain and discomfort NEC (cont)						
(cont)						
Grade 2	0	0	0	0	0	0
Chest pain	1 (5.9%)	1 (5.6%)	2 (5.7%)	0	1 (6.7%)	1 (3.4%)
Grade 1	1 (5.9%)	1 (5.6%)	2 (5.7%)	0	1 (6.7%)	1 (3.4%)
Pain	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Facial pain	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 1	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Pain and discomfort NEC (cont)						
Chest discomfort	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
General signs and symptoms NEC	4 (5.8%)	5 (6.6%)	9 (6.2%)	3 (6.0%)	3 (4.3%)	6 (5.0%)
Grade 1	3 (4.3%)	5 (6.6%)	8 (5.5%)	2 (4.0%)	2 (2.9%)	4 (3.4%)
Grade 2	1 (1.4%)	0	1 (0.7%)	1 (2.0%)	1 (1.4%)	2 (1.7%)
Peripheral swelling	3 (4.3%)	0	3 (2.1%)	1 (2.0%)	0	1 (0.8%)
Grade 1	2 (2.9%)	0	2 (1.4%)	1 (2.0%)	0	1 (0.8%)
Grade 2	1 (1.4%)	0	1 (0.7%)	0	0	0
Influenza like illness	1 (1.4%)	2 (2.6%)	3 (2.1%)	2 (4.0%)	3 (4.3%)	5 (4.2%)
Grade 1	1 (1.4%)	2 (2.6%)	3 (2.1%)	1 (2.0%)	2 (2.9%)	3 (2.5%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Pain and discomfort NEC (cont)						
Chest discomfort	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 1	0	1 (5.6%)	1 (2.9%)	0	0	0
General signs and symptoms NEC	1 (5.9%)	0	1 (2.9%)	1 (7.1%)	0	1 (3.4%)
Grade 1	1 (5.9%)	0	1 (2.9%)	1 (7.1%)	0	1 (3.4%)
Grade 2	0	0	0	0	0	0
Peripheral swelling	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Influenza like illness	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 1	1 (5.9%)	0	1 (2.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
General signs and symptoms NEC (cont)						
Influenza like illness (cont)						
Grade 2	0	0	0	1 (2.0%)	1 (1.4%)	2 (1.7%)
Crepitations	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
General physical health deterioration	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Swelling	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
General signs and symptoms NEC (cont)						
Influenza like illness (cont)						
Grade 2	0	0	0	0	0	0
Crepitations	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
General physical health deterioration	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Swelling	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
General signs and symptoms NEC (cont)						
Xerosis	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Mucosal findings abnormal	2 (2.9%)	1 (1.3%)	3 (2.1%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 3	1 (1.4%)	0	1 (0.7%)	0	0	0
Mucosal inflammation	2 (2.9%)	0	2 (1.4%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 3	1 (1.4%)	0	1 (0.7%)	0	0	0
Mucosal haemorrhage	0	1 (1.3%)	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
General signs and symptoms NEC (cont)						
Xerosis	0	0	0	1 (7.1%)	0	1 (3.4%)
Grade 1	0	0	0	1 (7.1%)	0	1 (3.4%)
Mucosal findings abnormal	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Mucosal inflammation	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Mucosal haemorrhage	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Mucosal findings abnormal (cont)						
Mucosal haemorrhage (cont)						
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0
Death and sudden death	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 5	1 (1.4%)	0	1 (0.7%)	0	0	0
Sudden death	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 5	1 (1.4%)	0	1 (0.7%)	0	0	0
Feelings and sensations NEC	1 (1.4%)	5 (6.6%)	6 (4.1%)	1 (2.0%)	1 (1.4%)	2 (1.7%)
Grade 1	1 (1.4%)	4 (5.3%)	5 (3.4%)	1 (2.0%)	1 (1.4%)	2 (1.7%)
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Mucosal findings abnormal (cont)						
Mucosal haemorrhage (cont)						
Grade 2	0	0	0	0	0	0
Death and sudden death	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Sudden death	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Feelings and sensations NEC	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 1	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Feelings and sensations NEC (cont)						
Chills	1 (1.4%)	3 (3.9%)	4 (2.8%)	0	0	0
Grade 1	1 (1.4%)	2 (2.6%)	3 (2.1%)	0	0	0
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0
Early satiety	0	2 (2.6%)	2 (1.4%)	1 (2.0%)	0	1 (0.8%)
Grade 1	0	2 (2.6%)	2 (1.4%)	1 (2.0%)	0	1 (0.8%)
Feeling cold	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Feeling hot	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Feelings and sensations NEC (cont)						
Chills	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Early satiety	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Feeling cold	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 1	0	1 (5.6%)	1 (2.9%)	0	0	0
Feeling hot	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Gait disturbances	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Gait disturbance	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Healing abnormal NEC	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Impaired healing	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Implant and catheter site reactions	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Gait disturbances	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Gait disturbance	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Healing abnormal NEC	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Impaired healing	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Implant and catheter site reactions	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 2	0	0	0	0	1 (6.7%)	1 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Implant and catheter site reactions (cont)						
Catheter site haemorrhage	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0
Catheter site pain	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Withdrawal and rebound effects	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Drug withdrawal syndrome	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Implant and catheter site reactions (cont)						
Catheter site haemorrhage	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Catheter site pain	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 2	0	0	0	0	1 (6.7%)	1 (3.4%)
Withdrawal and rebound effects	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Drug withdrawal syndrome	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations	34 (49.3%)	32 (42.1%)	66 (45.5%)	15 (30.0%)	22 (31.9%)	37 (31.1%)
Grade 1	14 (20.3%)	12 (15.8%)	26 (17.9%)	5 (10.0%)	6 (8.7%)	11 (9.2%)
Grade 2	9 (13.0%)	16 (21.1%)	25 (17.2%)	5 (10.0%)	13 (18.8%)	18 (15.1%)
Grade 3	9 (13.0%)	2 (2.6%)	11 (7.6%)	4 (8.0%)	3 (4.3%)	7 (5.9%)
Grade 4	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0
Grade 5	1 (1.4%)	1 (1.3%)	2 (1.4%)	1 (2.0%)	0	1 (0.8%)
Urinary tract infections	10 (14.5%)	3 (3.9%)	13 (9.0%)	4 (8.0%)	3 (4.3%)	7 (5.9%)
Grade 1	3 (4.3%)	0	3 (2.1%)	0	0	0
Grade 2	6 (8.7%)	3 (3.9%)	9 (6.2%)	3 (6.0%)	3 (4.3%)	6 (5.0%)
Grade 3	1 (1.4%)	0	1 (0.7%)	1 (2.0%)	0	1 (0.8%)
Urinary tract infection	6 (8.7%)	3 (3.9%)	9 (6.2%)	3 (6.0%)	3 (4.3%)	6 (5.0%)
Grade 1	2 (2.9%)	0	2 (1.4%)	0	0	0
Grade 2	4 (5.8%)	3 (3.9%)	7 (4.8%)	2 (4.0%)	3 (4.3%)	5 (4.2%)
Grade 3	0	0	0	1 (2.0%)	0	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations	3 (17.6%)	12 (66.7%)	15 (42.9%)	7 (50.0%)	11 (73.3%)	18 (62.1%)
Grade 1	2 (11.8%)	3 (16.7%)	5 (14.3%)	2 (14.3%)	2 (13.3%)	4 (13.8%)
Grade 2	1 (5.9%)	7 (38.9%)	8 (22.9%)	3 (21.4%)	7 (46.7%)	10 (34.5%)
Grade 3	0	2 (11.1%)	2 (5.7%)	2 (14.3%)	2 (13.3%)	4 (13.8%)
Grade 4	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Urinary tract infections	0	1 (5.6%)	1 (2.9%)	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (5.6%)	1 (2.9%)	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 3	0	0	0	0	0	0
Urinary tract infection	0	1 (5.6%)	1 (2.9%)	1 (7.1%)	0	1 (3.4%)
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (5.6%)	1 (2.9%)	1 (7.1%)	0	1 (3.4%)
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Urinary tract infections (cont)						
Cystitis	4 (5.8%)	0	4 (2.8%)	1 (2.0%)	0	1 (0.8%)
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 2	2 (2.9%)	0	2 (1.4%)	1 (2.0%)	0	1 (0.8%)
Grade 3	1 (1.4%)	0	1 (0.7%)	0	0	0
Pyelocystitis	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 2	1 (1.4%)	0	1 (0.7%)	0	0	0
Lower respiratory tract and lung infections	7 (10.1%)	6 (7.9%)	13 (9.0%)	3 (6.0%)	4 (5.8%)	7 (5.9%)
Grade 1	1 (1.4%)	2 (2.6%)	3 (2.1%)	0	0	0
Grade 2	1 (1.4%)	1 (1.3%)	2 (1.4%)	1 (2.0%)	2 (2.9%)	3 (2.5%)
Grade 3	5 (7.2%)	1 (1.3%)	6 (4.1%)	1 (2.0%)	2 (2.9%)	3 (2.5%)
Grade 4	0	1 (1.3%)	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Urinary tract infections (cont)						
Cystitis	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 3	0	0	0	0	0	0
Pyelocystitis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Lower respiratory tract and lung infections	1 (5.9%)	4 (22.2%)	5 (14.3%)	3 (21.4%)	5 (33.3%)	8 (27.6%)
Grade 1	1 (5.9%)	0	1 (2.9%)	0	1 (6.7%)	1 (3.4%)
Grade 2	0	4 (22.2%)	4 (11.4%)	1 (7.1%)	2 (13.3%)	3 (10.3%)
Grade 3	0	0	0	2 (14.3%)	2 (13.3%)	4 (13.8%)
Grade 4	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Lower respiratory tract and lung infections (cont)						
(cont)						
Grade 5	0	1 (1.3%)	1 (0.7%)	1 (2.0%)	0	1 (0.8%)
Pneumonia	4 (5.8%)	4 (5.3%)	8 (5.5%)	3 (6.0%)	2 (2.9%)	5 (4.2%)
Grade 2	0	1 (1.3%)	1 (0.7%)	1 (2.0%)	0	1 (0.8%)
Grade 3	4 (5.8%)	1 (1.3%)	5 (3.4%)	1 (2.0%)	2 (2.9%)	3 (2.5%)
Grade 4	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 5	0	1 (1.3%)	1 (0.7%)	1 (2.0%)	0	1 (0.8%)
Lower respiratory tract infection	2 (2.9%)	0	2 (1.4%)	0	1 (1.4%)	1 (0.8%)
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 2	1 (1.4%)	0	1 (0.7%)	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Lower respiratory tract and lung infections (cont)						
(cont)						
Grade 5	0	0	0	0	0	0
Pneumonia	0	1 (5.6%)	1 (2.9%)	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 2	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 3	0	0	0	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 4	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Lower respiratory tract infection	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 1	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Lower respiratory tract and lung infections (cont)						
Lung infection	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 3	1 (1.4%)	0	1 (0.7%)	0	0	0
Bronchitis	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 3	0	0	0	0	0	0
Tracheobronchitis	0	2 (2.6%)	2 (1.4%)	0	0	0
Grade 1	0	2 (2.6%)	2 (1.4%)	0	0	0
Upper respiratory tract infections	8 (11.6%)	8 (10.5%)	16 (11.0%)	2 (4.0%)	8 (11.6%)	10 (8.4%)
Grade 1	7 (10.1%)	4 (5.3%)	11 (7.6%)	2 (4.0%)	4 (5.8%)	6 (5.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Lower respiratory tract and lung infections (cont)						
Lung infection	0	0	0	1 (7.1%)	0	1 (3.4%)
Grade 3	0	0	0	1 (7.1%)	0	1 (3.4%)
Bronchitis	0	3 (16.7%)	3 (8.6%)	1 (7.1%)	4 (26.7%)	5 (17.2%)
Grade 1	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 2	0	3 (16.7%)	3 (8.6%)	1 (7.1%)	2 (13.3%)	3 (10.3%)
Grade 3	0	0	0	0	1 (6.7%)	1 (3.4%)
Tracheobronchitis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Upper respiratory tract infections	0	7 (38.9%)	7 (20.0%)	3 (21.4%)	4 (26.7%)	7 (24.1%)
Grade 1	0	3 (16.7%)	3 (8.6%)	1 (7.1%)	1 (6.7%)	2 (6.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Upper respiratory tract infections (cont)						
(cont)						
Grade 2	1 (1.4%)	4 (5.3%)	5 (3.4%)	0	4 (5.8%)	4 (3.4%)
Upper respiratory tract infection	5 (7.2%)	4 (5.3%)	9 (6.2%)	1 (2.0%)	6 (8.7%)	7 (5.9%)
Grade 1	5 (7.2%)	0	5 (3.4%)	1 (2.0%)	2 (2.9%)	3 (2.5%)
Grade 2	0	4 (5.3%)	4 (2.8%)	0	4 (5.8%)	4 (3.4%)
Nasopharyngitis	2 (2.9%)	2 (2.6%)	4 (2.8%)	1 (2.0%)	2 (2.9%)	3 (2.5%)
Grade 1	2 (2.9%)	2 (2.6%)	4 (2.8%)	1 (2.0%)	1 (1.4%)	2 (1.7%)
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Laryngitis	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 2	1 (1.4%)	0	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Upper respiratory tract infections (cont) (cont) (cont)						
Grade 2	0	4 (22.2%)	4 (11.4%)	2 (14.3%)	3 (20.0%)	5 (17.2%)
Upper respiratory tract infection	0	2 (11.1%)	2 (5.7%)	0	1 (6.7%)	1 (3.4%)
Grade 1	0	0	0	0	0	0
Grade 2	0	2 (11.1%)	2 (5.7%)	0	1 (6.7%)	1 (3.4%)
Nasopharyngitis	0	3 (16.7%)	3 (8.6%)	2 (14.3%)	1 (6.7%)	3 (10.3%)
Grade 1	0	2 (11.1%)	2 (5.7%)	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 2	0	1 (5.6%)	1 (2.9%)	1 (7.1%)	0	1 (3.4%)
Laryngitis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Upper respiratory tract infections (cont)						
Rhinitis	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 2	0	0	0	0	0	0
Sinusitis	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	0	0	0
Tonsillitis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Tracheitis	0	1 (1.3%)	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Upper respiratory tract infections (cont)						
Rhinitis	0	2 (11.1%)	2 (5.7%)	0	0	0
Grade 1	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 2	0	1 (5.6%)	1 (2.9%)	0	0	0
Sinusitis	0	0	0	0	2 (13.3%)	2 (6.9%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	2 (13.3%)	2 (6.9%)
Tonsillitis	0	0	0	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 1	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 2	0	0	0	1 (7.1%)	0	1 (3.4%)
Tracheitis	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Upper respiratory tract infections (cont)						
Tracheitis (cont)						
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Herpes viral infections	3 (4.3%)	6 (7.9%)	9 (6.2%)	2 (4.0%)	1 (1.4%)	3 (2.5%)
Grade 1	1 (1.4%)	1 (1.3%)	2 (1.4%)	1 (2.0%)	1 (1.4%)	2 (1.7%)
Grade 2	2 (2.9%)	5 (6.6%)	7 (4.8%)	1 (2.0%)	0	1 (0.8%)
Grade 3	0	0	0	0	0	0
Herpes zoster	3 (4.3%)	2 (2.6%)	5 (3.4%)	1 (2.0%)	0	1 (0.8%)
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 2	2 (2.9%)	2 (2.6%)	4 (2.8%)	1 (2.0%)	0	1 (0.8%)
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Upper respiratory tract infections (cont)						
Tracheitis (cont)						
Grade 1	0	0	0	0	0	0
Herpes viral infections	1 (5.9%)	2 (11.1%)	3 (8.6%)	1 (7.1%)	2 (13.3%)	3 (10.3%)
Grade 1	0	0	0	0	0	0
Grade 2	1 (5.9%)	1 (5.6%)	2 (5.7%)	1 (7.1%)	2 (13.3%)	3 (10.3%)
Grade 3	0	1 (5.6%)	1 (2.9%)	0	0	0
Herpes zoster	0	1 (5.6%)	1 (2.9%)	1 (7.1%)	0	1 (3.4%)
Grade 1	0	0	0	1 (7.1%)	0	1 (3.4%)
Grade 2	0	0	0	0	0	0
Grade 3	0	1 (5.6%)	1 (2.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Herpes viral infections (cont)						
Oral herpes	0	4 (5.3%)	4 (2.8%)	1 (2.0%)	0	1 (0.8%)
Grade 1	0	1 (1.3%)	1 (0.7%)	1 (2.0%)	0	1 (0.8%)
Grade 2	0	3 (3.9%)	3 (2.1%)	0	0	0
Genital herpes	0	0	0	1 (2.0%)	1 (1.4%)	2 (1.7%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	1 (2.0%)	0	1 (0.8%)
Herpes simplex	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Nasal herpes	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Herpes viral infections (cont)						
Oral herpes	1 (5.9%)	1 (5.6%)	2 (5.7%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	1 (5.9%)	1 (5.6%)	2 (5.7%)	0	0	0
Genital herpes	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Herpes simplex	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 2	0	0	0	0	1 (6.7%)	1 (3.4%)
Nasal herpes	0	0	0	1 (7.1%)	0	1 (3.4%)
Grade 2	0	0	0	1 (7.1%)	0	1 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Herpes viral infections (cont)						
Varicella zoster virus infection	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Dental and oral soft tissue infections	3 (4.3%)	1 (1.3%)	4 (2.8%)	0	1 (1.4%)	1 (0.8%)
Grade 1	3 (4.3%)	1 (1.3%)	4 (2.8%)	0	1 (1.4%)	1 (0.8%)
Gingivitis	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0
Grade 1	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0
Lip infection	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Periodontitis	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Herpes viral infections (cont)						
Varicella zoster virus infection	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 2	0	0	0	0	1 (6.7%)	1 (3.4%)
Dental and oral soft tissue infections	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Gingivitis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Lip infection	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Periodontitis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Dental and oral soft tissue infections (cont)						
Tooth abscess	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Infections NEC	3 (4.3%)	9 (11.8%)	12 (8.3%)	0	1 (1.4%)	1 (0.8%)
Grade 1	1 (1.4%)	2 (2.6%)	3 (2.1%)	0	0	0
Grade 2	1 (1.4%)	7 (9.2%)	8 (5.5%)	0	1 (1.4%)	1 (0.8%)
Grade 3	1 (1.4%)	0	1 (0.7%)	0	0	0
Infection	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	1 (1.4%)	0	1 (0.7%)	0	0	0
Localised infection	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Dental and oral soft tissue infections (cont)						
Tooth abscess	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Infections NEC	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 1	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Infection	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 1	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 3	0	0	0	0	0	0
Localised infection	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Infections NEC (cont)						
Localised infection (cont)						
Grade 2	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0
Respiratory tract infection	1 (1.4%)	6 (7.9%)	7 (4.8%)	0	1 (1.4%)	1 (0.8%)
Grade 1	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0
Grade 2	0	5 (6.6%)	5 (3.4%)	0	1 (1.4%)	1 (0.8%)
Postoperative wound infection	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Wound infection	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Infections NEC (cont)						
Localised infection (cont)						
Grade 2	0	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Postoperative wound infection	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Wound infection	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Sepsis, bacteraemia, viraemia and fungaemia NEC	3 (4.3%)	1 (1.3%)	4 (2.8%)	1 (2.0%)	0	1 (0.8%)
Grade 3	2 (2.9%)	1 (1.3%)	3 (2.1%)	1 (2.0%)	0	1 (0.8%)
Grade 5	1 (1.4%)	0	1 (0.7%)	0	0	0
Sepsis	3 (4.3%)	0	3 (2.1%)	1 (2.0%)	0	1 (0.8%)
Grade 3	2 (2.9%)	0	2 (1.4%)	1 (2.0%)	0	1 (0.8%)
Grade 5	1 (1.4%)	0	1 (0.7%)	0	0	0
Pulmonary sepsis	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 3	0	1 (1.3%)	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Sepsis, bacteraemia, viraemia and fungaemia NEC	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Sepsis	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Pulmonary sepsis	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Skin structures and soft tissue infections	3 (4.3%)	3 (3.9%)	6 (4.1%)	1 (2.0%)	0	1 (0.8%)
Grade 1	0	1 (1.3%)	1 (0.7%)	1 (2.0%)	0	1 (0.8%)
Grade 2	2 (2.9%)	2 (2.6%)	4 (2.8%)	0	0	0
Grade 3	1 (1.4%)	0	1 (0.7%)	0	0	0
Skin infection	3 (4.3%)	1 (1.3%)	4 (2.8%)	0	0	0
Grade 2	2 (2.9%)	1 (1.3%)	3 (2.1%)	0	0	0
Grade 3	1 (1.4%)	0	1 (0.7%)	0	0	0
Folliculitis	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0
Infected skin ulcer	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 1	0	0	0	1 (2.0%)	0	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Skin structures and soft tissue infections	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Skin infection	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Folliculitis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Infected skin ulcer	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Skin structures and soft tissue infections (cont)						
Paronychia	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Abdominal and gastrointestinal infections	1 (1.4%)	2 (2.6%)	3 (2.1%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 3	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 4	0	1 (1.3%)	1 (0.7%)	0	0	0
Anal abscess	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 3	1 (1.4%)	0	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Skin structures and soft tissue infections (cont)						
Paronychia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Abdominal and gastrointestinal infections	1 (5.9%)	1 (5.6%)	2 (5.7%)	0	1 (6.7%)	1 (3.4%)
Grade 1	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 2	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 3	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 4	0	0	0	0	0	0
Anal abscess	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Abdominal and gastrointestinal infections (cont)						
Gastroenteritis	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 3	0	0	0	0	0	0
Peritonitis	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 4	0	1 (1.3%)	1 (0.7%)	0	0	0
Bacterial infections NEC	2 (2.9%)	0	2 (1.4%)	1 (2.0%)	0	1 (0.8%)
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 3	1 (1.4%)	0	1 (0.7%)	1 (2.0%)	0	1 (0.8%)
Cellulitis	1 (1.4%)	0	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Abdominal and gastrointestinal infections (cont)						
Gastroenteritis	1 (5.9%)	1 (5.6%)	2 (5.7%)	0	1 (6.7%)	1 (3.4%)
Grade 1	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 2	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 3	0	1 (5.6%)	1 (2.9%)	0	0	0
Peritonitis	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Bacterial infections NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Cellulitis	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Bacterial infections NEC (cont)						
Cellulitis (cont)						
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Pneumonia bacterial	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 3	1 (1.4%)	0	1 (0.7%)	0	0	0
Gangrene	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 3	0	0	0	1 (2.0%)	0	1 (0.8%)
Fungal infections NEC	1 (1.4%)	1 (1.3%)	2 (1.4%)	1 (2.0%)	0	1 (0.8%)
Grade 1	1 (1.4%)	0	1 (0.7%)	1 (2.0%)	0	1 (0.8%)
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0
Fungal infection	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Bacterial infections NEC (cont)						
Cellulitis (cont)						
Grade 1	0	0	0	0	0	0
Pneumonia bacterial	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Gangrene	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Fungal infections NEC	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 1	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Fungal infection	1 (5.9%)	0	1 (2.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Fungal infections NEC (cont)						
Fungal infection (cont)						
Grade 1	0	0	0	0	0	0
Fungal skin infection	1 (1.4%)	0	1 (0.7%)	1 (2.0%)	0	1 (0.8%)
Grade 1	1 (1.4%)	0	1 (0.7%)	1 (2.0%)	0	1 (0.8%)
Fungal oesophagitis	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0
Borrelial infections	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Lyme disease	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Fungal infections NEC (cont)						
Fungal infection (cont)						
Grade 1	1 (5.9%)	0	1 (2.9%)	0	0	0
Fungal skin infection	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Fungal oesophagitis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Borrelial infections	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Lyme disease	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Candida infections	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	1 (1.4%)	1 (0.8%)
Grade 1	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Oral candidiasis	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Gastrointestinal candidiasis	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Vulvovaginal candidiasis	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Escherichia infections	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Candida infections	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Oral candidiasis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Gastrointestinal candidiasis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Vulvovaginal candidiasis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Escherichia infections	0	0	0	1 (7.1%)	0	1 (3.4%)
Grade 1	0	0	0	1 (7.1%)	0	1 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Escherichia infections (cont)						
(cont)						
Grade 4	1 (1.4%)	0	1 (0.7%)	0	0	0
Escherichia sepsis	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 4	1 (1.4%)	0	1 (0.7%)	0	0	0
Escherichia urinary tract infection	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Influenza viral infections	1 (1.4%)	3 (3.9%)	4 (2.8%)	0	1 (1.4%)	1 (0.8%)
Grade 1	1 (1.4%)	2 (2.6%)	3 (2.1%)	0	0	0
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 3	0	1 (1.3%)	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Escherichia infections (cont)						
(cont)						
Grade 4	0	0	0	0	0	0
Escherichia sepsis	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Escherichia urinary tract infection	0	0	0	1 (7.1%)	0	1 (3.4%)
Grade 1	0	0	0	1 (7.1%)	0	1 (3.4%)
Influenza viral infections	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 1	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Influenza viral infections (cont)						
Influenza	1 (1.4%)	3 (3.9%)	4 (2.8%)	0	1 (1.4%)	1 (0.8%)
Grade 1	1 (1.4%)	2 (2.6%)	3 (2.1%)	0	0	0
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 3	0	1 (1.3%)	1 (0.7%)	0	0	0
Male reproductive tract infections	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 2	1 (1.4%)	0	1 (0.7%)	0	0	0
Scrotal abscess	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 2	1 (1.4%)	0	1 (0.7%)	0	0	0
Tinea infections	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Influenza viral infections (cont)						
Influenza	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 1	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Male reproductive tract infections	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Scrotal abscess	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Tinea infections	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Tinea infections (cont)						
Tinea versicolour	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Bordetella infections	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Pertussis	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Clostridia infections	0	1 (1.3%)	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 3	0	0	0	0	1 (1.4%)	1 (0.8%)
Clostridium difficile colitis	0	1 (1.3%)	1 (0.7%)	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Tinea infections (cont)						
Tinea versicolour	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Bordetella infections	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Pertussis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Clostridia infections	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 2	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 3	0	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Clostridia infections (cont)						
Clostridium difficile colitis (cont)						
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 3	0	0	0	0	1 (1.4%)	1 (0.8%)
Clostridium difficile infection	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Ear infections	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Ear infection	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Clostridia infections (cont)						
Clostridium difficile colitis (cont)						
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 2	0	0	0	0	1 (6.7%)	1 (3.4%)
Ear infections	0	0	0	1 (7.1%)	0	1 (3.4%)
Grade 1	0	0	0	1 (7.1%)	0	1 (3.4%)
Grade 2	0	0	0	0	0	0
Ear infection	0	0	0	1 (7.1%)	0	1 (3.4%)
Grade 1	0	0	0	1 (7.1%)	0	1 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Ear infections (cont)						
Labyrinthitis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Otitis externa	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Eye and eyelid infections	0	3 (3.9%)	3 (2.1%)	0	0	0
Grade 1	0	3 (3.9%)	3 (2.1%)	0	0	0
Conjunctivitis	0	2 (2.6%)	2 (1.4%)	0	0	0
Grade 1	0	2 (2.6%)	2 (1.4%)	0	0	0
Hordeolum	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Ear infections (cont)						
Labyrinthitis	0	0	0	1 (7.1%)	0	1 (3.4%)
Grade 1	0	0	0	1 (7.1%)	0	1 (3.4%)
Otitis externa	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Eye and eyelid infections	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Conjunctivitis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hordeolum	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Streptococcal infections	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Erysipelas	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Viral infections NEC	0	0	0	1 (2.0%)	1 (1.4%)	2 (1.7%)
Grade 1	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Viral infection	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 1	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 2	0	0	0	0	0	0
Viral uveitis	0	0	0	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Streptococcal infections	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 2	0	0	0	0	1 (6.7%)	1 (3.4%)
Erysipelas	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 2	0	0	0	0	1 (6.7%)	1 (3.4%)
Viral infections NEC	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (6.7%)	1 (3.4%)
Viral infection	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (6.7%)	1 (3.4%)
Viral uveitis	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Viral infections NEC (cont)						
Viral uveitis (cont)						
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Nervous system disorders	26 (37.7%)	27 (35.5%)	53 (36.6%)	7 (14.0%)	19 (27.5%)	26 (21.8%)
Grade 1	17 (24.6%)	18 (23.7%)	35 (24.1%)	5 (10.0%)	11 (15.9%)	16 (13.4%)
Grade 2	6 (8.7%)	7 (9.2%)	13 (9.0%)	0	4 (5.8%)	4 (3.4%)
Grade 3	3 (4.3%)	1 (1.3%)	4 (2.8%)	1 (2.0%)	4 (5.8%)	5 (4.2%)
Grade 4	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 5	0	1 (1.3%)	1 (0.7%)	0	0	0
Neurological signs and symptoms NEC	15 (21.7%)	9 (11.8%)	24 (16.6%)	2 (4.0%)	6 (8.7%)	8 (6.7%)
Grade 1	11 (15.9%)	7 (9.2%)	18 (12.4%)	2 (4.0%)	5 (7.2%)	7 (5.9%)
Grade 2	3 (4.3%)	1 (1.3%)	4 (2.8%)	0	0	0
Grade 3	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Viral infections NEC (cont)						
Viral uveitis (cont)						
Grade 2	0	0	0	0	0	0
Nervous system disorders	10 (58.8%)	3 (16.7%)	13 (37.1%)	6 (42.9%)	4 (26.7%)	10 (34.5%)
Grade 1	6 (35.3%)	3 (16.7%)	9 (25.7%)	4 (28.6%)	3 (20.0%)	7 (24.1%)
Grade 2	4 (23.5%)	0	4 (11.4%)	2 (14.3%)	0	2 (6.9%)
Grade 3	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 4	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Neurological signs and symptoms NEC	1 (5.9%)	1 (5.6%)	2 (5.7%)	3 (21.4%)	1 (6.7%)	4 (13.8%)
Grade 1	1 (5.9%)	1 (5.6%)	2 (5.7%)	3 (21.4%)	0	3 (10.3%)
Grade 2	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Neurological signs and symptoms NEC (cont)						
Dizziness	14 (20.3%)	9 (11.8%)	23 (15.9%)	2 (4.0%)	6 (8.7%)	8 (6.7%)
Grade 1	12 (17.4%)	7 (9.2%)	19 (13.1%)	2 (4.0%)	5 (7.2%)	7 (5.9%)
Grade 2	2 (2.9%)	1 (1.3%)	3 (2.1%)	0	0	0
Grade 3	0	1 (1.3%)	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Presyncope	3 (4.3%)	0	3 (2.1%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 2	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 3	1 (1.4%)	0	1 (0.7%)	0	0	0
Headaches NEC	4 (5.8%)	14 (18.4%)	18 (12.4%)	0	2 (2.9%)	2 (1.7%)
Grade 1	3 (4.3%)	11 (14.5%)	14 (9.7%)	0	1 (1.4%)	1 (0.8%)
Grade 2	1 (1.4%)	3 (3.9%)	4 (2.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Neurological signs and symptoms NEC (cont)						
Dizziness	1 (5.9%)	1 (5.6%)	2 (5.7%)	3 (21.4%)	1 (6.7%)	4 (13.8%)
Grade 1	1 (5.9%)	1 (5.6%)	2 (5.7%)	3 (21.4%)	0	3 (10.3%)
Grade 2	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 3	0	0	0	0	0	0
Presyncope	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Headaches NEC	6 (35.3%)	1 (5.6%)	7 (20.0%)	1 (7.1%)	0	1 (3.4%)
Grade 1	4 (23.5%)	1 (5.6%)	5 (14.3%)	1 (7.1%)	0	1 (3.4%)
Grade 2	2 (11.8%)	0	2 (5.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Headaches NEC (cont)						
(cont)						
Grade 3	0	0	0	0	1 (1.4%)	1 (0.8%)
Headache	4 (5.8%)	14 (18.4%)	18 (12.4%)	0	1 (1.4%)	1 (0.8%)
Grade 1	3 (4.3%)	11 (14.5%)	14 (9.7%)	0	0	0
Grade 2	1 (1.4%)	3 (3.9%)	4 (2.8%)	0	0	0
Grade 3	0	0	0	0	1 (1.4%)	1 (0.8%)
Sinus headache	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Peripheral neuropathies NEC	6 (8.7%)	3 (3.9%)	9 (6.2%)	2 (4.0%)	7 (10.1%)	9 (7.6%)
Grade 1	5 (7.2%)	2 (2.6%)	7 (4.8%)	1 (2.0%)	4 (5.8%)	5 (4.2%)
Grade 2	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	2 (2.9%)	2 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Headaches NEC (cont)						
(cont)						
Grade 3	0	0	0	0	0	0
Headache	6 (35.3%)	1 (5.6%)	7 (20.0%)	1 (7.1%)	0	1 (3.4%)
Grade 1	4 (23.5%)	1 (5.6%)	5 (14.3%)	1 (7.1%)	0	1 (3.4%)
Grade 2	2 (11.8%)	0	2 (5.7%)	0	0	0
Grade 3	0	0	0	0	0	0
Sinus headache	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Peripheral neuropathies NEC	4 (23.5%)	2 (11.1%)	6 (17.1%)	0	2 (13.3%)	2 (6.9%)
Grade 1	2 (11.8%)	2 (11.1%)	4 (11.4%)	0	1 (6.7%)	1 (3.4%)
Grade 2	2 (11.8%)	0	2 (5.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Peripheral neuropathies NEC (cont)						
(cont)						
Grade 3	0	0	0	1 (2.0%)	1 (1.4%)	2 (1.7%)
Peripheral sensory neuropathy	6 (8.7%)	3 (3.9%)	9 (6.2%)	1 (2.0%)	7 (10.1%)	8 (6.7%)
Grade 1	5 (7.2%)	2 (2.6%)	7 (4.8%)	1 (2.0%)	4 (5.8%)	5 (4.2%)
Grade 2	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	2 (2.9%)	2 (1.7%)
Grade 3	0	0	0	0	1 (1.4%)	1 (0.8%)
Peripheral sensorimotor neuropathy	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 3	0	0	0	1 (2.0%)	0	1 (0.8%)
Paraesthesias and dysaesthesias	5 (7.2%)	3 (3.9%)	8 (5.5%)	1 (2.0%)	3 (4.3%)	4 (3.4%)
Grade 1	5 (7.2%)	3 (3.9%)	8 (5.5%)	1 (2.0%)	2 (2.9%)	3 (2.5%)
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Peripheral neuropathies NEC (cont)						
(cont)						
Grade 3	0	0	0	0	1 (6.7%)	1 (3.4%)
Peripheral sensory neuropathy	4 (23.5%)	2 (11.1%)	6 (17.1%)	0	2 (13.3%)	2 (6.9%)
Grade 1	2 (11.8%)	2 (11.1%)	4 (11.4%)	0	1 (6.7%)	1 (3.4%)
Grade 2	2 (11.8%)	0	2 (5.7%)	0	0	0
Grade 3	0	0	0	0	1 (6.7%)	1 (3.4%)
Peripheral sensorimotor neuropathy	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Paraesthesias and dysaesthesias	2 (11.8%)	0	2 (5.7%)	3 (21.4%)	1 (6.7%)	4 (13.8%)
Grade 1	2 (11.8%)	0	2 (5.7%)	2 (14.3%)	1 (6.7%)	3 (10.3%)
Grade 2	0	0	0	1 (7.1%)	0	1 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Paraesthesias and dysaesthesias (cont)						
Paraesthesia	5 (7.2%)	3 (3.9%)	8 (5.5%)	1 (2.0%)	2 (2.9%)	3 (2.5%)
Grade 1	5 (7.2%)	3 (3.9%)	8 (5.5%)	1 (2.0%)	1 (1.4%)	2 (1.7%)
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Dysaesthesia	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Hypoaesthesia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Disturbances in consciousness NEC	3 (4.3%)	1 (1.3%)	4 (2.8%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Paraesthesias and dysaesthesias (cont)						
Paraesthesia	2 (11.8%)	0	2 (5.7%)	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 1	2 (11.8%)	0	2 (5.7%)	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 2	0	0	0	0	0	0
Dysaesthesia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hypoaesthesia	0	0	0	3 (21.4%)	1 (6.7%)	4 (13.8%)
Grade 1	0	0	0	2 (14.3%)	1 (6.7%)	3 (10.3%)
Grade 2	0	0	0	1 (7.1%)	0	1 (3.4%)
Disturbances in consciousness NEC	1 (5.9%)	0	1 (2.9%)	0	1 (6.7%)	1 (3.4%)
Grade 1	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 2	1 (5.9%)	0	1 (2.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Disturbances in consciousness NEC (cont)						
(cont)						
Grade 3	2 (2.9%)	0	2 (1.4%)	0	0	0
Syncope	2 (2.9%)	0	2 (1.4%)	0	0	0
Grade 3	2 (2.9%)	0	2 (1.4%)	0	0	0
Lethargy	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0
Somnolence	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Coordination and balance disturbances	2 (2.9%)	0	2 (1.4%)	0	2 (2.9%)	2 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Disturbances in consciousness NEC (cont)						
(cont)						
Grade 3	0	0	0	0	0	0
Syncope	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Lethargy	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 2	1 (5.9%)	0	1 (2.9%)	0	0	0
Somnolence	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 1	0	0	0	0	1 (6.7%)	1 (3.4%)
Coordination and balance disturbances	0	0	0	1 (7.1%)	0	1 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Coordination and balance disturbances (cont)						
(cont)						
Grade 1	2 (2.9%)	0	2 (1.4%)	0	2 (2.9%)	2 (1.7%)
Grade 2	0	0	0	0	0	0
Balance disorder	2 (2.9%)	0	2 (1.4%)	0	1 (1.4%)	1 (0.8%)
Grade 1	2 (2.9%)	0	2 (1.4%)	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	0	0	0
Ataxia	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Memory loss (excl dementia)	2 (2.9%)	1 (1.3%)	3 (2.1%)	0	1 (1.4%)	1 (0.8%)
Grade 1	2 (2.9%)	1 (1.3%)	3 (2.1%)	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Coordination and balance disturbances (cont)						
(cont)						
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	1 (7.1%)	0	1 (3.4%)
Balance disorder	0	0	0	1 (7.1%)	0	1 (3.4%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	1 (7.1%)	0	1 (3.4%)
Ataxia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Memory loss (excl dementia)	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Memory loss (excl dementia) (cont)						
Amnesia	1 (1.4%)	0	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Grade 1	1 (1.4%)	0	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Memory impairment	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0
Grade 1	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0
Sensory abnormalities NEC	2 (2.9%)	1 (1.3%)	3 (2.1%)	0	1 (1.4%)	1 (0.8%)
Grade 1	2 (2.9%)	0	2 (1.4%)	0	1 (1.4%)	1 (0.8%)
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0
Taste disorder	2 (2.9%)	0	2 (1.4%)	0	0	0
Grade 1	2 (2.9%)	0	2 (1.4%)	0	0	0
Ageusia	0	0	0	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Memory loss (excl dementia) (cont)						
Amnesia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Memory impairment	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Sensory abnormalities NEC	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 1	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 2	0	0	0	0	0	0
Taste disorder	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Ageusia	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Sensory abnormalities NEC (cont)						
Ageusia (cont)						
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Dysgeusia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Post herpetic neuralgia	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0
Central nervous system haemorrhages and cerebrovascular accidents	1 (1.4%)	0	1 (0.7%)	1 (2.0%)	0	1 (0.8%)
Grade 2	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 4	0	0	0	1 (2.0%)	0	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Sensory abnormalities NEC (cont)						
Ageusia (cont)						
Grade 1	0	0	0	0	0	0
Dysgeusia	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 1	0	0	0	0	1 (6.7%)	1 (3.4%)
Post herpetic neuralgia	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Central nervous system haemorrhages and cerebrovascular accidents	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Central nervous system haemorrhages and cerebrovascular accidents (cont)						
Cerebral ischaemia	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 2	1 (1.4%)	0	1 (0.7%)	0	0	0
Cerebrovascular accident	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 4	0	0	0	1 (2.0%)	0	1 (0.8%)
Tremor (excl congenital)	1 (1.4%)	1 (1.3%)	2 (1.4%)	1 (2.0%)	0	1 (0.8%)
Grade 1	1 (1.4%)	1 (1.3%)	2 (1.4%)	1 (2.0%)	0	1 (0.8%)
Tremor	1 (1.4%)	1 (1.3%)	2 (1.4%)	1 (2.0%)	0	1 (0.8%)
Grade 1	1 (1.4%)	1 (1.3%)	2 (1.4%)	1 (2.0%)	0	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Central nervous system haemorrhages and cerebrovascular accidents (cont)						
Cerebral ischaemia	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Cerebrovascular accident	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Tremor (excl congenital)	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Tremor	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Central nervous system vascular disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Cerebral microangiopathy	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Coma states	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 5	0	1 (1.3%)	1 (0.7%)	0	0	0
Coma	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 5	0	1 (1.3%)	1 (0.7%)	0	0	0
Demyelinating disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Central nervous system vascular disorders NEC	0	0	0	1 (7.1%)	0	1 (3.4%)
Grade 1	0	0	0	1 (7.1%)	0	1 (3.4%)
Cerebral microangiopathy	0	0	0	1 (7.1%)	0	1 (3.4%)
Grade 1	0	0	0	1 (7.1%)	0	1 (3.4%)
Coma states	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Coma	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Demyelinating disorders NEC	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 1	0	0	0	0	1 (6.7%)	1 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Demyelinating disorders NEC (cont)						
Demyelination	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Encephalopathies NEC	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 4	0	1 (1.3%)	1 (0.7%)	0	0	0
Encephalopathy	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 4	0	1 (1.3%)	1 (0.7%)	0	0	0
Lumbar spinal cord and nerve root disorders	0	1 (1.3%)	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Grade 2	0	1 (1.3%)	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Sciatica	0	1 (1.3%)	1 (0.7%)	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Demyelinating disorders NEC (cont)						
Demyelination	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 1	0	0	0	0	1 (6.7%)	1 (3.4%)
Encephalopathies NEC	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Encephalopathy	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Lumbar spinal cord and nerve root disorders	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Sciatica	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Lumbar spinal cord and nerve root disorders (cont)						
Sciatica (cont)						
Grade 2	0	1 (1.3%)	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Transient cerebrovascular events	0	1 (1.3%)	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 3	0	0	0	0	1 (1.4%)	1 (0.8%)
Transient ischaemic attack	0	1 (1.3%)	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 3	0	0	0	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Lumbar spinal cord and nerve root disorders (cont)						
Sciatica (cont)						
Grade 2	0	0	0	0	0	0
Transient cerebrovascular events	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Transient ischaemic attack	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders	27 (39.1%)	44 (57.9%)	71 (49.0%)	9 (18.0%)	20 (29.0%)	29 (24.4%)
Grade 1	6 (8.7%)	6 (7.9%)	12 (8.3%)	2 (4.0%)	3 (4.3%)	5 (4.2%)
Grade 2	4 (5.8%)	13 (17.1%)	17 (11.7%)	0	5 (7.2%)	5 (4.2%)
Grade 3	15 (21.7%)	20 (26.3%)	35 (24.1%)	6 (12.0%)	9 (13.0%)	15 (12.6%)
Grade 4	2 (2.9%)	5 (6.6%)	7 (4.8%)	1 (2.0%)	2 (2.9%)	3 (2.5%)
Grade 5	0	0	0	0	1 (1.4%)	1 (0.8%)
Thrombocytopenias	12 (17.4%)	24 (31.6%)	36 (24.8%)	6 (12.0%)	10 (14.5%)	16 (13.4%)
Grade 1	3 (4.3%)	9 (11.8%)	12 (8.3%)	2 (4.0%)	1 (1.4%)	3 (2.5%)
Grade 2	2 (2.9%)	11 (14.5%)	13 (9.0%)	0	4 (5.8%)	4 (3.4%)
Grade 3	5 (7.2%)	4 (5.3%)	9 (6.2%)	4 (8.0%)	3 (4.3%)	7 (5.9%)
Grade 4	2 (2.9%)	0	2 (1.4%)	0	2 (2.9%)	2 (1.7%)
Thrombocytopenia	12 (17.4%)	24 (31.6%)	36 (24.8%)	6 (12.0%)	10 (14.5%)	16 (13.4%)
Grade 1	3 (4.3%)	9 (11.8%)	12 (8.3%)	2 (4.0%)	1 (1.4%)	3 (2.5%)
Grade 2	2 (2.9%)	11 (14.5%)	13 (9.0%)	0	4 (5.8%)	4 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders	8 (47.1%)	14 (77.8%)	22 (62.9%)	1 (7.1%)	3 (20.0%)	4 (13.8%)
Grade 1	1 (5.9%)	2 (11.1%)	3 (8.6%)	1 (7.1%)	0	1 (3.4%)
Grade 2	5 (29.4%)	4 (22.2%)	9 (25.7%)	0	2 (13.3%)	2 (6.9%)
Grade 3	1 (5.9%)	4 (22.2%)	5 (14.3%)	0	1 (6.7%)	1 (3.4%)
Grade 4	1 (5.9%)	4 (22.2%)	5 (14.3%)	0	0	0
Grade 5	0	0	0	0	0	0
Thrombocytopenias	7 (41.2%)	8 (44.4%)	15 (42.9%)	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 1	1 (5.9%)	4 (22.2%)	5 (14.3%)	1 (7.1%)	0	1 (3.4%)
Grade 2	4 (23.5%)	2 (11.1%)	6 (17.1%)	0	1 (6.7%)	1 (3.4%)
Grade 3	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 4	1 (5.9%)	2 (11.1%)	3 (8.6%)	0	0	0
Thrombocytopenia	7 (41.2%)	8 (44.4%)	15 (42.9%)	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 1	1 (5.9%)	4 (22.2%)	5 (14.3%)	1 (7.1%)	0	1 (3.4%)
Grade 2	4 (23.5%)	2 (11.1%)	6 (17.1%)	0	1 (6.7%)	1 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Thrombocytopenias (cont)						
Thrombocytopenia (cont)						
Grade 3	5 (7.2%)	4 (5.3%)	9 (6.2%)	4 (8.0%)	3 (4.3%)	7 (5.9%)
Grade 4	2 (2.9%)	0	2 (1.4%)	0	2 (2.9%)	2 (1.7%)
Anaemias NEC	13 (18.8%)	29 (38.2%)	42 (29.0%)	2 (4.0%)	7 (10.1%)	9 (7.6%)
Grade 1	0	2 (2.6%)	2 (1.4%)	0	1 (1.4%)	1 (0.8%)
Grade 2	3 (4.3%)	7 (9.2%)	10 (6.9%)	0	2 (2.9%)	2 (1.7%)
Grade 3	10 (14.5%)	17 (22.4%)	27 (18.6%)	1 (2.0%)	4 (5.8%)	5 (4.2%)
Grade 4	0	3 (3.9%)	3 (2.1%)	1 (2.0%)	0	1 (0.8%)
Anaemia	13 (18.8%)	29 (38.2%)	42 (29.0%)	2 (4.0%)	7 (10.1%)	9 (7.6%)
Grade 1	0	2 (2.6%)	2 (1.4%)	0	1 (1.4%)	1 (0.8%)
Grade 2	3 (4.3%)	7 (9.2%)	10 (6.9%)	0	2 (2.9%)	2 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Thrombocytopenias (cont)						
Thrombocytopenia (cont)						
Grade 3	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 4	1 (5.9%)	2 (11.1%)	3 (8.6%)	0	0	0
Anaemias NEC	1 (5.9%)	7 (38.9%)	8 (22.9%)	0	1 (6.7%)	1 (3.4%)
Grade 1	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 2	1 (5.9%)	0	1 (2.9%)	0	1 (6.7%)	1 (3.4%)
Grade 3	0	4 (22.2%)	4 (11.4%)	0	0	0
Grade 4	0	2 (11.1%)	2 (5.7%)	0	0	0
Anaemia	1 (5.9%)	7 (38.9%)	8 (22.9%)	0	1 (6.7%)	1 (3.4%)
Grade 1	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 2	1 (5.9%)	0	1 (2.9%)	0	1 (6.7%)	1 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Anaemias NEC (cont)						
Anaemia (cont)						
Grade 3	10 (14.5%)	17 (22.4%)	27 (18.6%)	1 (2.0%)	4 (5.8%)	5 (4.2%)
Grade 4	0	3 (3.9%)	3 (2.1%)	1 (2.0%)	0	1 (0.8%)
Neutropenias	5 (7.2%)	6 (7.9%)	11 (7.6%)	2 (4.0%)	2 (2.9%)	4 (3.4%)
Grade 1	1 (1.4%)	0	1 (0.7%)	1 (2.0%)	0	1 (0.8%)
Grade 2	0	0	0	0	0	0
Grade 3	3 (4.3%)	3 (3.9%)	6 (4.1%)	1 (2.0%)	2 (2.9%)	3 (2.5%)
Grade 4	1 (1.4%)	3 (3.9%)	4 (2.8%)	0	0	0
Neutropenia	4 (5.8%)	6 (7.9%)	10 (6.9%)	2 (4.0%)	2 (2.9%)	4 (3.4%)
Grade 1	1 (1.4%)	0	1 (0.7%)	1 (2.0%)	0	1 (0.8%)
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Anaemias NEC (cont)						
Anaemia (cont)						
Grade 3	0	4 (22.2%)	4 (11.4%)	0	0	0
Grade 4	0	2 (11.1%)	2 (5.7%)	0	0	0
Neutropenias	0	3 (16.7%)	3 (8.6%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	2 (11.1%)	2 (5.7%)	0	0	0
Grade 3	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 4	0	0	0	0	0	0
Neutropenia	0	3 (16.7%)	3 (8.6%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	2 (11.1%)	2 (5.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Neutropenias (cont)						
Neutropenia (cont)						
Grade 3	2 (2.9%)	3 (3.9%)	5 (3.4%)	1 (2.0%)	2 (2.9%)	3 (2.5%)
Grade 4	1 (1.4%)	3 (3.9%)	4 (2.8%)	0	0	0
Febrile neutropenia	1 (1.4%)	0	1 (0.7%)	1 (2.0%)	0	1 (0.8%)
Grade 3	1 (1.4%)	0	1 (0.7%)	1 (2.0%)	0	1 (0.8%)
Leukopenias NEC	2 (2.9%)	1 (1.3%)	3 (2.1%)	0	0	0
Grade 1	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0
Grade 3	1 (1.4%)	0	1 (0.7%)	0	0	0
Leukopenia	2 (2.9%)	1 (1.3%)	3 (2.1%)	0	0	0
Grade 1	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Neutropenias (cont)						
Neutropenia (cont)						
Grade 3	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 4	0	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Leukopenias NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Leukopenia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Leukopenias NEC (cont)						
Leukopenia (cont)						
Grade 3	1 (1.4%)	0	1 (0.7%)	0	0	0
Bleeding tendencies	1 (1.4%)	0	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Grade 1	1 (1.4%)	0	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Increased tendency to bruise	1 (1.4%)	0	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Grade 1	1 (1.4%)	0	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Coagulation factor deficiencies	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 2	1 (1.4%)	0	1 (0.7%)	0	0	0
Hypoprothrombinaemia	1 (1.4%)	0	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Other Races					
(Continued)	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Leukopenias NEC (cont)						
Leukopenia (cont)						
Grade 3	0	0	0	0	0	0
Bleeding tendencies	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Increased tendency to bruise	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Coagulation factor deficiencies	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Hypoprothrombinaemia	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Coagulation factor deficiencies (cont)						
Hypoprothrombinaemia (cont)						
Grade 2	1 (1.4%)	0	1 (0.7%)	0	0	0
Leukocytoses NEC	1 (1.4%)	0	1 (0.7%)	1 (2.0%)	2 (2.9%)	3 (2.5%)
Grade 1	1 (1.4%)	0	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 3	0	0	0	1 (2.0%)	0	1 (0.8%)
Leukocytosis	1 (1.4%)	0	1 (0.7%)	1 (2.0%)	2 (2.9%)	3 (2.5%)
Grade 1	1 (1.4%)	0	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 3	0	0	0	1 (2.0%)	0	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Coagulation factor deficiencies (cont)						
Hypoprothrombinaemia (cont)						
Grade 2	0	0	0	0	0	0
Leukocytoses NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Leukocytosis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Leukocytoses NEC (cont)						
Neutrophilia	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Spleen disorders	1 (1.4%)	0	1 (0.7%)	1 (2.0%)	1 (1.4%)	2 (1.7%)
Grade 3	1 (1.4%)	0	1 (0.7%)	1 (2.0%)	0	1 (0.8%)
Grade 5	0	0	0	0	1 (1.4%)	1 (0.8%)
Splenomegaly	1 (1.4%)	0	1 (0.7%)	1 (2.0%)	0	1 (0.8%)
Grade 3	1 (1.4%)	0	1 (0.7%)	1 (2.0%)	0	1 (0.8%)
Splenic haematoma	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 5	0	0	0	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Leukocytoses NEC (cont)						
Neutrophilia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Spleen disorders	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Splenomegaly	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Splenic haematoma	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Thrombocytoses	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Thrombocytosis	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Thrombocytoses	0	1 (5.6%)	1 (2.9%)	0	1 (6.7%)	1 (3.4%)
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 3	0	0	0	0	1 (6.7%)	1 (3.4%)
Thrombocytosis	0	1 (5.6%)	1 (2.9%)	0	1 (6.7%)	1 (3.4%)
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 3	0	0	0	0	1 (6.7%)	1 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders	27 (39.1%)	17 (22.4%)	44 (30.3%)	10 (20.0%)	15 (21.7%)	25 (21.0%)
Grade 1	19 (27.5%)	9 (11.8%)	28 (19.3%)	5 (10.0%)	8 (11.6%)	13 (10.9%)
Grade 2	4 (5.8%)	6 (7.9%)	10 (6.9%)	5 (10.0%)	6 (8.7%)	11 (9.2%)
Grade 3	2 (2.9%)	1 (1.3%)	3 (2.1%)	0	1 (1.4%)	1 (0.8%)
Grade 4	2 (2.9%)	1 (1.3%)	3 (2.1%)	0	0	0
Breathing abnormalities	12 (17.4%)	9 (11.8%)	21 (14.5%)	0	3 (4.3%)	3 (2.5%)
Grade 1	10 (14.5%)	3 (3.9%)	13 (9.0%)	0	1 (1.4%)	1 (0.8%)
Grade 2	2 (2.9%)	5 (6.6%)	7 (4.8%)	0	1 (1.4%)	1 (0.8%)
Grade 3	0	1 (1.3%)	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Dyspnoea	9 (13.0%)	8 (10.5%)	17 (11.7%)	0	3 (4.3%)	3 (2.5%)
Grade 1	7 (10.1%)	2 (2.6%)	9 (6.2%)	0	1 (1.4%)	1 (0.8%)
Grade 2	2 (2.9%)	5 (6.6%)	7 (4.8%)	0	1 (1.4%)	1 (0.8%)
Grade 3	0	1 (1.3%)	1 (0.7%)	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders	5 (29.4%)	10 (55.6%)	15 (42.9%)	4 (28.6%)	4 (26.7%)	8 (27.6%)
Grade 1	4 (23.5%)	8 (44.4%)	12 (34.3%)	3 (21.4%)	2 (13.3%)	5 (17.2%)
Grade 2	1 (5.9%)	2 (11.1%)	3 (8.6%)	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 3	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 4	0	0	0	0	0	0
Breathing abnormalities	4 (23.5%)	2 (11.1%)	6 (17.1%)	0	1 (6.7%)	1 (3.4%)
Grade 1	4 (23.5%)	1 (5.6%)	5 (14.3%)	0	0	0
Grade 2	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 3	0	0	0	0	1 (6.7%)	1 (3.4%)
Dyspnoea	2 (11.8%)	0	2 (5.7%)	0	1 (6.7%)	1 (3.4%)
Grade 1	2 (11.8%)	0	2 (5.7%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	1 (6.7%)	1 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Breathing abnormalities (cont)						
Dyspnoea exertional	3 (4.3%)	2 (2.6%)	5 (3.4%)	0	0	0
Grade 1	3 (4.3%)	2 (2.6%)	5 (3.4%)	0	0	0
Grade 2	0	0	0	0	0	0
Coughing and associated symptoms	12 (17.4%)	5 (6.6%)	17 (11.7%)	5 (10.0%)	7 (10.1%)	12 (10.1%)
Grade 1	10 (14.5%)	4 (5.3%)	14 (9.7%)	3 (6.0%)	5 (7.2%)	8 (6.7%)
Grade 2	2 (2.9%)	1 (1.3%)	3 (2.1%)	2 (4.0%)	2 (2.9%)	4 (3.4%)
Cough	11 (15.9%)	5 (6.6%)	16 (11.0%)	4 (8.0%)	7 (10.1%)	11 (9.2%)
Grade 1	10 (14.5%)	4 (5.3%)	14 (9.7%)	3 (6.0%)	5 (7.2%)	8 (6.7%)
Grade 2	1 (1.4%)	1 (1.3%)	2 (1.4%)	1 (2.0%)	2 (2.9%)	3 (2.5%)
Haemoptysis	1 (1.4%)	0	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Breathing abnormalities (cont)						
Dyspnoea exertional	2 (11.8%)	2 (11.1%)	4 (11.4%)	0	0	0
Grade 1	2 (11.8%)	1 (5.6%)	3 (8.6%)	0	0	0
Grade 2	0	1 (5.6%)	1 (2.9%)	0	0	0
Coughing and associated symptoms	1 (5.9%)	5 (27.8%)	6 (17.1%)	3 (21.4%)	3 (20.0%)	6 (20.7%)
Grade 1	0	5 (27.8%)	5 (14.3%)	3 (21.4%)	2 (13.3%)	5 (17.2%)
Grade 2	1 (5.9%)	0	1 (2.9%)	0	1 (6.7%)	1 (3.4%)
Cough	1 (5.9%)	4 (22.2%)	5 (14.3%)	3 (21.4%)	3 (20.0%)	6 (20.7%)
Grade 1	0	4 (22.2%)	4 (11.4%)	3 (21.4%)	2 (13.3%)	5 (17.2%)
Grade 2	1 (5.9%)	0	1 (2.9%)	0	1 (6.7%)	1 (3.4%)
Haemoptysis	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Coughing and associated symptoms (cont)						
Haemoptysis (cont)						
Grade 2	1 (1.4%)	0	1 (0.7%)	0	0	0
Productive cough	1 (1.4%)	0	1 (0.7%)	1 (2.0%)	0	1 (0.8%)
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 2	0	0	0	1 (2.0%)	0	1 (0.8%)
Nasal disorders NEC	4 (5.8%)	2 (2.6%)	6 (4.1%)	3 (6.0%)	1 (1.4%)	4 (3.4%)
Grade 1	2 (2.9%)	1 (1.3%)	3 (2.1%)	2 (4.0%)	1 (1.4%)	3 (2.5%)
Grade 2	2 (2.9%)	1 (1.3%)	3 (2.1%)	1 (2.0%)	0	1 (0.8%)
Epistaxis	4 (5.8%)	2 (2.6%)	6 (4.1%)	3 (6.0%)	1 (1.4%)	4 (3.4%)
Grade 1	2 (2.9%)	1 (1.3%)	3 (2.1%)	2 (4.0%)	1 (1.4%)	3 (2.5%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Coughing and associated symptoms (cont)						
Haemoptysis (cont)						
Grade 2	0	0	0	0	0	0
Productive cough	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 1	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Nasal disorders NEC	0	3 (16.7%)	3 (8.6%)	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 1	0	2 (11.1%)	2 (5.7%)	0	0	0
Grade 2	0	1 (5.6%)	1 (2.9%)	1 (7.1%)	1 (6.7%)	2 (6.9%)
Epistaxis	0	3 (16.7%)	3 (8.6%)	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 1	0	2 (11.1%)	2 (5.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Nasal disorders NEC (cont)						
Epistaxis (cont)						
Grade 2	2 (2.9%)	1 (1.3%)	3 (2.1%)	1 (2.0%)	0	1 (0.8%)
Upper respiratory tract signs and symptoms	4 (5.8%)	2 (2.6%)	6 (4.1%)	0	2 (2.9%)	2 (1.7%)
Grade 1	4 (5.8%)	2 (2.6%)	6 (4.1%)	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Dysphonia	2 (2.9%)	0	2 (1.4%)	0	1 (1.4%)	1 (0.8%)
Grade 1	2 (2.9%)	0	2 (1.4%)	0	0	0
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Rhinorrhoea	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Nasal disorders NEC (cont)						
Epistaxis (cont)						
Grade 2	0	1 (5.6%)	1 (2.9%)	1 (7.1%)	1 (6.7%)	2 (6.9%)
Upper respiratory tract signs and symptoms	0	1 (5.6%)	1 (2.9%)	1 (7.1%)	0	1 (3.4%)
Grade 1	0	1 (5.6%)	1 (2.9%)	1 (7.1%)	0	1 (3.4%)
Grade 2	0	0	0	0	0	0
Dysphonia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Rhinorrhoea	0	0	0	1 (7.1%)	0	1 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Upper respiratory tract signs and symptoms (cont)						
Rhinorrhoea (cont)						
Grade 1	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0
Throat tightness	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Catarrh	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Oropharyngeal pain	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Upper respiratory tract signs and symptoms (cont)						
Rhinorrhoea (cont)						
Grade 1	0	0	0	1 (7.1%)	0	1 (3.4%)
Throat tightness	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Catarrh	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Oropharyngeal pain	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 1	0	1 (5.6%)	1 (2.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Lower respiratory tract signs and symptoms	2 (2.9%)	1 (1.3%)	3 (2.1%)	1 (2.0%)	0	1 (0.8%)
Grade 1	1 (1.4%)	1 (1.3%)	2 (1.4%)	1 (2.0%)	0	1 (0.8%)
Grade 2	1 (1.4%)	0	1 (0.7%)	0	0	0
Rales	2 (2.9%)	0	2 (1.4%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 2	1 (1.4%)	0	1 (0.7%)	0	0	0
Hiccups	0	1 (1.3%)	1 (0.7%)	1 (2.0%)	0	1 (0.8%)
Grade 1	0	1 (1.3%)	1 (0.7%)	1 (2.0%)	0	1 (0.8%)
Bronchospasm and obstruction	1 (1.4%)	0	1 (0.7%)	1 (2.0%)	1 (1.4%)	2 (1.7%)
Grade 1	0	0	0	1 (2.0%)	0	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Lower respiratory tract signs and symptoms	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Rales	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Hiccups	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Bronchospasm and obstruction	0	0	0	1 (7.1%)	0	1 (3.4%)
Grade 1	0	0	0	1 (7.1%)	0	1 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Bronchospasm and obstruction (cont)						
(cont)						
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 3	1 (1.4%)	0	1 (0.7%)	0	0	0
Chronic obstructive pulmonary disease	1 (1.4%)	0	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 3	1 (1.4%)	0	1 (0.7%)	0	0	0
Bronchitis chronic	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Wheezing	0	0	0	1 (2.0%)	0	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Bronchospasm and obstruction (cont) (cont)						
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Chronic obstructive pulmonary disease	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Bronchitis chronic	0	0	0	1 (7.1%)	0	1 (3.4%)
Grade 1	0	0	0	1 (7.1%)	0	1 (3.4%)
Wheezing	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Bronchospasm and obstruction (cont)						
Wheezing (cont)						
Grade 1	0	0	0	1 (2.0%)	0	1 (0.8%)
Conditions associated with abnormal gas exchange	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 4	1 (1.4%)	0	1 (0.7%)	0	0	0
Hypoxia	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 4	1 (1.4%)	0	1 (0.7%)	0	0	0
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)	1 (1.4%)	0	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Grade 2	1 (1.4%)	0	1 (0.7%)	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Bronchospasm and obstruction (cont)						
Wheezing (cont)						
Grade 1	0	0	0	0	0	0
Conditions associated with abnormal gas exchange	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Hypoxia	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms) (cont)						
Reflux laryngitis	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 2	1 (1.4%)	0	1 (0.7%)	0	0	0
Laryngeal inflammation	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Lower respiratory tract inflammatory and immunologic conditions	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 3	1 (1.4%)	0	1 (0.7%)	0	0	0
Pneumonia aspiration	1 (1.4%)	0	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms) (cont)						
Reflux laryngitis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Laryngeal inflammation	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Lower respiratory tract inflammatory and immunologic conditions	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Pneumonia aspiration	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
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Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Lower respiratory tract inflammatory and immunologic conditions (cont)						
Pneumonia aspiration (cont)						
Grade 3	1 (1.4%)	0	1 (0.7%)	0	0	0
Pharyngeal disorders (excl infections and neoplasms)	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 3	1 (1.4%)	0	1 (0.7%)	0	0	0
Pharyngeal ulceration	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 3	1 (1.4%)	0	1 (0.7%)	0	0	0
Respiratory failures (excl neonatal)	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
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Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Lower respiratory tract inflammatory and immunologic conditions (cont)						
Pneumonia aspiration (cont)						
Grade 3	0	0	0	0	0	0
Pharyngeal disorders (excl infections and neoplasms)	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Pharyngeal ulceration	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Respiratory failures (excl neonatal)	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 3	0	0	0	0	1 (6.7%)	1 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Respiratory failures (excl neonatal) (cont)						
(cont)						
Grade 4	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0
Respiratory failure	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 3	0	0	0	0	0	0
Grade 4	1 (1.4%)	0	1 (0.7%)	0	0	0
Acute respiratory failure	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 4	0	1 (1.3%)	1 (0.7%)	0	0	0
Parenchymal lung disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Other Races					
(Continued)	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Respiratory failures (excl neonatal) (cont)						
(cont)						
Grade 4	0	0	0	0	0	0
Respiratory failure	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 3	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 4	0	0	0	0	0	0
Acute respiratory failure	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Parenchymal lung disorders NEC	0	0	0	1 (7.1%)	0	1 (3.4%)
Grade 1	0	0	0	1 (7.1%)	0	1 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Parenchymal lung disorders NEC (cont)						
Emphysema	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Pleural infections and inflammations	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Pleurisy	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Pneumothorax and pleural effusions NEC	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Pleural effusion	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Parenchymal lung disorders NEC (cont)						
Emphysema	0	0	0	1 (7.1%)	0	1 (3.4%)
Grade 1	0	0	0	1 (7.1%)	0	1 (3.4%)
Pleural infections and inflammations	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Pleurisy	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Pneumothorax and pleural effusions NEC	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 3	0	0	0	0	1 (6.7%)	1 (3.4%)
Pleural effusion	0	0	0	0	1 (6.7%)	1 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Pneumothorax and pleural effusions NEC (cont)						
Pleural effusion (cont)						
Grade 3	0	0	0	0	0	0
Pulmonary oedemas	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 2	0	0	0	1 (2.0%)	0	1 (0.8%)
Pulmonary oedema	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 2	0	0	0	1 (2.0%)	0	1 (0.8%)
Pulmonary thrombotic and embolic conditions	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 2	0	0	0	1 (2.0%)	0	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Pneumothorax and pleural effusions NEC (cont)						
Pleural effusion (cont)						
Grade 3	0	0	0	0	1 (6.7%)	1 (3.4%)
Pulmonary oedemas	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Pulmonary oedema	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Pulmonary thrombotic and embolic conditions	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Pulmonary thrombotic and embolic conditions (cont)						
Pulmonary embolism	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 2	0	0	0	1 (2.0%)	0	1 (0.8%)
Respiratory tract disorders NEC	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Lung disorder	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Pulmonary thrombotic and embolic conditions (cont)						
Pulmonary embolism	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Respiratory tract disorders NEC	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Lung disorder	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders	21 (30.4%)	16 (21.1%)	37 (25.5%)	9 (18.0%)	19 (27.5%)	28 (23.5%)
Grade 1	8 (11.6%)	7 (9.2%)	15 (10.3%)	2 (4.0%)	10 (14.5%)	12 (10.1%)
Grade 2	7 (10.1%)	6 (7.9%)	13 (9.0%)	5 (10.0%)	7 (10.1%)	12 (10.1%)
Grade 3	4 (5.8%)	2 (2.6%)	6 (4.1%)	2 (4.0%)	1 (1.4%)	3 (2.5%)
Grade 4	2 (2.9%)	1 (1.3%)	3 (2.1%)	0	1 (1.4%)	1 (0.8%)
Potassium imbalance	5 (7.2%)	2 (2.6%)	7 (4.8%)	1 (2.0%)	3 (4.3%)	4 (3.4%)
Grade 1	0	0	0	0	2 (2.9%)	2 (1.7%)
Grade 2	3 (4.3%)	0	3 (2.1%)	0	1 (1.4%)	1 (0.8%)
Grade 3	2 (2.9%)	1 (1.3%)	3 (2.1%)	1 (2.0%)	0	1 (0.8%)
Grade 4	0	1 (1.3%)	1 (0.7%)	0	0	0
Hyperkalaemia	4 (5.8%)	1 (1.3%)	5 (3.4%)	1 (2.0%)	1 (1.4%)	2 (1.7%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 2	2 (2.9%)	0	2 (1.4%)	0	0	0
Grade 3	2 (2.9%)	1 (1.3%)	3 (2.1%)	1 (2.0%)	0	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders	6 (35.3%)	4 (22.2%)	10 (28.6%)	1 (7.1%)	4 (26.7%)	5 (17.2%)
Grade 1	3 (17.6%)	0	3 (8.6%)	1 (7.1%)	2 (13.3%)	3 (10.3%)
Grade 2	1 (5.9%)	3 (16.7%)	4 (11.4%)	0	1 (6.7%)	1 (3.4%)
Grade 3	2 (11.8%)	1 (5.6%)	3 (8.6%)	0	0	0
Grade 4	0	0	0	0	1 (6.7%)	1 (3.4%)
Potassium imbalance	2 (11.8%)	2 (11.1%)	4 (11.4%)	0	0	0
Grade 1	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 2	1 (5.9%)	1 (5.6%)	2 (5.7%)	0	0	0
Grade 3	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 4	0	0	0	0	0	0
Hyperkalaemia	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	1 (5.6%)	1 (2.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Potassium imbalance (cont)						
Hypokalaemia	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	2 (2.9%)	2 (1.7%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 2	1 (1.4%)	0	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Grade 4	0	1 (1.3%)	1 (0.7%)	0	0	0
Disorders of purine metabolism	4 (5.8%)	2 (2.6%)	6 (4.1%)	1 (2.0%)	2 (2.9%)	3 (2.5%)
Grade 1	2 (2.9%)	1 (1.3%)	3 (2.1%)	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	0	0	0
Grade 3	0	1 (1.3%)	1 (0.7%)	1 (2.0%)	0	1 (0.8%)
Grade 4	2 (2.9%)	0	2 (1.4%)	0	1 (1.4%)	1 (0.8%)
Hyperuricaemia	4 (5.8%)	2 (2.6%)	6 (4.1%)	0	2 (2.9%)	2 (1.7%)
Grade 1	2 (2.9%)	1 (1.3%)	3 (2.1%)	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Potassium imbalance (cont)						
Hypokalaemia	2 (11.8%)	1 (5.6%)	3 (8.6%)	0	0	0
Grade 1	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 2	1 (5.9%)	1 (5.6%)	2 (5.7%)	0	0	0
Grade 4	0	0	0	0	0	0
Disorders of purine metabolism	2 (11.8%)	1 (5.6%)	3 (8.6%)	0	3 (20.0%)	3 (10.3%)
Grade 1	1 (5.9%)	0	1 (2.9%)	0	2 (13.3%)	2 (6.9%)
Grade 2	1 (5.9%)	1 (5.6%)	2 (5.7%)	0	0	0
Grade 3	0	0	0	0	0	0
Grade 4	0	0	0	0	1 (6.7%)	1 (3.4%)
Hyperuricaemia	1 (5.9%)	1 (5.6%)	2 (5.7%)	0	3 (20.0%)	3 (10.3%)
Grade 1	1 (5.9%)	0	1 (2.9%)	0	2 (13.3%)	2 (6.9%)
Grade 2	0	1 (5.6%)	1 (2.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Disorders of purine metabolism (cont)						
Hyperuricaemia (cont)						
Grade 3	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 4	2 (2.9%)	0	2 (1.4%)	0	1 (1.4%)	1 (0.8%)
Gout	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	1 (2.0%)	0	1 (0.8%)
Water soluble vitamin deficiencies	5 (7.2%)	6 (7.9%)	11 (7.6%)	3 (6.0%)	4 (5.8%)	7 (5.9%)
Grade 1	2 (2.9%)	5 (6.6%)	7 (4.8%)	0	4 (5.8%)	4 (3.4%)
Grade 2	3 (4.3%)	1 (1.3%)	4 (2.8%)	3 (6.0%)	0	3 (2.5%)
Vitamin B1 deficiency	5 (7.2%)	5 (6.6%)	10 (6.9%)	3 (6.0%)	4 (5.8%)	7 (5.9%)
Grade 1	2 (2.9%)	4 (5.3%)	6 (4.1%)	0	4 (5.8%)	4 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Disorders of purine metabolism (cont)						
Hyperuricaemia (cont)						
Grade 3	0	0	0	0	0	0
Grade 4	0	0	0	0	1 (6.7%)	1 (3.4%)
Gout	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 2	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 3	0	0	0	0	0	0
Water soluble vitamin deficiencies	1 (5.9%)	1 (5.6%)	2 (5.7%)	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 1	1 (5.9%)	0	1 (2.9%)	1 (7.1%)	0	1 (3.4%)
Grade 2	0	1 (5.6%)	1 (2.9%)	0	1 (6.7%)	1 (3.4%)
Vitamin B1 deficiency	0	1 (5.6%)	1 (2.9%)	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 1	0	0	0	1 (7.1%)	0	1 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Water soluble vitamin deficiencies (cont)						
Vitamin B1 deficiency (cont)						
Grade 2	3 (4.3%)	1 (1.3%)	4 (2.8%)	3 (6.0%)	0	3 (2.5%)
Vitamin B complex deficiency	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Magnesium metabolism disorders	3 (4.3%)	0	3 (2.1%)	0	0	0
Grade 1	2 (2.9%)	0	2 (1.4%)	0	0	0
Grade 2	1 (1.4%)	0	1 (0.7%)	0	0	0
Hypomagnesaemia	3 (4.3%)	0	3 (2.1%)	0	0	0
Grade 1	2 (2.9%)	0	2 (1.4%)	0	0	0
Grade 2	1 (1.4%)	0	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Water soluble vitamin deficiencies (cont)						
Vitamin B1 deficiency (cont)						
Grade 2	0	1 (5.6%)	1 (2.9%)	0	1 (6.7%)	1 (3.4%)
Vitamin B complex deficiency	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 1	1 (5.9%)	0	1 (2.9%)	0	0	0
Magnesium metabolism disorders	2 (11.8%)	0	2 (5.7%)	0	0	0
Grade 1	2 (11.8%)	0	2 (5.7%)	0	0	0
Grade 2	0	0	0	0	0	0
Hypomagnesaemia	2 (11.8%)	0	2 (5.7%)	0	0	0
Grade 1	2 (11.8%)	0	2 (5.7%)	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Appetite disorders	4 (5.8%)	5 (6.6%)	9 (6.2%)	3 (6.0%)	5 (7.2%)	8 (6.7%)
Grade 1	3 (4.3%)	3 (3.9%)	6 (4.1%)	2 (4.0%)	3 (4.3%)	5 (4.2%)
Grade 2	1 (1.4%)	2 (2.6%)	3 (2.1%)	1 (2.0%)	2 (2.9%)	3 (2.5%)
Grade 3	0	0	0	0	0	0
Decreased appetite	4 (5.8%)	5 (6.6%)	9 (6.2%)	3 (6.0%)	5 (7.2%)	8 (6.7%)
Grade 1	3 (4.3%)	3 (3.9%)	6 (4.1%)	2 (4.0%)	3 (4.3%)	5 (4.2%)
Grade 2	1 (1.4%)	2 (2.6%)	3 (2.1%)	1 (2.0%)	2 (2.9%)	3 (2.5%)
Grade 3	0	0	0	0	0	0
Calcium metabolism disorders	2 (2.9%)	0	2 (1.4%)	0	1 (1.4%)	1 (0.8%)
Grade 2	2 (2.9%)	0	2 (1.4%)	0	1 (1.4%)	1 (0.8%)
Hypocalcaemia	2 (2.9%)	0	2 (1.4%)	0	1 (1.4%)	1 (0.8%)
Grade 2	2 (2.9%)	0	2 (1.4%)	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Appetite disorders	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	1 (5.6%)	1 (2.9%)	0	0	0
Decreased appetite	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	1 (5.6%)	1 (2.9%)	0	0	0
Calcium metabolism disorders	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 2	1 (5.9%)	0	1 (2.9%)	0	0	0
Hypocalcaemia	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 2	1 (5.9%)	0	1 (2.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Fat soluble vitamin deficiencies and disorders	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	1 (1.4%)	1 (0.8%)
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 2	0	1 (1.3%)	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Vitamin D deficiency	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	1 (1.4%)	1 (0.8%)
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 2	0	1 (1.3%)	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Vitamin K deficiency	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Iron excess	2 (2.9%)	1 (1.3%)	3 (2.1%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Fat soluble vitamin deficiencies and disorders	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 1	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Vitamin D deficiency	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 1	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Vitamin K deficiency	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 1	1 (5.9%)	0	1 (2.9%)	0	0	0
Iron excess	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Iron excess (cont)						
(cont)						
Grade 3	1 (1.4%)	0	1 (0.7%)	0	0	0
Haemosiderosis	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Iron overload	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 3	1 (1.4%)	0	1 (0.7%)	0	0	0
Hyperglycaemic conditions NEC	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Iron excess (cont)						
(cont)						
Grade 3	0	0	0	0	0	0
Haemosiderosis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Iron overload	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Hyperglycaemic conditions NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Hyperglycaemic conditions NEC (cont)						
Hyperglycaemia	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0
Hypoglycaemic conditions NEC	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Hypoglycaemia	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Phosphorus metabolism disorders	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Hypophosphataemia	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Hyperglycaemic conditions NEC (cont)						
Hyperglycaemia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Hypoglycaemic conditions NEC	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 3	1 (5.9%)	0	1 (2.9%)	0	0	0
Hypoglycaemia	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 3	1 (5.9%)	0	1 (2.9%)	0	0	0
Phosphorus metabolism disorders	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 3	1 (5.9%)	0	1 (2.9%)	0	0	0
Hypophosphataemia	1 (5.9%)	0	1 (2.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Phosphorus metabolism disorders (cont)						
Hypophosphataemia (cont)						
Grade 3	0	0	0	0	0	0
Protein metabolism disorders NEC	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	0	0	0
Hypoalbuminaemia	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	0	0	0
Sodium imbalance	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 3	0	0	0	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Phosphorus metabolism disorders (cont)						
Hypophosphataemia (cont)						
Grade 3	1 (5.9%)	0	1 (2.9%)	0	0	0
Protein metabolism disorders NEC	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	1 (5.9%)	0	1 (2.9%)	0	0	0
Hypoalbuminaemia	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	1 (5.9%)	0	1 (2.9%)	0	0	0
Sodium imbalance	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 3	1 (5.9%)	0	1 (2.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Sodium imbalance (cont)						
Hyponatraemia	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 3	0	0	0	0	1 (1.4%)	1 (0.8%)
Total fluid volume decreased	1 (1.4%)	0	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 3	1 (1.4%)	0	1 (0.7%)	0	0	0
Dehydration	1 (1.4%)	0	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 3	1 (1.4%)	0	1 (0.7%)	0	0	0
Diabetes mellitus (incl subtypes)	0	0	0	0	3 (4.3%)	3 (2.5%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	0	2 (2.9%)	2 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Sodium imbalance (cont)						
Hyponatraemia	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 3	1 (5.9%)	0	1 (2.9%)	0	0	0
Total fluid volume decreased	0	1 (5.6%)	1 (2.9%)	0	1 (6.7%)	1 (3.4%)
Grade 2	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 3	0	0	0	0	1 (6.7%)	1 (3.4%)
Dehydration	0	1 (5.6%)	1 (2.9%)	0	1 (6.7%)	1 (3.4%)
Grade 2	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 3	0	0	0	0	1 (6.7%)	1 (3.4%)
Diabetes mellitus (incl subtypes)	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Diabetes mellitus (incl subtypes) (cont)						
Diabetes mellitus	0	0	0	0	3 (4.3%)	3 (2.5%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	0	2 (2.9%)	2 (1.7%)
Electrolyte imbalance NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Electrolyte imbalance	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Diabetes mellitus (incl subtypes) (cont)						
Diabetes mellitus	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Electrolyte imbalance NEC	0	1 (5.6%)	1 (2.9%)	0	1 (6.7%)	1 (3.4%)
Grade 1	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 3	0	1 (5.6%)	1 (2.9%)	0	0	0
Electrolyte imbalance	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 1	0	0	0	0	1 (6.7%)	1 (3.4%)
Tumour lysis syndrome	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 3	0	1 (5.6%)	1 (2.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
General nutritional disorders NEC	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Abnormal loss of weight	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Total fluid volume increased	0	1 (1.3%)	1 (0.7%)	1 (2.0%)	0	1 (0.8%)
Grade 2	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 3	0	1 (1.3%)	1 (0.7%)	0	0	0
Fluid retention	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 2	0	0	0	1 (2.0%)	0	1 (0.8%)
Hypervolaemia	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 3	0	1 (1.3%)	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
General nutritional disorders NEC	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Abnormal loss of weight	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Total fluid volume increased	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Fluid retention	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Hypervolaemia	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders	16 (23.2%)	20 (26.3%)	36 (24.8%)	5 (10.0%)	14 (20.3%)	19 (16.0%)
Grade 1	10 (14.5%)	13 (17.1%)	23 (15.9%)	3 (6.0%)	7 (10.1%)	10 (8.4%)
Grade 2	5 (7.2%)	7 (9.2%)	12 (8.3%)	2 (4.0%)	7 (10.1%)	9 (7.6%)
Grade 3	1 (1.4%)	0	1 (0.7%)	0	0	0
Musculoskeletal and connective tissue pain and discomfort	12 (17.4%)	6 (7.9%)	18 (12.4%)	3 (6.0%)	9 (13.0%)	12 (10.1%)
Grade 1	8 (11.6%)	5 (6.6%)	13 (9.0%)	2 (4.0%)	5 (7.2%)	7 (5.9%)
Grade 2	3 (4.3%)	1 (1.3%)	4 (2.8%)	1 (2.0%)	4 (5.8%)	5 (4.2%)
Grade 3	1 (1.4%)	0	1 (0.7%)	0	0	0
Pain in extremity	8 (11.6%)	4 (5.3%)	12 (8.3%)	1 (2.0%)	2 (2.9%)	3 (2.5%)
Grade 1	6 (8.7%)	3 (3.9%)	9 (6.2%)	0	1 (1.4%)	1 (0.8%)
Grade 2	2 (2.9%)	1 (1.3%)	3 (2.1%)	1 (2.0%)	1 (1.4%)	2 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders	6 (35.3%)	3 (16.7%)	9 (25.7%)	3 (21.4%)	4 (26.7%)	7 (24.1%)
Grade 1	3 (17.6%)	3 (16.7%)	6 (17.1%)	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 2	3 (17.6%)	0	3 (8.6%)	2 (14.3%)	3 (20.0%)	5 (17.2%)
Grade 3	0	0	0	0	0	0
Musculoskeletal and connective tissue pain and discomfort	2 (11.8%)	1 (5.6%)	3 (8.6%)	2 (14.3%)	4 (26.7%)	6 (20.7%)
Grade 1	1 (5.9%)	1 (5.6%)	2 (5.7%)	1 (7.1%)	2 (13.3%)	3 (10.3%)
Grade 2	1 (5.9%)	0	1 (2.9%)	1 (7.1%)	2 (13.3%)	3 (10.3%)
Grade 3	0	0	0	0	0	0
Pain in extremity	1 (5.9%)	1 (5.6%)	2 (5.7%)	2 (14.3%)	2 (13.3%)	4 (13.8%)
Grade 1	0	1 (5.6%)	1 (2.9%)	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 2	1 (5.9%)	0	1 (2.9%)	1 (7.1%)	1 (6.7%)	2 (6.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Musculoskeletal and connective tissue pain and discomfort (cont)						
Back pain	5 (7.2%)	2 (2.6%)	7 (4.8%)	2 (4.0%)	5 (7.2%)	7 (5.9%)
Grade 1	3 (4.3%)	1 (1.3%)	4 (2.8%)	2 (4.0%)	3 (4.3%)	5 (4.2%)
Grade 2	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	2 (2.9%)	2 (1.7%)
Grade 3	1 (1.4%)	0	1 (0.7%)	0	0	0
Musculoskeletal pain	2 (2.9%)	1 (1.3%)	3 (2.1%)	0	1 (1.4%)	1 (0.8%)
Grade 1	2 (2.9%)	1 (1.3%)	3 (2.1%)	0	1 (1.4%)	1 (0.8%)
Flank pain	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Musculoskeletal chest pain	1 (1.4%)	0	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Musculoskeletal and connective tissue pain and discomfort (cont)						
Back pain	1 (5.9%)	0	1 (2.9%)	0	2 (13.3%)	2 (6.9%)
Grade 1	1 (5.9%)	0	1 (2.9%)	0	1 (6.7%)	1 (3.4%)
Grade 2	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 3	0	0	0	0	0	0
Musculoskeletal pain	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Flank pain	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Musculoskeletal chest pain	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Musculoskeletal and connective tissue pain and discomfort (cont)						
Musculoskeletal chest pain (cont)						
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Neck pain	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Bone related signs and symptoms	4 (5.8%)	8 (10.5%)	12 (8.3%)	2 (4.0%)	3 (4.3%)	5 (4.2%)
Grade 1	3 (4.3%)	3 (3.9%)	6 (4.1%)	1 (2.0%)	1 (1.4%)	2 (1.7%)
Grade 2	1 (1.4%)	5 (6.6%)	6 (4.1%)	1 (2.0%)	2 (2.9%)	3 (2.5%)
Bone pain	2 (2.9%)	8 (10.5%)	10 (6.9%)	1 (2.0%)	3 (4.3%)	4 (3.4%)
Grade 1	2 (2.9%)	3 (3.9%)	5 (3.4%)	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Musculoskeletal and connective tissue pain and discomfort (cont)						
Musculoskeletal chest pain (cont)						
Grade 1	0	0	0	0	0	0
Neck pain	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Bone related signs and symptoms	0	1 (5.6%)	1 (2.9%)	1 (7.1%)	0	1 (3.4%)
Grade 1	0	1 (5.6%)	1 (2.9%)	1 (7.1%)	0	1 (3.4%)
Grade 2	0	0	0	0	0	0
Bone pain	0	1 (5.6%)	1 (2.9%)	1 (7.1%)	0	1 (3.4%)
Grade 1	0	1 (5.6%)	1 (2.9%)	1 (7.1%)	0	1 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Bone related signs and symptoms (cont)						
Bone pain (cont)						
Grade 2	0	5 (6.6%)	5 (3.4%)	1 (2.0%)	2 (2.9%)	3 (2.5%)
Pain in jaw	1 (1.4%)	0	1 (0.7%)	1 (2.0%)	0	1 (0.8%)
Grade 1	1 (1.4%)	0	1 (0.7%)	1 (2.0%)	0	1 (0.8%)
Spinal pain	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 2	1 (1.4%)	0	1 (0.7%)	0	0	0
Joint related signs and symptoms	3 (4.3%)	2 (2.6%)	5 (3.4%)	1 (2.0%)	0	1 (0.8%)
Grade 1	2 (2.9%)	2 (2.6%)	4 (2.8%)	0	0	0
Grade 2	1 (1.4%)	0	1 (0.7%)	1 (2.0%)	0	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Other Races					
(Continued)	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Bone related signs and symptoms (cont)						
Bone pain (cont)						
Grade 2	0	0	0	0	0	0
Pain in jaw	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Spinal pain	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Joint related signs and symptoms	1 (5.9%)	0	1 (2.9%)	0	1 (6.7%)	1 (3.4%)
Grade 1	0	0	0	0	0	0
Grade 2	1 (5.9%)	0	1 (2.9%)	0	1 (6.7%)	1 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Joint related signs and symptoms (cont)						
Arthralgia	3 (4.3%)	2 (2.6%)	5 (3.4%)	1 (2.0%)	0	1 (0.8%)
Grade 1	2 (2.9%)	2 (2.6%)	4 (2.8%)	0	0	0
Grade 2	1 (1.4%)	0	1 (0.7%)	1 (2.0%)	0	1 (0.8%)
Joint effusion	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Muscle related signs and symptoms NEC	0	4 (5.3%)	4 (2.8%)	0	2 (2.9%)	2 (1.7%)
Grade 1	0	3 (3.9%)	3 (2.1%)	0	1 (1.4%)	1 (0.8%)
Grade 2	0	1 (1.3%)	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Muscle spasms	0	4 (5.3%)	4 (2.8%)	0	2 (2.9%)	2 (1.7%)
Grade 1	0	3 (3.9%)	3 (2.1%)	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Joint related signs and symptoms (cont)						
Arthralgia	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	1 (5.9%)	0	1 (2.9%)	0	0	0
Joint effusion	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 2	0	0	0	0	1 (6.7%)	1 (3.4%)
Muscle related signs and symptoms NEC	2 (11.8%)	2 (11.1%)	4 (11.4%)	0	0	0
Grade 1	2 (11.8%)	2 (11.1%)	4 (11.4%)	0	0	0
Grade 2	0	0	0	0	0	0
Muscle spasms	2 (11.8%)	2 (11.1%)	4 (11.4%)	0	0	0
Grade 1	2 (11.8%)	2 (11.1%)	4 (11.4%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Muscle related signs and symptoms NEC (cont)						
Muscle spasms (cont)						
Grade 2	0	1 (1.3%)	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Soft tissue disorders NEC	2 (2.9%)	0	2 (1.4%)	0	0	0
Grade 1	2 (2.9%)	0	2 (1.4%)	0	0	0
Groin pain	2 (2.9%)	0	2 (1.4%)	0	0	0
Grade 1	2 (2.9%)	0	2 (1.4%)	0	0	0
Bursal disorders	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Muscle related signs and symptoms NEC (cont)						
Muscle spasms (cont)						
Grade 2	0	0	0	0	0	0
Soft tissue disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Groin pain	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Bursal disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Bursal disorders (cont)						
Bursal fluid accumulation	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Crystal arthropathic disorders	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Gouty arthritis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Muscle pains	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 2	1 (1.4%)	0	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Bursal disorders (cont)						
Bursal fluid accumulation	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Crystal arthropathic disorders	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 2	1 (5.9%)	0	1 (2.9%)	0	0	0
Gouty arthritis	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 2	1 (5.9%)	0	1 (2.9%)	0	0	0
Muscle pains	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Muscle pains (cont)						
Myalgia	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 2	1 (1.4%)	0	1 (0.7%)	0	0	0
Tendon disorders	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Tendonitis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Arthropathies NEC	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Muscle pains (cont)						
Myalgia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Tendon disorders	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 2	1 (5.9%)	0	1 (2.9%)	0	0	0
Tendonitis	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 2	1 (5.9%)	0	1 (2.9%)	0	0	0
Arthropathies NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Arthropathies NEC (cont)						
Arthritis	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Bone disorders NEC	0	0	0	0	2 (2.9%)	2 (1.7%)
Grade 1	0	0	0	0	2 (2.9%)	2 (1.7%)
Bone lesion	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Osteosclerosis	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Muscle weakness conditions	0	3 (3.9%)	3 (2.1%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Arthropathies NEC (cont)						
Arthritis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Bone disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Bone lesion	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Osteosclerosis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Muscle weakness conditions	0	0	0	1 (7.1%)	0	1 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Muscle weakness conditions (cont) (cont)						
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 2	0	2 (2.6%)	2 (1.4%)	0	0	0
Muscular weakness	0	3 (3.9%)	3 (2.1%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 2	0	2 (2.6%)	2 (1.4%)	0	0	0
Musculoskeletal and connective tissue infections and inflammations NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Fasciitis	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Muscle weakness conditions (cont) (cont)						
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	1 (7.1%)	0	1 (3.4%)
Muscular weakness	0	0	0	1 (7.1%)	0	1 (3.4%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	1 (7.1%)	0	1 (3.4%)
Musculoskeletal and connective tissue infections and inflammations NEC	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 1	0	0	0	0	1 (6.7%)	1 (3.4%)
Fasciitis	0	0	0	0	1 (6.7%)	1 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Musculoskeletal and connective tissue infections and inflammations NEC (cont)						
Fasciitis (cont)						
Grade 1	0	0	0	0	0	0
Investigations	17 (24.6%)	15 (19.7%)	32 (22.1%)	9 (18.0%)	14 (20.3%)	23 (19.3%)
Grade 1	6 (8.7%)	8 (10.5%)	14 (9.7%)	3 (6.0%)	9 (13.0%)	12 (10.1%)
Grade 2	6 (8.7%)	4 (5.3%)	10 (6.9%)	5 (10.0%)	5 (7.2%)	10 (8.4%)
Grade 3	4 (5.8%)	3 (3.9%)	7 (4.8%)	1 (2.0%)	0	1 (0.8%)
Grade 4	1 (1.4%)	0	1 (0.7%)	0	0	0
Liver function analyses	9 (13.0%)	9 (11.8%)	18 (12.4%)	2 (4.0%)	5 (7.2%)	7 (5.9%)
Grade 1	4 (5.8%)	5 (6.6%)	9 (6.2%)	1 (2.0%)	1 (1.4%)	2 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Musculoskeletal and connective tissue infections and inflammations NEC (cont)						
Fasciitis (cont)						
Grade 1	0	0	0	0	1 (6.7%)	1 (3.4%)
Investigations	4 (23.5%)	4 (22.2%)	8 (22.9%)	2 (14.3%)	1 (6.7%)	3 (10.3%)
Grade 1	3 (17.6%)	1 (5.6%)	4 (11.4%)	1 (7.1%)	0	1 (3.4%)
Grade 2	1 (5.9%)	3 (16.7%)	4 (11.4%)	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 3	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Liver function analyses	2 (11.8%)	2 (11.1%)	4 (11.4%)	1 (7.1%)	0	1 (3.4%)
Grade 1	1 (5.9%)	0	1 (2.9%)	1 (7.1%)	0	1 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Liver function analyses (cont)						
(cont)						
Grade 2	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	4 (5.8%)	4 (3.4%)
Grade 3	4 (5.8%)	3 (3.9%)	7 (4.8%)	1 (2.0%)	0	1 (0.8%)
Alanine aminotransferase increased	7 (10.1%)	5 (6.6%)	12 (8.3%)	0	3 (4.3%)	3 (2.5%)
Grade 1	3 (4.3%)	4 (5.3%)	7 (4.8%)	0	2 (2.9%)	2 (1.7%)
Grade 2	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	1 (1.4%)	1 (0.8%)
Grade 3	3 (4.3%)	0	3 (2.1%)	0	0	0
Gamma-glutamyltransferase increased	4 (5.8%)	4 (5.3%)	8 (5.5%)	1 (2.0%)	2 (2.9%)	3 (2.5%)
Grade 1	2 (2.9%)	0	2 (1.4%)	1 (2.0%)	0	1 (0.8%)
Grade 2	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	2 (2.9%)	2 (1.7%)
Grade 3	1 (1.4%)	3 (3.9%)	4 (2.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Liver function analyses (cont)						
(cont)						
Grade 2	1 (5.9%)	2 (11.1%)	3 (8.6%)	0	0	0
Grade 3	0	0	0	0	0	0
Alanine aminotransferase increased	0	1 (5.6%)	1 (2.9%)	1 (7.1%)	0	1 (3.4%)
Grade 1	0	1 (5.6%)	1 (2.9%)	1 (7.1%)	0	1 (3.4%)
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Gamma-glutamyltransferase increased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Liver function analyses (cont)						
Aspartate aminotransferase increased	3 (4.3%)	2 (2.6%)	5 (3.4%)	0	1 (1.4%)	1 (0.8%)
Grade 1	2 (2.9%)	2 (2.6%)	4 (2.8%)	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	0	0	0
Grade 3	1 (1.4%)	0	1 (0.7%)	0	0	0
Blood bilirubin increased	0	1 (1.3%)	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Transaminases increased	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Liver function test abnormal	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 3	0	0	0	1 (2.0%)	0	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Liver function analyses (cont)						
Aspartate aminotransferase increased	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 3	0	0	0	0	0	0
Blood bilirubin increased	1 (5.9%)	1 (5.6%)	2 (5.7%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	1 (5.9%)	1 (5.6%)	2 (5.7%)	0	0	0
Transaminases increased	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 1	1 (5.9%)	0	1 (2.9%)	0	0	0
Liver function test abnormal	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Physical examination procedures and organ system status	4 (5.8%)	2 (2.6%)	6 (4.1%)	2 (4.0%)	2 (2.9%)	4 (3.4%)
Grade 1	4 (5.8%)	1 (1.3%)	5 (3.4%)	0	2 (2.9%)	2 (1.7%)
Grade 2	0	1 (1.3%)	1 (0.7%)	2 (4.0%)	0	2 (1.7%)
Weight decreased	2 (2.9%)	0	2 (1.4%)	1 (2.0%)	1 (1.4%)	2 (1.7%)
Grade 1	2 (2.9%)	0	2 (1.4%)	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	1 (2.0%)	0	1 (0.8%)
Weight increased	1 (1.4%)	1 (1.3%)	2 (1.4%)	1 (2.0%)	1 (1.4%)	2 (1.7%)
Grade 1	1 (1.4%)	0	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Grade 2	0	1 (1.3%)	1 (0.7%)	1 (2.0%)	0	1 (0.8%)
Lymph node palpable	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Physical examination procedures and organ system status	2 (11.8%)	2 (11.1%)	4 (11.4%)	1 (7.1%)	0	1 (3.4%)
Grade 1	2 (11.8%)	1 (5.6%)	3 (8.6%)	0	0	0
Grade 2	0	1 (5.6%)	1 (2.9%)	1 (7.1%)	0	1 (3.4%)
Weight decreased	1 (5.9%)	1 (5.6%)	2 (5.7%)	1 (7.1%)	0	1 (3.4%)
Grade 1	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 2	0	1 (5.6%)	1 (2.9%)	1 (7.1%)	0	1 (3.4%)
Weight increased	1 (5.9%)	1 (5.6%)	2 (5.7%)	0	0	0
Grade 1	1 (5.9%)	1 (5.6%)	2 (5.7%)	0	0	0
Grade 2	0	0	0	0	0	0
Lymph node palpable	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Physical examination procedures and organ system status (cont)						
Body temperature increased	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Renal function analyses	6 (8.7%)	1 (1.3%)	7 (4.8%)	3 (6.0%)	3 (4.3%)	6 (5.0%)
Grade 1	3 (4.3%)	1 (1.3%)	4 (2.8%)	1 (2.0%)	3 (4.3%)	4 (3.4%)
Grade 2	3 (4.3%)	0	3 (2.1%)	2 (4.0%)	0	2 (1.7%)
Blood creatinine increased	4 (5.8%)	1 (1.3%)	5 (3.4%)	2 (4.0%)	2 (2.9%)	4 (3.4%)
Grade 1	3 (4.3%)	1 (1.3%)	4 (2.8%)	1 (2.0%)	2 (2.9%)	3 (2.5%)
Grade 2	1 (1.4%)	0	1 (0.7%)	1 (2.0%)	0	1 (0.8%)
Creatinine renal clearance decreased	2 (2.9%)	0	2 (1.4%)	1 (2.0%)	1 (1.4%)	2 (1.7%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Physical examination procedures and organ system status (cont)						
Body temperature increased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Renal function analyses	0	0	0	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 1	0	0	0	1 (7.1%)	0	1 (3.4%)
Grade 2	0	0	0	0	1 (6.7%)	1 (3.4%)
Blood creatinine increased	0	0	0	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 1	0	0	0	1 (7.1%)	0	1 (3.4%)
Grade 2	0	0	0	0	1 (6.7%)	1 (3.4%)
Creatinine renal clearance decreased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Renal function analyses (cont)						
Creatinine renal clearance decreased (cont)						
Grade 2	2 (2.9%)	0	2 (1.4%)	1 (2.0%)	0	1 (0.8%)
ECG investigations	2 (2.9%)	2 (2.6%)	4 (2.8%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 2	0	2 (2.6%)	2 (1.4%)	0	0	0
Grade 4	1 (1.4%)	0	1 (0.7%)	0	0	0
Electrocardiogram QT prolonged	1 (1.4%)	2 (2.6%)	3 (2.1%)	0	0	0
Grade 2	0	2 (2.6%)	2 (1.4%)	0	0	0
Grade 4	1 (1.4%)	0	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Renal function analyses (cont)						
Creatinine renal clearance decreased (cont)						
Grade 2	0	0	0	0	0	0
ECG investigations	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Electrocardiogram QT prolonged	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
ECG investigations (cont)						
Electrocardiogram ST segment depression	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Protein analyses NEC	2 (2.9%)	0	2 (1.4%)	1 (2.0%)	0	1 (0.8%)
Grade 1	2 (2.9%)	0	2 (1.4%)	1 (2.0%)	0	1 (0.8%)
Protein total increased	2 (2.9%)	0	2 (1.4%)	1 (2.0%)	0	1 (0.8%)
Grade 1	2 (2.9%)	0	2 (1.4%)	1 (2.0%)	0	1 (0.8%)
Tissue enzyme analyses NEC	2 (2.9%)	2 (2.6%)	4 (2.8%)	0	1 (1.4%)	1 (0.8%)
Grade 1	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	1 (1.4%)	1 (0.8%)
Grade 2	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
ECG investigations (cont)						
Electrocardiogram ST segment depression	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Protein analyses NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Protein total increased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Tissue enzyme analyses NEC	0	2 (11.1%)	2 (5.7%)	0	0	0
Grade 1	0	2 (11.1%)	2 (5.7%)	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
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Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Tissue enzyme analyses NEC (cont)						
Blood alkaline phosphatase increased	2 (2.9%)	2 (2.6%)	4 (2.8%)	0	0	0
Grade 1	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0
Grade 2	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0
Blood lactate dehydrogenase increased	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Blood gas and acid base analyses	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Blood lactic acid increased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
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Data Extracted: CRF data: 01JUL2019
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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Tissue enzyme analyses NEC (cont)						
Blood alkaline phosphatase increased	0	2 (11.1%)	2 (5.7%)	0	0	0
Grade 1	0	2 (11.1%)	2 (5.7%)	0	0	0
Grade 2	0	0	0	0	0	0
Blood lactate dehydrogenase increased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Blood gas and acid base analyses	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 1	1 (5.9%)	0	1 (2.9%)	0	0	0
Blood lactic acid increased	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 1	1 (5.9%)	0	1 (2.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Mineral and electrolyte analyses	1 (1.4%)	0	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Grade 2	1 (1.4%)	0	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Blood bicarbonate decreased	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 2	1 (1.4%)	0	1 (0.7%)	0	0	0
Serum ferritin increased	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Autoimmunity analyses	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 2	0	0	0	1 (2.0%)	0	1 (0.8%)
Antiphospholipid antibodies positive	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 2	0	0	0	1 (2.0%)	0	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Mineral and electrolyte analyses	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Blood bicarbonate decreased	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Serum ferritin increased	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Autoimmunity analyses	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Antiphospholipid antibodies positive	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Cardiac auscultatory investigations	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Cardiac murmur	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Coagulation and bleeding analyses	0	0	0	0	3 (4.3%)	3 (2.5%)
Grade 1	0	0	0	0	3 (4.3%)	3 (2.5%)
Activated partial thromboplastin time prolonged	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
International normalised ratio increased	0	0	0	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Cardiac auscultatory investigations	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Cardiac murmur	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Coagulation and bleeding analyses	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Activated partial thromboplastin time prolonged	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
International normalised ratio increased	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Coagulation and bleeding analyses (cont)						
International normalised ratio increased (cont)						
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Prothrombin time prolonged	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Digestive enzymes	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Lipase increased	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Coagulation and bleeding analyses (cont)						
International normalised ratio increased (cont)						
Grade 1	0	0	0	0	0	0
Prothrombin time prolonged	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Digestive enzymes	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Lipase increased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Reproductive organ and breast imaging procedures	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Computerised tomogram pelvis abnormal	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Respiratory tract and thoracic imaging procedures	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Chest X-ray abnormal	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Reproductive organ and breast imaging procedures	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Computerised tomogram pelvis abnormal	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Respiratory tract and thoracic imaging procedures	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Chest X-ray abnormal	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Skeletal and cardiac muscle analyses	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Blood creatine phosphokinase increased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Vitamin analyses	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 2	0	0	0	1 (2.0%)	0	1 (0.8%)
Blood folate decreased	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 2	0	0	0	1 (2.0%)	0	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Skeletal and cardiac muscle analyses	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 1	0	1 (5.6%)	1 (2.9%)	0	0	0
Blood creatine phosphokinase increased	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 1	0	1 (5.6%)	1 (2.9%)	0	0	0
Vitamin analyses	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Blood folate decreased	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders	16 (23.2%)	14 (18.4%)	30 (20.7%)	9 (18.0%)	14 (20.3%)	23 (19.3%)
Grade 1	13 (18.8%)	9 (11.8%)	22 (15.2%)	6 (12.0%)	12 (17.4%)	18 (15.1%)
Grade 2	3 (4.3%)	4 (5.3%)	7 (4.8%)	2 (4.0%)	2 (2.9%)	4 (3.4%)
Grade 3	0	1 (1.3%)	1 (0.7%)	1 (2.0%)	0	1 (0.8%)
Rashes, eruptions and exanthems NEC	4 (5.8%)	1 (1.3%)	5 (3.4%)	2 (4.0%)	6 (8.7%)	8 (6.7%)
Grade 1	4 (5.8%)	0	4 (2.8%)	2 (4.0%)	6 (8.7%)	8 (6.7%)
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0
Rash	2 (2.9%)	1 (1.3%)	3 (2.1%)	2 (4.0%)	3 (4.3%)	5 (4.2%)
Grade 1	2 (2.9%)	0	2 (1.4%)	2 (4.0%)	3 (4.3%)	5 (4.2%)
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0
Rash maculo-papular	2 (2.9%)	0	2 (1.4%)	0	1 (1.4%)	1 (0.8%)
Grade 1	2 (2.9%)	0	2 (1.4%)	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders	4 (23.5%)	1 (5.6%)	5 (14.3%)	4 (28.6%)	3 (20.0%)	7 (24.1%)
Grade 1	3 (17.6%)	1 (5.6%)	4 (11.4%)	3 (21.4%)	2 (13.3%)	5 (17.2%)
Grade 2	1 (5.9%)	0	1 (2.9%)	1 (7.1%)	0	1 (3.4%)
Grade 3	0	0	0	0	1 (6.7%)	1 (3.4%)
Rashes, eruptions and exanthems NEC	3 (17.6%)	1 (5.6%)	4 (11.4%)	1 (7.1%)	2 (13.3%)	3 (10.3%)
Grade 1	2 (11.8%)	1 (5.6%)	3 (8.6%)	1 (7.1%)	2 (13.3%)	3 (10.3%)
Grade 2	1 (5.9%)	0	1 (2.9%)	0	0	0
Rash	3 (17.6%)	1 (5.6%)	4 (11.4%)	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 1	2 (11.8%)	1 (5.6%)	3 (8.6%)	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 2	1 (5.9%)	0	1 (2.9%)	0	0	0
Rash maculo-papular	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Rashes, eruptions and exanthems NEC (cont)						
Rash macular	1 (1.4%)	0	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Grade 1	1 (1.4%)	0	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Rash generalised	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Rash papular	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Apocrine and eccrine gland disorders	3 (4.3%)	4 (5.3%)	7 (4.8%)	3 (6.0%)	5 (7.2%)	8 (6.7%)
Grade 1	3 (4.3%)	2 (2.6%)	5 (3.4%)	3 (6.0%)	4 (5.8%)	7 (5.9%)
Grade 2	0	2 (2.6%)	2 (1.4%)	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Rashes, eruptions and exanthems NEC (cont)						
Rash macular	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Rash generalised	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 1	0	0	0	0	1 (6.7%)	1 (3.4%)
Rash papular	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Apocrine and eccrine gland disorders	1 (5.9%)	0	1 (2.9%)	2 (14.3%)	0	2 (6.9%)
Grade 1	1 (5.9%)	0	1 (2.9%)	2 (14.3%)	0	2 (6.9%)
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Apocrine and eccrine gland disorders (cont)						
Night sweats	3 (4.3%)	1 (1.3%)	4 (2.8%)	3 (6.0%)	3 (4.3%)	6 (5.0%)
Grade 1	3 (4.3%)	0	3 (2.1%)	3 (6.0%)	2 (2.9%)	5 (4.2%)
Grade 2	0	1 (1.3%)	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Hyperhidrosis	0	3 (3.9%)	3 (2.1%)	0	3 (4.3%)	3 (2.5%)
Grade 1	0	2 (2.6%)	2 (1.4%)	0	3 (4.3%)	3 (2.5%)
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0
Purpura and related conditions	4 (5.8%)	1 (1.3%)	5 (3.4%)	2 (4.0%)	0	2 (1.7%)
Grade 1	4 (5.8%)	1 (1.3%)	5 (3.4%)	1 (2.0%)	0	1 (0.8%)
Grade 2	0	0	0	1 (2.0%)	0	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Apocrine and eccrine gland disorders (cont)						
Night sweats	1 (5.9%)	0	1 (2.9%)	2 (14.3%)	0	2 (6.9%)
Grade 1	1 (5.9%)	0	1 (2.9%)	2 (14.3%)	0	2 (6.9%)
Grade 2	0	0	0	0	0	0
Hyperhidrosis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Purpura and related conditions	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Purpura and related conditions (cont)						
Ecchymosis	2 (2.9%)	0	2 (1.4%)	1 (2.0%)	0	1 (0.8%)
Grade 1	2 (2.9%)	0	2 (1.4%)	0	0	0
Grade 2	0	0	0	1 (2.0%)	0	1 (0.8%)
Petechiae	2 (2.9%)	1 (1.3%)	3 (2.1%)	0	0	0
Grade 1	2 (2.9%)	1 (1.3%)	3 (2.1%)	0	0	0
Purpura	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 1	0	0	0	1 (2.0%)	0	1 (0.8%)
Dermatitis and eczema	2 (2.9%)	0	2 (1.4%)	1 (2.0%)	0	1 (0.8%)
Grade 1	2 (2.9%)	0	2 (1.4%)	0	0	0
Grade 3	0	0	0	1 (2.0%)	0	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Purpura and related conditions (cont)						
Ecchymosis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Petechiae	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Purpura	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dermatitis and eczema	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Dermatitis and eczema (cont)						
Dermatitis contact	2 (2.9%)	0	2 (1.4%)	0	0	0
Grade 1	2 (2.9%)	0	2 (1.4%)	0	0	0
Dermatitis allergic	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 3	0	0	0	1 (2.0%)	0	1 (0.8%)
Pruritus NEC	2 (2.9%)	7 (9.2%)	9 (6.2%)	0	6 (8.7%)	6 (5.0%)
Grade 1	2 (2.9%)	5 (6.6%)	7 (4.8%)	0	5 (7.2%)	5 (4.2%)
Grade 2	0	2 (2.6%)	2 (1.4%)	0	1 (1.4%)	1 (0.8%)
Pruritus	1 (1.4%)	6 (7.9%)	7 (4.8%)	0	6 (8.7%)	6 (5.0%)
Grade 1	1 (1.4%)	5 (6.6%)	6 (4.1%)	0	5 (7.2%)	5 (4.2%)
Grade 2	0	1 (1.3%)	1 (0.7%)	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Dermatitis and eczema (cont)						
Dermatitis contact	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dermatitis allergic	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Pruritus NEC	0	0	0	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 1	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 2	0	0	0	1 (7.1%)	0	1 (3.4%)
Pruritus	0	0	0	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 1	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 2	0	0	0	1 (7.1%)	0	1 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Pruritus NEC (cont)						
Pruritus generalised	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Aquagenic pruritus	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Rash pruritic	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0
Alopecias	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Alopecia	1 (1.4%)	0	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Pruritus NEC (cont)						
Pruritus generalised	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Aquagenic pruritus	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Rash pruritic	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Alopecias	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Alopecia	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Alopecias (cont)						
Alopecia (cont)						
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Bullous conditions	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Blister	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Blood blister	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Dermal and epidermal conditions NEC	1 (1.4%)	3 (3.9%)	4 (2.8%)	1 (2.0%)	0	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Other Races					
(Continued)	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Alopecias (cont)						
Alopecia (cont)						
Grade 1	0	0	0	0	0	0
Bullous conditions	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Blister	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Blood blister	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dermal and epidermal conditions NEC	0	0	0	1 (7.1%)	0	1 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Dermal and epidermal conditions NEC (cont)						
(cont)						
Grade 1	0	2 (2.6%)	2 (1.4%)	0	0	0
Grade 2	1 (1.4%)	1 (1.3%)	2 (1.4%)	1 (2.0%)	0	1 (0.8%)
Skin lesion	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0
Grade 2	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0
Dermatosis	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 2	0	0	0	1 (2.0%)	0	1 (0.8%)
Dry skin	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Other Races					
(Continued)	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Dermal and epidermal conditions NEC (cont)						
(cont)						
Grade 1	0	0	0	1 (7.1%)	0	1 (3.4%)
Grade 2	0	0	0	0	0	0
Skin lesion	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Dermatosis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Dry skin	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
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Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Dermal and epidermal conditions NEC (cont)						
Pain of skin	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Skin fragility	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Erythemas	1 (1.4%)	0	1 (0.7%)	1 (2.0%)	0	1 (0.8%)
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 2	0	0	0	1 (2.0%)	0	1 (0.8%)
Erythema	1 (1.4%)	0	1 (0.7%)	1 (2.0%)	0	1 (0.8%)
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Dermal and epidermal conditions NEC (cont)						
Pain of skin	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Skin fragility	0	0	0	1 (7.1%)	0	1 (3.4%)
Grade 1	0	0	0	1 (7.1%)	0	1 (3.4%)
Erythemas	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Erythema	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Erythemas (cont)						
Erythema (cont)						
Grade 2	0	0	0	1 (2.0%)	0	1 (0.8%)
Hyperkeratoses	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 2	1 (1.4%)	0	1 (0.7%)	0	0	0
Hyperkeratosis	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 2	1 (1.4%)	0	1 (0.7%)	0	0	0
Nail and nail bed conditions (excl infections and infestations)	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 2	1 (1.4%)	0	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Erythemas (cont)						
Erythema (cont)						
Grade 2	0	0	0	0	0	0
Hyperkeratoses	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Hyperkeratosis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Nail and nail bed conditions (excl infections and infestations)	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Nail and nail bed conditions (excl infections and infestations) (cont)						
Ingrowing nail	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 2	1 (1.4%)	0	1 (0.7%)	0	0	0
Skin haemorrhages	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Skin haemorrhage	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Telangiectasia and related conditions	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Nail and nail bed conditions (excl infections and infestations) (cont)						
Ingrowing nail	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Skin haemorrhages	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Skin haemorrhage	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Telangiectasia and related conditions	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Telangiectasia and related conditions (cont)						
Telangiectasia	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Dermatitis ascribed to specific agent	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 3	0	0	0	1 (2.0%)	0	1 (0.8%)
Drug eruption	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Toxic skin eruption	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 3	0	0	0	1 (2.0%)	0	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Telangiectasia and related conditions (cont)						
Telangiectasia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dermatitis ascribed to specific agent	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 3	0	0	0	0	1 (6.7%)	1 (3.4%)
Drug eruption	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 3	0	0	0	0	1 (6.7%)	1 (3.4%)
Toxic skin eruption	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Exfoliative conditions	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 1	0	0	0	1 (2.0%)	0	1 (0.8%)
Skin exfoliation	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 1	0	0	0	1 (2.0%)	0	1 (0.8%)
Skin and subcutaneous tissue ulcerations	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 3	0	1 (1.3%)	1 (0.7%)	0	0	0
Skin ulcer	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 3	0	1 (1.3%)	1 (0.7%)	0	0	0
Skin preneoplastic conditions NEC	0	0	0	2 (4.0%)	0	2 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Exfoliative conditions	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Skin exfoliation	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Skin and subcutaneous tissue ulcerations	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Skin ulcer	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Skin preneoplastic conditions NEC	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Skin preneoplastic conditions NEC (cont)						
(cont)						
Grade 1	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 2	0	0	0	1 (2.0%)	0	1 (0.8%)
Actinic keratosis	0	0	0	2 (4.0%)	0	2 (1.7%)
Grade 1	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 2	0	0	0	1 (2.0%)	0	1 (0.8%)
Vascular disorders	14 (20.3%)	8 (10.5%)	22 (15.2%)	6 (12.0%)	10 (14.5%)	16 (13.4%)
Grade 1	6 (8.7%)	2 (2.6%)	8 (5.5%)	2 (4.0%)	4 (5.8%)	6 (5.0%)
Grade 2	5 (7.2%)	1 (1.3%)	6 (4.1%)	3 (6.0%)	3 (4.3%)	6 (5.0%)
Grade 3	3 (4.3%)	4 (5.3%)	7 (4.8%)	1 (2.0%)	3 (4.3%)	4 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Skin preneoplastic conditions NEC (cont)						
(cont)						
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Actinic keratosis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Vascular disorders	4 (23.5%)	2 (11.1%)	6 (17.1%)	2 (14.3%)	2 (13.3%)	4 (13.8%)
Grade 1	4 (23.5%)	1 (5.6%)	5 (14.3%)	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 2	0	1 (5.6%)	1 (2.9%)	0	1 (6.7%)	1 (3.4%)
Grade 3	0	0	0	1 (7.1%)	0	1 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont) (cont) (cont) Grade 4	0	1 (1.3%)	1 (0.7%)	0	0	0
Vascular hypotensive disorders	11 (15.9%)	0	11 (7.6%)	0	2 (2.9%)	2 (1.7%)
Grade 1	5 (7.2%)	0	5 (3.4%)	0	0	0
Grade 2	4 (5.8%)	0	4 (2.8%)	0	2 (2.9%)	2 (1.7%)
Grade 3	2 (2.9%)	0	2 (1.4%)	0	0	0
Hypotension	11 (15.9%)	0	11 (7.6%)	0	2 (2.9%)	2 (1.7%)
Grade 1	5 (7.2%)	0	5 (3.4%)	0	0	0
Grade 2	4 (5.8%)	0	4 (2.8%)	0	2 (2.9%)	2 (1.7%)
Grade 3	2 (2.9%)	0	2 (1.4%)	0	0	0
Peripheral vascular disorders NEC	2 (2.9%)	0	2 (1.4%)	1 (2.0%)	1 (1.4%)	2 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont) (cont) (cont)						
Grade 4	0	0	0	0	0	0
Vascular hypotensive disorders	1 (5.9%)	0	1 (2.9%)	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 1	1 (5.9%)	0	1 (2.9%)	0	1 (6.7%)	1 (3.4%)
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	1 (7.1%)	0	1 (3.4%)
Hypotension	1 (5.9%)	0	1 (2.9%)	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 1	1 (5.9%)	0	1 (2.9%)	0	1 (6.7%)	1 (3.4%)
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	1 (7.1%)	0	1 (3.4%)
Peripheral vascular disorders NEC	3 (17.6%)	0	3 (8.6%)	0	1 (6.7%)	1 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Peripheral vascular disorders NEC (cont) (cont)						
Grade 1	1 (1.4%)	0	1 (0.7%)	1 (2.0%)	1 (1.4%)	2 (1.7%)
Grade 2	1 (1.4%)	0	1 (0.7%)	0	0	0
Flushing	1 (1.4%)	0	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 2	1 (1.4%)	0	1 (0.7%)	0	0	0
Hot flush	1 (1.4%)	0	1 (0.7%)	1 (2.0%)	0	1 (0.8%)
Grade 1	1 (1.4%)	0	1 (0.7%)	1 (2.0%)	0	1 (0.8%)
Haemorrhages NEC	1 (1.4%)	1 (1.3%)	2 (1.4%)	1 (2.0%)	1 (1.4%)	2 (1.7%)
Grade 1	1 (1.4%)	1 (1.3%)	2 (1.4%)	1 (2.0%)	1 (1.4%)	2 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Peripheral vascular disorders NEC (cont)						
(cont)						
Grade 1	3 (17.6%)	0	3 (8.6%)	0	1 (6.7%)	1 (3.4%)
Grade 2	0	0	0	0	0	0
Flushing	3 (17.6%)	0	3 (8.6%)	0	0	0
Grade 1	3 (17.6%)	0	3 (8.6%)	0	0	0
Grade 2	0	0	0	0	0	0
Hot flush	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 1	0	0	0	0	1 (6.7%)	1 (3.4%)
Haemorrhages NEC	0	1 (5.6%)	1 (2.9%)	1 (7.1%)	0	1 (3.4%)
Grade 1	0	1 (5.6%)	1 (2.9%)	1 (7.1%)	0	1 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Haemorrhages NEC (cont)						
Haematoma	1 (1.4%)	1 (1.3%)	2 (1.4%)	1 (2.0%)	1 (1.4%)	2 (1.7%)
Grade 1	1 (1.4%)	1 (1.3%)	2 (1.4%)	1 (2.0%)	1 (1.4%)	2 (1.7%)
Non-site specific vascular disorders NEC	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Poor venous access	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Peripheral vasoconstriction, necrosis and vascular insufficiency	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Haemorrhages NEC (cont)						
Haematoma	0	1 (5.6%)	1 (2.9%)	1 (7.1%)	0	1 (3.4%)
Grade 1	0	1 (5.6%)	1 (2.9%)	1 (7.1%)	0	1 (3.4%)
Non-site specific vascular disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Poor venous access	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Peripheral vasoconstriction, necrosis and vascular insufficiency	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (6.7%)	1 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Peripheral vasoconstriction, necrosis and vascular insufficiency (cont) (cont)						
Grade 4	0	1 (1.3%)	1 (0.7%)	0	0	0
Peripheral arterial occlusive disease	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 2	0	0	0	0	0	0
Peripheral ischaemia	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 4	0	1 (1.3%)	1 (0.7%)	0	0	0
Vascular hypertensive disorders NEC	1 (1.4%)	6 (7.9%)	7 (4.8%)	3 (6.0%)	4 (5.8%)	7 (5.9%)
Grade 1	0	1 (1.3%)	1 (0.7%)	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Peripheral vasoconstriction, necrosis and vascular insufficiency (cont) (cont)						
Grade 4	0	0	0	0	0	0
Peripheral arterial occlusive disease	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (6.7%)	1 (3.4%)
Peripheral ischaemia	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Vascular hypertensive disorders NEC	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Vascular hypertensive disorders NEC (cont) (cont)						
Grade 2	0	1 (1.3%)	1 (0.7%)	2 (4.0%)	0	2 (1.7%)
Grade 3	1 (1.4%)	4 (5.3%)	5 (3.4%)	1 (2.0%)	3 (4.3%)	4 (3.4%)
Hypertension	1 (1.4%)	6 (7.9%)	7 (4.8%)	3 (6.0%)	4 (5.8%)	7 (5.9%)
Grade 1	0	1 (1.3%)	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Grade 2	0	1 (1.3%)	1 (0.7%)	2 (4.0%)	0	2 (1.7%)
Grade 3	1 (1.4%)	4 (5.3%)	5 (3.4%)	1 (2.0%)	3 (4.3%)	4 (3.4%)
Accelerated and malignant hypertension	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 3	0	1 (1.3%)	1 (0.7%)	0	0	0
Hypertensive crisis	0	1 (1.3%)	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Vascular hypertensive disorders NEC (cont) (cont)						
Grade 2	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 3	0	0	0	0	0	0
Hypertension	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 3	0	0	0	0	0	0
Accelerated and malignant hypertension	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Hypertensive crisis	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Accelerated and malignant hypertension (cont)						
Hypertensive crisis (cont)						
Grade 3	0	1 (1.3%)	1 (0.7%)	0	0	0
Aortic necrosis and vascular insufficiency	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Aortic stenosis	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Non-site specific necrosis and vascular insufficiency NEC	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Accelerated and malignant hypertension (cont)						
Hypertensive crisis (cont)						
Grade 3	0	0	0	0	0	0
Aortic necrosis and vascular insufficiency	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Aortic stenosis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Non-site specific necrosis and vascular insufficiency NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Non-site specific necrosis and vascular insufficiency NEC (cont)						
Arteriosclerosis	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Peripheral embolism and thrombosis	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 2	0	0	0	1 (2.0%)	0	1 (0.8%)
Thrombophlebitis superficial	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 2	0	0	0	1 (2.0%)	0	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Non-site specific necrosis and vascular insufficiency NEC (cont)						
Arteriosclerosis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Peripheral embolism and thrombosis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Thrombophlebitis superficial	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders	10 (14.5%)	8 (10.5%)	18 (12.4%)	1 (2.0%)	7 (10.1%)	8 (6.7%)
Grade 1	5 (7.2%)	2 (2.6%)	7 (4.8%)	0	1 (1.4%)	1 (0.8%)
Grade 2	1 (1.4%)	4 (5.3%)	5 (3.4%)	0	3 (4.3%)	3 (2.5%)
Grade 3	2 (2.9%)	2 (2.6%)	4 (2.8%)	1 (2.0%)	3 (4.3%)	4 (3.4%)
Grade 4	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 5	1 (1.4%)	0	1 (0.7%)	0	0	0
Renal failure and impairment	6 (8.7%)	1 (1.3%)	7 (4.8%)	1 (2.0%)	4 (5.8%)	5 (4.2%)
Grade 1	3 (4.3%)	1 (1.3%)	4 (2.8%)	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	0	2 (2.9%)	2 (1.7%)
Grade 3	1 (1.4%)	0	1 (0.7%)	1 (2.0%)	1 (1.4%)	2 (1.7%)
Grade 4	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 5	1 (1.4%)	0	1 (0.7%)	0	0	0
Acute kidney injury	2 (2.9%)	0	2 (1.4%)	1 (2.0%)	1 (1.4%)	2 (1.7%)
Grade 1	2 (2.9%)	0	2 (1.4%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
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Data Extracted: CRF data: 01JUL2019
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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders	3 (17.6%)	1 (5.6%)	4 (11.4%)	2 (14.3%)	1 (6.7%)	3 (10.3%)
Grade 1	3 (17.6%)	0	3 (8.6%)	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 2	0	0	0	1 (7.1%)	0	1 (3.4%)
Grade 3	0	0	0	0	0	0
Grade 4	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 5	0	0	0	0	0	0
Renal failure and impairment	1 (5.9%)	1 (5.6%)	2 (5.7%)	2 (14.3%)	0	2 (6.9%)
Grade 1	1 (5.9%)	0	1 (2.9%)	1 (7.1%)	0	1 (3.4%)
Grade 2	0	0	0	1 (7.1%)	0	1 (3.4%)
Grade 3	0	0	0	0	0	0
Grade 4	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 5	0	0	0	0	0	0
Acute kidney injury	0	1 (5.6%)	1 (2.9%)	1 (7.1%)	0	1 (3.4%)
Grade 1	0	0	0	1 (7.1%)	0	1 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Renal failure and impairment (cont)						
Acute kidney injury (cont)						
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 3	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 4	0	0	0	0	0	0
Renal failure	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	2 (2.9%)	2 (1.7%)
Grade 1	0	1 (1.3%)	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 5	1 (1.4%)	0	1 (0.7%)	0	0	0
Renal impairment	2 (2.9%)	0	2 (1.4%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 3	1 (1.4%)	0	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Renal failure and impairment (cont)						
Acute kidney injury (cont)						
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Grade 4	0	1 (5.6%)	1 (2.9%)	0	0	0
Renal failure	1 (5.9%)	0	1 (2.9%)	1 (7.1%)	0	1 (3.4%)
Grade 1	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 2	0	0	0	1 (7.1%)	0	1 (3.4%)
Grade 5	0	0	0	0	0	0
Renal impairment	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Renal failure and impairment (cont)						
Chronic kidney disease	1 (1.4%)	0	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Grade 3	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 4	1 (1.4%)	0	1 (0.7%)	0	0	0
Bladder and urethral symptoms	3 (4.3%)	2 (2.6%)	5 (3.4%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 2	2 (2.9%)	0	2 (1.4%)	0	0	0
Grade 3	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0
Dysuria	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0
Grade 1	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0
Pollakiuria	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Renal failure and impairment (cont)						
Chronic kidney disease	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Bladder and urethral symptoms	2 (11.8%)	0	2 (5.7%)	0	0	0
Grade 1	2 (11.8%)	0	2 (5.7%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Dysuria	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 1	1 (5.9%)	0	1 (2.9%)	0	0	0
Pollakiuria	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 1	1 (5.9%)	0	1 (2.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Bladder and urethral symptoms (cont)						
Pollakiuria (cont)						
Grade 3	1 (1.4%)	0	1 (0.7%)	0	0	0
Urinary incontinence	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0
Grade 2	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 3	0	1 (1.3%)	1 (0.7%)	0	0	0
Urinary retention	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 2	1 (1.4%)	0	1 (0.7%)	0	0	0
Urinary tract signs and symptoms NEC	2 (2.9%)	3 (3.9%)	5 (3.4%)	0	1 (1.4%)	1 (0.8%)
Grade 1	2 (2.9%)	0	2 (1.4%)	0	0	0
Grade 2	0	3 (3.9%)	3 (2.1%)	0	0	0
Grade 3	0	0	0	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Bladder and urethral symptoms (cont)						
Pollakiuria (cont)						
Grade 3	0	0	0	0	0	0
Urinary incontinence	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Urinary retention	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Urinary tract signs and symptoms NEC	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 1	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Urinary tract signs and symptoms NEC (cont)						
Nocturia	2 (2.9%)	0	2 (1.4%)	0	0	0
Grade 1	2 (2.9%)	0	2 (1.4%)	0	0	0
Renal colic	0	3 (3.9%)	3 (2.1%)	0	1 (1.4%)	1 (0.8%)
Grade 2	0	3 (3.9%)	3 (2.1%)	0	0	0
Grade 3	0	0	0	0	1 (1.4%)	1 (0.8%)
Renal lithiasis	1 (1.4%)	2 (2.6%)	3 (2.1%)	0	1 (1.4%)	1 (0.8%)
Grade 1	1 (1.4%)	0	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 3	0	1 (1.3%)	1 (0.7%)	0	0	0
Nephrolithiasis	1 (1.4%)	2 (2.6%)	3 (2.1%)	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Other Races					
(Continued)	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Urinary tract signs and symptoms NEC (cont)						
Nocturia	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 1	0	0	0	0	1 (6.7%)	1 (3.4%)
Renal colic	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Renal lithiasis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Nephrolithiasis	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Renal lithiasis (cont)						
Nephrolithiasis (cont)						
Grade 1	1 (1.4%)	0	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 3	0	1 (1.3%)	1 (0.7%)	0	0	0
Urinary abnormalities	1 (1.4%)	0	1 (0.7%)	0	2 (2.9%)	2 (1.7%)
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 3	0	0	0	0	1 (1.4%)	1 (0.8%)
Chromaturia	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Haematuria	1 (1.4%)	0	1 (0.7%)	0	2 (2.9%)	2 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Renal lithiasis (cont)						
Nephrolithiasis (cont)						
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Urinary abnormalities	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	1 (5.6%)	1 (2.9%)	0	0	0
Chromaturia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Haematuria	0	1 (5.6%)	1 (2.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Urinary abnormalities (cont)						
Haematuria (cont)						
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 3	0	0	0	0	1 (1.4%)	1 (0.8%)
Renal vascular and ischaemic conditions	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0
Renal artery stenosis	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Urinary abnormalities (cont)						
Haematuria (cont)						
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	1 (5.6%)	1 (2.9%)	0	0	0
Renal vascular and ischaemic conditions	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Renal artery stenosis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders	11 (15.9%)	7 (9.2%)	18 (12.4%)	2 (4.0%)	5 (7.2%)	7 (5.9%)
Grade 1	3 (4.3%)	2 (2.6%)	5 (3.4%)	1 (2.0%)	2 (2.9%)	3 (2.5%)
Grade 2	2 (2.9%)	1 (1.3%)	3 (2.1%)	1 (2.0%)	2 (2.9%)	3 (2.5%)
Grade 3	5 (7.2%)	4 (5.3%)	9 (6.2%)	0	1 (1.4%)	1 (0.8%)
Grade 4	1 (1.4%)	0	1 (0.7%)	0	0	0
Supraventricular arrhythmias	5 (7.2%)	2 (2.6%)	7 (4.8%)	1 (2.0%)	2 (2.9%)	3 (2.5%)
Grade 1	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0
Grade 2	2 (2.9%)	0	2 (1.4%)	1 (2.0%)	1 (1.4%)	2 (1.7%)
Grade 3	2 (2.9%)	1 (1.3%)	3 (2.1%)	0	1 (1.4%)	1 (0.8%)
Atrial fibrillation	4 (5.8%)	1 (1.3%)	5 (3.4%)	1 (2.0%)	2 (2.9%)	3 (2.5%)
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 2	1 (1.4%)	0	1 (0.7%)	1 (2.0%)	1 (1.4%)	2 (1.7%)
Grade 3	2 (2.9%)	1 (1.3%)	3 (2.1%)	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders	1 (5.9%)	1 (5.6%)	2 (5.7%)	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 1	0	0	0	0	0	0
Grade 2	1 (5.9%)	1 (5.6%)	2 (5.7%)	0	0	0
Grade 3	0	0	0	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 4	0	0	0	0	0	0
Supraventricular arrhythmias	1 (5.9%)	0	1 (2.9%)	1 (7.1%)	0	1 (3.4%)
Grade 1	0	0	0	0	0	0
Grade 2	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 3	0	0	0	1 (7.1%)	0	1 (3.4%)
Atrial fibrillation	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Supraventricular arrhythmias (cont)						
Supraventricular tachycardia	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 2	1 (1.4%)	0	1 (0.7%)	0	0	0
Atrial flutter	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Sinus bradycardia	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 3	0	0	0	0	0	0
Heart failures NEC	3 (4.3%)	4 (5.3%)	7 (4.8%)	0	2 (2.9%)	2 (1.7%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 2	0	2 (2.6%)	2 (1.4%)	0	1 (1.4%)	1 (0.8%)
Grade 3	3 (4.3%)	2 (2.6%)	5 (3.4%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Supraventricular arrhythmias (cont)						
Supraventricular tachycardia	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Atrial flutter	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Sinus bradycardia	0	0	0	1 (7.1%)	0	1 (3.4%)
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	1 (7.1%)	0	1 (3.4%)
Heart failures NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Heart failures NEC (cont)						
Cardiac failure	2 (2.9%)	2 (2.6%)	4 (2.8%)	0	2 (2.9%)	2 (1.7%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 2	0	2 (2.6%)	2 (1.4%)	0	1 (1.4%)	1 (0.8%)
Grade 3	2 (2.9%)	0	2 (1.4%)	0	0	0
Cardiac failure congestive	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 3	1 (1.4%)	0	1 (0.7%)	0	0	0
Cardiac failure acute	0	2 (2.6%)	2 (1.4%)	0	0	0
Grade 3	0	2 (2.6%)	2 (1.4%)	0	0	0
Rate and rhythm disorders NEC	2 (2.9%)	0	2 (1.4%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Heart failures NEC (cont)						
Cardiac failure	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Cardiac failure congestive	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Cardiac failure acute	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Rate and rhythm disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Rate and rhythm disorders NEC (cont)						
(cont)						
Grade 2	1 (1.4%)	0	1 (0.7%)	0	0	0
Extrasystoles	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Tachycardia	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 2	1 (1.4%)	0	1 (0.7%)	0	0	0
Cardiac conduction disorders	1 (1.4%)	0	1 (0.7%)	1 (2.0%)	0	1 (0.8%)
Grade 1	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 3	1 (1.4%)	0	1 (0.7%)	0	0	0
Atrioventricular block complete	1 (1.4%)	0	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Rate and rhythm disorders NEC (cont)						
(cont)						
Grade 2	0	0	0	0	0	0
Extrasystoles	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Tachycardia	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Cardiac conduction disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Atrioventricular block complete	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Cardiac conduction disorders (cont)						
Atrioventricular block complete (cont)						
Grade 3	1 (1.4%)	0	1 (0.7%)	0	0	0
Atrioventricular block first degree	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 1	0	0	0	1 (2.0%)	0	1 (0.8%)
Cardiac signs and symptoms NEC	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Palpitations	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Cardiac conduction disorders (cont)						
Atrioventricular block complete (cont)						
Grade 3	0	0	0	0	0	0
Atrioventricular block first degree	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Cardiac signs and symptoms NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Palpitations	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Ischaemic coronary artery disorders	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 3	0	0	0	0	0	0
Grade 4	1 (1.4%)	0	1 (0.7%)	0	0	0
Acute myocardial infarction	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 4	1 (1.4%)	0	1 (0.7%)	0	0	0
Angina pectoris	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 3	1 (1.4%)	0	1 (0.7%)	0	0	0
Myocardial disorders NEC	1 (1.4%)	0	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Ischaemic coronary artery disorders	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 4	0	0	0	0	0	0
Acute myocardial infarction	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Angina pectoris	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	1 (6.7%)	1 (3.4%)
Myocardial disorders NEC	0	1 (5.6%)	1 (2.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Myocardial disorders NEC (cont)						
(cont)						
Grade 2	1 (1.4%)	0	1 (0.7%)	0	0	0
Cardiomegaly	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 2	1 (1.4%)	0	1 (0.7%)	0	0	0
Left ventricular dysfunction	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Pericardial disorders NEC	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 3	1 (1.4%)	0	1 (0.7%)	0	0	0
Pericardial effusion	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 3	1 (1.4%)	0	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Myocardial disorders NEC (cont)						
(cont)						
Grade 2	0	1 (5.6%)	1 (2.9%)	0	0	0
Cardiomegaly	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Left ventricular dysfunction	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 2	0	1 (5.6%)	1 (2.9%)	0	0	0
Pericardial disorders NEC	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Pericardial effusion	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Cardiac hypertensive complications	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 3	0	1 (1.3%)	1 (0.7%)	0	0	0
Hypertensive heart disease	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 3	0	1 (1.3%)	1 (0.7%)	0	0	0
Cardiac valve disorders NEC	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Cardiac valve disease	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Left ventricular failures	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Cardiac hypertensive complications	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Hypertensive heart disease	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Cardiac valve disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Cardiac valve disease	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Left ventricular failures	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Left ventricular failures (cont)						
Left ventricular failure	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Mitral valvular disorders	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0
Mitral valve incompetence	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0
Injury, poisoning and procedural complications	10 (14.5%)	14 (18.4%)	24 (16.6%)	4 (8.0%)	6 (8.7%)	10 (8.4%)
Grade 1	6 (8.7%)	9 (11.8%)	15 (10.3%)	3 (6.0%)	2 (2.9%)	5 (4.2%)
Grade 2	3 (4.3%)	4 (5.3%)	7 (4.8%)	1 (2.0%)	4 (5.8%)	5 (4.2%)
Grade 3	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Left ventricular failures (cont)						
Left ventricular failure	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Mitral valvular disorders	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Mitral valve incompetence	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Injury, poisoning and procedural complications	2 (11.8%)	1 (5.6%)	3 (8.6%)	2 (14.3%)	2 (13.3%)	4 (13.8%)
Grade 1	2 (11.8%)	0	2 (5.7%)	1 (7.1%)	0	1 (3.4%)
Grade 2	0	1 (5.6%)	1 (2.9%)	1 (7.1%)	0	1 (3.4%)
Grade 3	0	0	0	0	2 (13.3%)	2 (6.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Skin injuries NEC	6 (8.7%)	6 (7.9%)	12 (8.3%)	2 (4.0%)	3 (4.3%)	5 (4.2%)
Grade 1	5 (7.2%)	5 (6.6%)	10 (6.9%)	2 (4.0%)	2 (2.9%)	4 (3.4%)
Grade 2	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	1 (1.4%)	1 (0.8%)
Contusion	6 (8.7%)	3 (3.9%)	9 (6.2%)	2 (4.0%)	2 (2.9%)	4 (3.4%)
Grade 1	5 (7.2%)	2 (2.6%)	7 (4.8%)	2 (4.0%)	2 (2.9%)	4 (3.4%)
Grade 2	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0
Skin abrasion	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Skin laceration	0	2 (2.6%)	2 (1.4%)	0	1 (1.4%)	1 (0.8%)
Grade 1	0	2 (2.6%)	2 (1.4%)	0	0	0
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Skin injuries NEC	2 (11.8%)	1 (5.6%)	3 (8.6%)	1 (7.1%)	0	1 (3.4%)
Grade 1	2 (11.8%)	0	2 (5.7%)	1 (7.1%)	0	1 (3.4%)
Grade 2	0	1 (5.6%)	1 (2.9%)	0	0	0
Contusion	1 (5.9%)	1 (5.6%)	2 (5.7%)	1 (7.1%)	0	1 (3.4%)
Grade 1	1 (5.9%)	0	1 (2.9%)	1 (7.1%)	0	1 (3.4%)
Grade 2	0	1 (5.6%)	1 (2.9%)	0	0	0
Skin abrasion	1 (5.9%)	1 (5.6%)	2 (5.7%)	0	0	0
Grade 1	1 (5.9%)	1 (5.6%)	2 (5.7%)	0	0	0
Skin laceration	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
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Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Non-site specific injuries NEC	4 (5.8%)	3 (3.9%)	7 (4.8%)	1 (2.0%)	3 (4.3%)	4 (3.4%)
Grade 1	4 (5.8%)	3 (3.9%)	7 (4.8%)	1 (2.0%)	1 (1.4%)	2 (1.7%)
Grade 2	0	0	0	0	2 (2.9%)	2 (1.7%)
Fall	4 (5.8%)	3 (3.9%)	7 (4.8%)	1 (2.0%)	3 (4.3%)	4 (3.4%)
Grade 1	4 (5.8%)	3 (3.9%)	7 (4.8%)	1 (2.0%)	1 (1.4%)	2 (1.7%)
Grade 2	0	0	0	0	2 (2.9%)	2 (1.7%)
Wound	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Non-site specific injuries NEC	0	1 (5.6%)	1 (2.9%)	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 1	0	1 (5.6%)	1 (2.9%)	0	1 (6.7%)	1 (3.4%)
Grade 2	0	0	0	1 (7.1%)	0	1 (3.4%)
Fall	0	1 (5.6%)	1 (2.9%)	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 1	0	1 (5.6%)	1 (2.9%)	0	1 (6.7%)	1 (3.4%)
Grade 2	0	0	0	1 (7.1%)	0	1 (3.4%)
Wound	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Non-site specific procedural complications	3 (4.3%)	3 (3.9%)	6 (4.1%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 2	1 (1.4%)	2 (2.6%)	3 (2.1%)	0	0	0
Grade 3	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0
Post procedural complication	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 2	1 (1.4%)	0	1 (0.7%)	0	0	0
Post procedural contusion	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Procedural pain	1 (1.4%)	2 (2.6%)	3 (2.1%)	0	0	0
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Non-site specific procedural complications	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	1 (6.7%)	1 (3.4%)
Post procedural complication	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Post procedural contusion	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Procedural pain	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 2	0	0	0	0	1 (6.7%)	1 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Non-site specific procedural complications (cont)						
Procedural pain (cont)						
Grade 3	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0
Post procedural haemorrhage	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Seroma	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0
Site specific injuries NEC	3 (4.3%)	1 (1.3%)	4 (2.8%)	1 (2.0%)	2 (2.9%)	3 (2.5%)
Grade 1	2 (2.9%)	0	2 (1.4%)	0	1 (1.4%)	1 (0.8%)
Grade 2	1 (1.4%)	1 (1.3%)	2 (1.4%)	1 (2.0%)	1 (1.4%)	2 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Non-site specific procedural complications (cont)						
Procedural pain (cont)						
Grade 3	0	0	0	0	0	0
Post procedural haemorrhage	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 3	0	0	0	0	1 (6.7%)	1 (3.4%)
Seroma	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Site specific injuries NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Site specific injuries NEC (cont)						
Limb injury	2 (2.9%)	0	2 (1.4%)	1 (2.0%)	1 (1.4%)	2 (1.7%)
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 2	1 (1.4%)	0	1 (0.7%)	1 (2.0%)	1 (1.4%)	2 (1.7%)
Limb crushing injury	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Head injury	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Mouth injury	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Site specific injuries NEC (cont)						
Limb injury	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Limb crushing injury	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Head injury	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Mouth injury	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Chest and respiratory tract injuries NEC	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Traumatic haemothorax	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Eye injuries NEC	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Eye contusion	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Chest and respiratory tract injuries NEC	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 3	0	0	0	0	1 (6.7%)	1 (3.4%)
Traumatic haemothorax	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 3	0	0	0	0	1 (6.7%)	1 (3.4%)
Eye injuries NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Eye contusion	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Gastrointestinal and hepatobiliary procedural complications	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Procedural nausea	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Limb fractures and dislocations	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Patella fracture	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Muscle, tendon and ligament injuries	0	2 (2.6%)	2 (1.4%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Gastrointestinal and hepatobiliary procedural complications	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 2	0	0	0	0	1 (6.7%)	1 (3.4%)
Procedural nausea	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 2	0	0	0	0	1 (6.7%)	1 (3.4%)
Limb fractures and dislocations	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Patella fracture	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Muscle, tendon and ligament injuries	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
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Data Extracted: CRF data: 01JUL2019
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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Muscle, tendon and ligament injuries (cont)						
(cont)						
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0
Ligament rupture	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0
Ligament sprain	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Skull fractures, facial bone fractures and dislocations	0	0	0	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Muscle, tendon and ligament injuries (cont)						
(cont)						
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Ligament rupture	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Ligament sprain	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Skull fractures, facial bone fractures and dislocations	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Skull fractures, facial bone fractures and dislocations (cont) (cont)						
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Facial bones fracture	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Transfusion related complications	0	2 (2.6%)	2 (1.4%)	0	0	0
Grade 1	0	2 (2.6%)	2 (1.4%)	0	0	0
Transfusion reaction	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
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Data Extracted: CRF data: 01JUL2019
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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Skull fractures, facial bone fractures and dislocations (cont) (cont)						
Grade 1	0	0	0	0	0	0
Facial bones fracture	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Transfusion related complications	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Transfusion reaction	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Transfusion related complications (cont)						
Transfusion related complication	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Eye disorders	7 (10.1%)	5 (6.6%)	12 (8.3%)	5 (10.0%)	2 (2.9%)	7 (5.9%)
Grade 1	6 (8.7%)	3 (3.9%)	9 (6.2%)	4 (8.0%)	2 (2.9%)	6 (5.0%)
Grade 2	1 (1.4%)	2 (2.6%)	3 (2.1%)	0	0	0
Grade 3	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 4	0	0	0	0	0	0
Cataract conditions	3 (4.3%)	0	3 (2.1%)	3 (6.0%)	0	3 (2.5%)
Grade 1	2 (2.9%)	0	2 (1.4%)	2 (4.0%)	0	2 (1.7%)
Grade 2	1 (1.4%)	0	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Transfusion related complications (cont)						
Transfusion related complication	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Eye disorders	3 (17.6%)	2 (11.1%)	5 (14.3%)	3 (21.4%)	2 (13.3%)	5 (17.2%)
Grade 1	3 (17.6%)	1 (5.6%)	4 (11.4%)	2 (14.3%)	2 (13.3%)	4 (13.8%)
Grade 2	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 3	0	0	0	0	0	0
Grade 4	0	0	0	1 (7.1%)	0	1 (3.4%)
Cataract conditions	0	1 (5.6%)	1 (2.9%)	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 1	0	1 (5.6%)	1 (2.9%)	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Cataract conditions (cont)						
(cont)						
Grade 3	0	0	0	1 (2.0%)	0	1 (0.8%)
Cataract	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Cataract cortical	1 (1.4%)	0	1 (0.7%)	1 (2.0%)	0	1 (0.8%)
Grade 1	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 2	1 (1.4%)	0	1 (0.7%)	0	0	0
Cataract nuclear	1 (1.4%)	0	1 (0.7%)	2 (4.0%)	0	2 (1.7%)
Grade 1	1 (1.4%)	0	1 (0.7%)	1 (2.0%)	0	1 (0.8%)
Grade 3	0	0	0	1 (2.0%)	0	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Cataract conditions (cont)						
(cont)						
Grade 3	0	0	0	0	0	0
Cataract	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Cataract cortical	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 1	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 2	0	0	0	0	0	0
Cataract nuclear	0	1 (5.6%)	1 (2.9%)	1 (7.1%)	0	1 (3.4%)
Grade 1	0	1 (5.6%)	1 (2.9%)	1 (7.1%)	0	1 (3.4%)
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Cataract conditions (cont)						
Cataract subcapsular	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Visual disorders NEC	1 (1.4%)	2 (2.6%)	3 (2.1%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 2	0	2 (2.6%)	2 (1.4%)	0	0	0
Grade 3	0	0	0	0	0	0
Vision blurred	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 3	0	0	0	0	0	0
Diplopia	0	1 (1.3%)	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Cataract conditions (cont)						
Cataract subcapsular	0	1 (5.6%)	1 (2.9%)	1 (7.1%)	0	1 (3.4%)
Grade 1	0	1 (5.6%)	1 (2.9%)	1 (7.1%)	0	1 (3.4%)
Visual disorders NEC	2 (11.8%)	0	2 (5.7%)	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 1	2 (11.8%)	0	2 (5.7%)	0	1 (6.7%)	1 (3.4%)
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	1 (7.1%)	0	1 (3.4%)
Vision blurred	2 (11.8%)	0	2 (5.7%)	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 1	2 (11.8%)	0	2 (5.7%)	0	1 (6.7%)	1 (3.4%)
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	1 (7.1%)	0	1 (3.4%)
Diplopia	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Visual disorders NEC (cont)						
Diplopia (cont)						
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0
Lacrimation disorders	2 (2.9%)	1 (1.3%)	3 (2.1%)	0	1 (1.4%)	1 (0.8%)
Grade 1	2 (2.9%)	1 (1.3%)	3 (2.1%)	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	0	0	0
Lacrimation increased	2 (2.9%)	0	2 (1.4%)	0	0	0
Grade 1	2 (2.9%)	0	2 (1.4%)	0	0	0
Dry eye	0	1 (1.3%)	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Grade 1	0	1 (1.3%)	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Visual disorders NEC (cont)						
Diplopia (cont)						
Grade 2	0	0	0	0	0	0
Lacrimation disorders	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (5.6%)	1 (2.9%)	0	0	0
Lacrimation increased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dry eye	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (5.6%)	1 (2.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Choroid and vitreous structural change, deposit and degeneration	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hyalosis asteroid	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Corneal infections, oedemas and inflammations	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Keratitis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Ocular disorders NEC	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Choroid and vitreous structural change, deposit and degeneration	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 1	1 (5.9%)	0	1 (2.9%)	0	0	0
Hyalosis asteroid	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 1	1 (5.9%)	0	1 (2.9%)	0	0	0
Corneal infections, oedemas and inflammations	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 1	1 (5.9%)	0	1 (2.9%)	0	0	0
Keratitis	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 1	1 (5.9%)	0	1 (2.9%)	0	0	0
Ocular disorders NEC	0	0	0	1 (7.1%)	0	1 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
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Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Ocular disorders NEC (cont)						
(cont)						
Grade 1	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0
Grade 3	0	0	0	0	0	0
Periorbital oedema	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Eye oedema	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Eye pain	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Ocular disorders NEC (cont)						
(cont)						
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	1 (7.1%)	0	1 (3.4%)
Periorbital oedema	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Eye oedema	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Eye pain	0	0	0	1 (7.1%)	0	1 (3.4%)
Grade 3	0	0	0	1 (7.1%)	0	1 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Retinal bleeding and vascular disorders (excl retinopathy)	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Retinal haemorrhage	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Retinal structural change, deposit and degeneration	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Macular degeneration	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Retinal bleeding and vascular disorders (excl retinopathy)	0	0	0	1 (7.1%)	0	1 (3.4%)
Grade 1	0	0	0	1 (7.1%)	0	1 (3.4%)
Retinal haemorrhage	0	0	0	1 (7.1%)	0	1 (3.4%)
Grade 1	0	0	0	1 (7.1%)	0	1 (3.4%)
Retinal structural change, deposit and degeneration	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Macular degeneration	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Visual impairment and blindness (excl colour blindness)	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0
Grade 1	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0
Visual acuity reduced	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Visual impairment	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Conjunctival and corneal bleeding and vascular disorders	0	0	0	1 (2.0%)	1 (1.4%)	2 (1.7%)
Grade 1	0	0	0	1 (2.0%)	1 (1.4%)	2 (1.7%)
Conjunctival haemorrhage	0	0	0	1 (2.0%)	1 (1.4%)	2 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Visual impairment and blindness (excl colour blindness)	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 1	0	1 (5.6%)	1 (2.9%)	0	0	0
Visual acuity reduced	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 1	0	1 (5.6%)	1 (2.9%)	0	0	0
Visual impairment	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Conjunctival and corneal bleeding and vascular disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Conjunctival haemorrhage	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Conjunctival and corneal bleeding and vascular disorders (cont)						
Conjunctival haemorrhage (cont)						
Grade 1	0	0	0	1 (2.0%)	1 (1.4%)	2 (1.7%)
Eyelid movement disorders	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 1	0	0	0	1 (2.0%)	0	1 (0.8%)
Eyelid ptosis	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 1	0	0	0	1 (2.0%)	0	1 (0.8%)
Lid, lash and lacrimal infections, irritations and inflammations	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Conjunctival and corneal bleeding and vascular disorders (cont)						
Conjunctival haemorrhage (cont)						
Grade 1	0	0	0	0	0	0
Eyelid movement disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Eyelid ptosis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Lid, lash and lacrimal infections, irritations and inflammations	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 1	0	0	0	0	1 (6.7%)	1 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Lid, lash and lacrimal infections, irritations and inflammations (cont)						
Eyelid oedema	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Ocular bleeding and vascular disorders NEC	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Eye haemorrhage	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Psychiatric disorders	6 (8.7%)	6 (7.9%)	12 (8.3%)	3 (6.0%)	6 (8.7%)	9 (7.6%)
Grade 1	3 (4.3%)	4 (5.3%)	7 (4.8%)	2 (4.0%)	1 (1.4%)	3 (2.5%)
Grade 2	3 (4.3%)	2 (2.6%)	5 (3.4%)	1 (2.0%)	5 (7.2%)	6 (5.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Lid, lash and lacrimal infections, irritations and inflammations (cont)						
Eyelid oedema	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 1	0	0	0	0	1 (6.7%)	1 (3.4%)
Ocular bleeding and vascular disorders NEC	0	0	0	1 (7.1%)	0	1 (3.4%)
Grade 4	0	0	0	1 (7.1%)	0	1 (3.4%)
Eye haemorrhage	0	0	0	1 (7.1%)	0	1 (3.4%)
Grade 4	0	0	0	1 (7.1%)	0	1 (3.4%)
Psychiatric disorders	2 (11.8%)	0	2 (5.7%)	3 (21.4%)	2 (13.3%)	5 (17.2%)
Grade 1	1 (5.9%)	0	1 (2.9%)	2 (14.3%)	2 (13.3%)	4 (13.8%)
Grade 2	1 (5.9%)	0	1 (2.9%)	1 (7.1%)	0	1 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Anxiety symptoms	2 (2.9%)	3 (3.9%)	5 (3.4%)	1 (2.0%)	0	1 (0.8%)
Grade 1	1 (1.4%)	2 (2.6%)	3 (2.1%)	1 (2.0%)	0	1 (0.8%)
Grade 2	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0
Anxiety	2 (2.9%)	3 (3.9%)	5 (3.4%)	1 (2.0%)	0	1 (0.8%)
Grade 1	1 (1.4%)	2 (2.6%)	3 (2.1%)	1 (2.0%)	0	1 (0.8%)
Grade 2	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	0	0
Depressive disorders	2 (2.9%)	0	2 (1.4%)	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	0	0
Grade 2	2 (2.9%)	0	2 (1.4%)	0	1 (1.4%)	1 (0.8%)
Depression	2 (2.9%)	0	2 (1.4%)	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	0	0
Grade 2	2 (2.9%)	0	2 (1.4%)	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Anxiety symptoms	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	1 (5.9%)	0	1 (2.9%)	0	0	0
Anxiety	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	1 (5.9%)	0	1 (2.9%)	0	0	0
Depressive disorders	1 (5.9%)	0	1 (2.9%)	1 (7.1%)	0	1 (3.4%)
Grade 1	1 (5.9%)	0	1 (2.9%)	1 (7.1%)	0	1 (3.4%)
Grade 2	0	0	0	0	0	0
Depression	1 (5.9%)	0	1 (2.9%)	1 (7.1%)	0	1 (3.4%)
Grade 1	1 (5.9%)	0	1 (2.9%)	1 (7.1%)	0	1 (3.4%)
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Confusion and disorientation	1 (1.4%)	0	1 (0.7%)	1 (2.0%)	1 (1.4%)	2 (1.7%)
Grade 1	1 (1.4%)	0	1 (0.7%)	1 (2.0%)	0	1 (0.8%)
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Confusional state	1 (1.4%)	0	1 (0.7%)	1 (2.0%)	1 (1.4%)	2 (1.7%)
Grade 1	1 (1.4%)	0	1 (0.7%)	1 (2.0%)	0	1 (0.8%)
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Disturbances in initiating and maintaining sleep	1 (1.4%)	2 (2.6%)	3 (2.1%)	1 (2.0%)	3 (4.3%)	4 (3.4%)
Grade 1	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	1 (1.4%)	1 (0.8%)
Grade 2	0	1 (1.3%)	1 (0.7%)	1 (2.0%)	2 (2.9%)	3 (2.5%)
Insomnia	1 (1.4%)	2 (2.6%)	3 (2.1%)	1 (2.0%)	3 (4.3%)	4 (3.4%)
Grade 1	1 (1.4%)	1 (1.3%)	2 (1.4%)	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Confusion and disorientation	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Confusional state	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Disturbances in initiating and maintaining sleep	0	0	0	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 1	0	0	0	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 2	0	0	0	0	0	0
Insomnia	0	0	0	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 1	0	0	0	1 (7.1%)	1 (6.7%)	2 (6.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Disturbances in initiating and maintaining sleep (cont)						
Insomnia (cont)						
Grade 2	0	1 (1.3%)	1 (0.7%)	1 (2.0%)	2 (2.9%)	3 (2.5%)
Hallucinations (excl sleep-related)	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Hallucination	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Mental disorders NEC	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Mental status changes	1 (1.4%)	0	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Disturbances in initiating and maintaining sleep (cont)						
Insomnia (cont)						
Grade 2	0	0	0	0	0	0
Hallucinations (excl sleep-related)	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hallucination	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Mental disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Mental status changes	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Mental disorders NEC (cont)						
Mental status changes (cont)						
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Anxiety disorders NEC	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Anxiety disorder	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Parasomnias	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Nightmare	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Mental disorders NEC (cont)						
Mental status changes (cont)						
Grade 1	0	0	0	0	0	0
Anxiety disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Anxiety disorder	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Parasomnias	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Nightmare	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Sexual desire disorders	0	0	0	1 (2.0%)	1 (1.4%)	2 (1.7%)
Grade 1	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Libido decreased	0	0	0	1 (2.0%)	1 (1.4%)	2 (1.7%)
Grade 1	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 2	0	0	0	0	1 (1.4%)	1 (0.8%)
Sleep disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Sleep disorder	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Suicidal and self-injurious behaviour	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Sexual desire disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Libido decreased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Sleep disorders NEC	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 1	0	0	0	0	1 (6.7%)	1 (3.4%)
Sleep disorder	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 1	0	0	0	0	1 (6.7%)	1 (3.4%)
Suicidal and self-injurious behaviour	0	0	0	1 (7.1%)	0	1 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Suicidal and self-injurious behaviour (cont)						
(cont)						
Grade 2	0	0	0	0	0	0
Suicidal ideation	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Ear and labyrinth disorders	5 (7.2%)	4 (5.3%)	9 (6.2%)	2 (4.0%)	2 (2.9%)	4 (3.4%)
Grade 1	3 (4.3%)	4 (5.3%)	7 (4.8%)	1 (2.0%)	2 (2.9%)	3 (2.5%)
Grade 2	2 (2.9%)	0	2 (1.4%)	1 (2.0%)	0	1 (0.8%)
Grade 3	0	0	0	0	0	0
Inner ear signs and symptoms	4 (5.8%)	2 (2.6%)	6 (4.1%)	1 (2.0%)	1 (1.4%)	2 (1.7%)
Grade 1	3 (4.3%)	2 (2.6%)	5 (3.4%)	1 (2.0%)	1 (1.4%)	2 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Suicidal and self-injurious behaviour (cont)						
(cont)						
Grade 2	0	0	0	1 (7.1%)	0	1 (3.4%)
Suicidal ideation	0	0	0	1 (7.1%)	0	1 (3.4%)
Grade 2	0	0	0	1 (7.1%)	0	1 (3.4%)
Ear and labyrinth disorders	0	2 (11.1%)	2 (5.7%)	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 1	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 2	0	0	0	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 3	0	1 (5.6%)	1 (2.9%)	0	0	0
Inner ear signs and symptoms	0	2 (11.1%)	2 (5.7%)	0	1 (6.7%)	1 (3.4%)
Grade 1	0	1 (5.6%)	1 (2.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Ear and labyrinth disorders (cont)						
Inner ear signs and symptoms (cont)						
(cont)						
Grade 2	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 3	0	0	0	0	0	0
Vertigo	4 (5.8%)	2 (2.6%)	6 (4.1%)	0	1 (1.4%)	1 (0.8%)
Grade 1	3 (4.3%)	2 (2.6%)	5 (3.4%)	0	1 (1.4%)	1 (0.8%)
Grade 2	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 3	0	0	0	0	0	0
Motion sickness	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 1	0	0	0	1 (2.0%)	0	1 (0.8%)
Hearing losses	1 (1.4%)	0	1 (0.7%)	1 (2.0%)	1 (1.4%)	2 (1.7%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Ear and labyrinth disorders (cont)						
Inner ear signs and symptoms (cont)						
(cont)						
Grade 2	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 3	0	1 (5.6%)	1 (2.9%)	0	0	0
Vertigo	0	2 (11.1%)	2 (5.7%)	0	1 (6.7%)	1 (3.4%)
Grade 1	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 2	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 3	0	1 (5.6%)	1 (2.9%)	0	0	0
Motion sickness	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hearing losses	0	0	0	1 (7.1%)	0	1 (3.4%)
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Ear and labyrinth disorders (cont)						
Hearing losses (cont)						
(cont)						
Grade 2	1 (1.4%)	0	1 (0.7%)	1 (2.0%)	0	1 (0.8%)
Hypoacusis	1 (1.4%)	0	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 2	1 (1.4%)	0	1 (0.7%)	0	0	0
Deafness	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Sudden hearing loss	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 2	0	0	0	1 (2.0%)	0	1 (0.8%)
Ear disorders NEC	0	2 (2.6%)	2 (1.4%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Ear and labyrinth disorders (cont)						
Hearing losses (cont)						
(cont)						
Grade 2	0	0	0	1 (7.1%)	0	1 (3.4%)
Hypoacusis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Deafness	0	0	0	1 (7.1%)	0	1 (3.4%)
Grade 2	0	0	0	1 (7.1%)	0	1 (3.4%)
Sudden hearing loss	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Ear disorders NEC	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Ear and labyrinth disorders (cont)						
Ear disorders NEC (cont)						
(cont)						
Grade 1	0	2 (2.6%)	2 (1.4%)	0	0	0
Ear discomfort	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Ear pain	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Ear and labyrinth disorders (cont)						
Ear disorders NEC (cont)						
(cont)						
Grade 1	0	0	0	0	0	0
Ear discomfort	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Ear pain	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (2.9%)	5 (6.6%)	7 (4.8%)	1 (2.0%)	4 (5.8%)	5 (4.2%)
Grade 1	0	1 (1.3%)	1 (0.7%)	0	3 (4.3%)	3 (2.5%)
Grade 2	0	3 (3.9%)	3 (2.1%)	0	1 (1.4%)	1 (0.8%)
Grade 3	1 (1.4%)	1 (1.3%)	2 (1.4%)	1 (2.0%)	0	1 (0.8%)
Grade 4	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 5	0	0	0	0	0	0
Leukaemias acute myeloid	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Acute myeloid leukaemia	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Ovarian neoplasms malignant (excl germ cell)	1 (1.4%)	0	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (5.9%)	1 (5.6%)	2 (5.7%)	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 4	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 5	0	1 (5.6%)	1 (2.9%)	0	0	0
Leukaemias acute myeloid	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 4	1 (5.9%)	0	1 (2.9%)	0	0	0
Acute myeloid leukaemia	1 (5.9%)	0	1 (2.9%)	0	0	0
Grade 4	1 (5.9%)	0	1 (2.9%)	0	0	0
Ovarian neoplasms malignant (excl germ cell)	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Ovarian neoplasms malignant (excl germ cell) (cont) (cont)						
Grade 3	1 (1.4%)	0	1 (0.7%)	0	0	0
Ovarian clear cell carcinoma	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 3	1 (1.4%)	0	1 (0.7%)	0	0	0
Splenic marginal zone lymphomas	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 4	1 (1.4%)	0	1 (0.7%)	0	0	0
Splenic marginal zone lymphoma	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 4	1 (1.4%)	0	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Other Races					
(Continued)	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Ovarian neoplasms malignant (excl germ cell) (cont) (cont)						
Grade 3	0	0	0	0	0	0
Ovarian clear cell carcinoma	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Splenic marginal zone lymphomas	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Splenic marginal zone lymphoma	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Uterine neoplasms malignant NEC	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 3	1 (1.4%)	0	1 (0.7%)	0	0	0
Uterine cancer	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 3	1 (1.4%)	0	1 (0.7%)	0	0	0
Bone neoplasms benign (excl cysts)	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Haemangioma of bone	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Colorectal neoplasms malignant	0	0	0	1 (2.0%)	0	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Uterine neoplasms malignant NEC	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Uterine cancer	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Bone neoplasms benign (excl cysts)	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Haemangioma of bone	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Colorectal neoplasms malignant	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Colorectal neoplasms malignant (cont) (cont)						
Grade 3	0	0	0	1 (2.0%)	0	1 (0.8%)
Rectal cancer	0	0	0	1 (2.0%)	0	1 (0.8%)
Grade 3	0	0	0	1 (2.0%)	0	1 (0.8%)
Mantle cell lymphomas	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Mantle cell lymphoma recurrent	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cists and polyps) (cont)						
Colorectal neoplasms malignant (cont) (cont)						
Grade 3	0	0	0	0	0	0
Rectal cancer	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Mantle cell lymphomas	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 5	0	1 (5.6%)	1 (2.9%)	0	0	0
Mantle cell lymphoma recurrent	0	1 (5.6%)	1 (2.9%)	0	0	0
Grade 5	0	1 (5.6%)	1 (2.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Myeloproliferative disorders (excl leukaemias)	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Leukoerythroblastosis	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Nasal and paranasal sinus neoplasms benign	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 3	0	0	0	0	0	0
Nasal neoplasm benign	0	1 (1.3%)	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Myeloproliferative disorders (excl leukaemias)	0	0	0	1 (7.1%)	0	1 (3.4%)
Grade 3	0	0	0	1 (7.1%)	0	1 (3.4%)
Leukoerythroblastosis	0	0	0	1 (7.1%)	0	1 (3.4%)
Grade 3	0	0	0	1 (7.1%)	0	1 (3.4%)
Nasal and paranasal sinus neoplasms benign	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	1 (6.7%)	1 (3.4%)
Nasal neoplasm benign	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Nasal and paranasal sinus neoplasms benign (cont)						
Nasal neoplasm benign (cont)						
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Sinonasal papilloma	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Neoplasms malignant site unspecified NEC	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Metastatic squamous cell carcinoma	0	0	0	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Nasal and paranasal sinus neoplasms benign (cont)						
Nasal neoplasm benign (cont)						
Grade 1	0	0	0	0	0	0
Sinonasal papilloma	0	0	0	0	1 (6.7%)	1 (3.4%)
Grade 3	0	0	0	0	1 (6.7%)	1 (3.4%)
Neoplasms malignant site unspecified NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Metastatic squamous cell carcinoma	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Neoplasms malignant site unspecified NEC (cont)						
Metastatic squamous cell carcinoma (cont)						
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Prostatic neoplasms malignant	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0
Prostate cancer recurrent	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0
Skin neoplasms benign	0	0	0	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Other Races					
(Continued)	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Neoplasms malignant site unspecified NEC (cont)						
Metastatic squamous cell carcinoma (cont)						
Grade 1	0	0	0	0	0	0
Prostatic neoplasms malignant	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Prostate cancer recurrent	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Skin neoplasms benign	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Skin neoplasms benign (cont) (cont)						
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Seborrhoeic keratosis	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Skin neoplasms malignant and unspecified (excl melanoma)	0	3 (3.9%)	3 (2.1%)	0	1 (1.4%)	1 (0.8%)
Grade 2	0	2 (2.6%)	2 (1.4%)	0	1 (1.4%)	1 (0.8%)
Grade 3	0	1 (1.3%)	1 (0.7%)	0	0	0
Squamous cell carcinoma of skin	0	3 (3.9%)	3 (2.1%)	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Skin neoplasms benign (cont) (cont)						
Grade 1	0	0	0	0	0	0
Seborrhoeic keratosis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Skin neoplasms malignant and unspecified (excl melanoma)	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Squamous cell carcinoma of skin	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Skin neoplasms malignant and unspecified (excl melanoma) (cont)						
Squamous cell carcinoma of skin (cont)						
Grade 2	0	2 (2.6%)	2 (1.4%)	0	1 (1.4%)	1 (0.8%)
Grade 3	0	1 (1.3%)	1 (0.7%)	0	0	0
Uterine neoplasms benign	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)
Uterine leiomyoma	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 1	0	0	0	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Skin neoplasms malignant and unspecified (excl melanoma) (cont)						
Squamous cell carcinoma of skin (cont)						
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Uterine neoplasms benign	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Uterine leiomyoma	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Reproductive system and breast disorders	3 (4.3%)	1 (1.3%)	4 (2.8%)	0	1 (1.4%)	1 (0.8%)
Grade 1	3 (4.3%)	0	3 (2.1%)	0	0	0
Grade 3	0	1 (1.3%)	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Prostatic neoplasms and hypertrophy	1 (1.4%)	0	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 3	0	0	0	0	1 (1.4%)	1 (0.8%)
Benign prostatic hyperplasia	1 (1.4%)	0	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 3	0	0	0	0	1 (1.4%)	1 (0.8%)
Vulvovaginal disorders NEC	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Vaginal haemorrhage	1 (1.4%)	0	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Reproductive system and breast disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Prostatic neoplasms and hypertrophy	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Benign prostatic hyperplasia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Vulvovaginal disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Vaginal haemorrhage	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Reproductive system and breast disorders (cont)						
Vulvovaginal disorders NEC (cont)						
Vaginal haemorrhage (cont)						
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Vulvovaginal signs and symptoms	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Vulvovaginal pain	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Scrotal disorders NEC	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 3	0	1 (1.3%)	1 (0.7%)	0	0	0
Scrotal oedema	0	1 (1.3%)	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Other Races					
(Continued)	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Reproductive system and breast disorders (cont)						
Vulvovaginal disorders NEC (cont)						
Vaginal haemorrhage (cont)						
Grade 1	0	0	0	0	0	0
Vulvovaginal signs and symptoms	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Vulvovaginal pain	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Scrotal disorders NEC	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Scrotal oedema	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Reproductive system and breast disorders (cont)						
Scrotal disorders NEC (cont)						
Scrotal oedema (cont)						
Grade 3	0	1 (1.3%)	1 (0.7%)	0	0	0
Surgical and medical procedures	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Dental and gingival therapeutic procedures	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0
Tooth extraction	1 (1.4%)	0	1 (0.7%)	0	0	0
Grade 1	1 (1.4%)	0	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Reproductive system and breast disorders (cont)						
Scrotal disorders NEC (cont)						
Scrotal oedema (cont)						
Grade 3	0	0	0	0	0	0
Surgical and medical procedures	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dental and gingival therapeutic procedures	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Tooth extraction	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Congenital, familial and genetic disorders	0	2 (2.6%)	2 (1.4%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0
Male reproductive tract disorders congenital	0	2 (2.6%)	2 (1.4%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0
Hydrocele	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Phimosis	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Congenital, familial and genetic disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Male reproductive tract disorders congenital	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Hydrocele	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Phimosis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Hepatobiliary disorders	0	4 (5.3%)	4 (2.8%)	0	1 (1.4%)	1 (0.8%)
Grade 1	0	2 (2.6%)	2 (1.4%)	0	0	0
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 3	0	1 (1.3%)	1 (0.7%)	0	1 (1.4%)	1 (0.8%)
Bile duct infections and inflammations	0	2 (2.6%)	2 (1.4%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 3	0	1 (1.3%)	1 (0.7%)	0	0	0
Biliary colic	0	2 (2.6%)	2 (1.4%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 3	0	1 (1.3%)	1 (0.7%)	0	0	0
Cholestasis and jaundice	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Hepatobiliary disorders	0	0	0	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 1	0	0	0	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Bile duct infections and inflammations	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Biliary colic	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Cholestasis and jaundice	0	0	0	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 1	0	0	0	1 (7.1%)	1 (6.7%)	2 (6.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Hepatobiliary disorders (cont)						
Cholestasis and jaundice (cont)						
Ocular icterus	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hepatic enzymes and function abnormalities	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Hepatic function abnormal	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 1	0	1 (1.3%)	1 (0.7%)	0	0	0
Hepatic vascular disorders	0	0	0	0	1 (1.4%)	1 (0.8%)
Grade 3	0	0	0	0	1 (1.4%)	1 (0.8%)
Portal hypertension	0	0	0	0	1 (1.4%)	1 (0.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Hepatobiliary disorders (cont)						
Cholestasis and jaundice (cont)						
Ocular icterus	0	0	0	1 (7.1%)	1 (6.7%)	2 (6.9%)
Grade 1	0	0	0	1 (7.1%)	1 (6.7%)	2 (6.9%)
Hepatic enzymes and function abnormalities	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hepatic function abnormal	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hepatic vascular disorders	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Portal hypertension	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-db.pdf 29AUG2023: 9:41

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	White					
	DB Phase MMB (N=69)	DB Phase RUX (N=76)	DB Phase Total (N=145)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 - 48) Total (N=119)
Number of Subjects with Any Treatment-Emergent AE	65 (94.2%)	73 (96.1%)	138 (95.2%)	41 (82.0%)	59 (85.5%)	100 (84.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Hepatobiliary disorders (cont)						
Hepatic vascular disorders (cont)						
Portal hypertension (cont)						
Grade 3	0	0	0	0	1 (1.4%)	1 (0.8%)
Hepatocellular damage and hepatitis NEC	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0
Hepatocellular injury	0	1 (1.3%)	1 (0.7%)	0	0	0
Grade 2	0	1 (1.3%)	1 (0.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0805: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	DB Phase MMB (N=17)	DB Phase RUX (N=18)	DB Phase Total (N=35)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 - 48) Total (N=29)
Number of Subjects with Any Treatment-Emergent AE	16 (94.1%)	18 (100.0%)	34 (97.1%)	12 (85.7%)	15 (100.0%)	27 (93.1%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Hepatobiliary disorders (cont)						
Hepatic vascular disorders (cont)						
Portal hypertension (cont)						
Grade 3	0	0	0	0	0	0
Hepatocellular damage and hepatitis NEC	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Hepatocellular injury	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders	19 (38.0%)	43 (62.3%)	62 (52.1%)	87 (63.0%)
Grade 1	12 (24.0%)	14 (20.3%)	26 (21.8%)	39 (28.3%)
Grade 2	6 (12.0%)	20 (29.0%)	26 (21.8%)	33 (23.9%)
Grade 3	0	9 (13.0%)	9 (7.6%)	14 (10.1%)
Grade 4	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 5	0	0	0	0
Diarrhoea (excl infective)	8 (16.0%)	14 (20.3%)	22 (18.5%)	34 (24.6%)
Grade 1	6 (12.0%)	6 (8.7%)	12 (10.1%)	17 (12.3%)
Grade 2	2 (4.0%)	4 (5.8%)	6 (5.0%)	12 (8.7%)
Grade 3	0	4 (5.8%)	4 (3.4%)	5 (3.6%)
Diarrhoea	8 (16.0%)	14 (20.3%)	22 (18.5%)	34 (24.6%)
Grade 1	6 (12.0%)	6 (8.7%)	12 (10.1%)	17 (12.3%)
Grade 2	2 (4.0%)	4 (5.8%)	6 (5.0%)	12 (8.7%)
Grade 3	0	4 (5.8%)	4 (3.4%)	5 (3.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders	11 (78.6%)	11 (73.3%)	22 (75.9%)	25 (78.1%)
Grade 1	7 (50.0%)	5 (33.3%)	12 (41.4%)	14 (43.8%)
Grade 2	3 (21.4%)	5 (33.3%)	8 (27.6%)	8 (25.0%)
Grade 3	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 4	0	0	0	0
Grade 5	0	1 (6.7%)	1 (3.4%)	2 (6.3%)
Diarrhoea (excl infective)	6 (42.9%)	7 (46.7%)	13 (44.8%)	16 (50.0%)
Grade 1	6 (42.9%)	6 (40.0%)	12 (41.4%)	13 (40.6%)
Grade 2	0	1 (6.7%)	1 (3.4%)	2 (6.3%)
Grade 3	0	0	0	1 (3.1%)
Diarrhoea	6 (42.9%)	7 (46.7%)	13 (44.8%)	16 (50.0%)
Grade 1	6 (42.9%)	6 (40.0%)	12 (41.4%)	13 (40.6%)
Grade 2	0	1 (6.7%)	1 (3.4%)	2 (6.3%)
Grade 3	0	0	0	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Nausea and vomiting symptoms	5 (10.0%)	13 (18.8%)	18 (15.1%)	33 (23.9%)
Grade 1	4 (8.0%)	8 (11.6%)	12 (10.1%)	21 (15.2%)
Grade 2	1 (2.0%)	4 (5.8%)	5 (4.2%)	10 (7.2%)
Grade 3	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Nausea	4 (8.0%)	10 (14.5%)	14 (11.8%)	27 (19.6%)
Grade 1	4 (8.0%)	8 (11.6%)	12 (10.1%)	22 (15.9%)
Grade 2	0	2 (2.9%)	2 (1.7%)	4 (2.9%)
Grade 3	0	0	0	1 (0.7%)
Vomiting	4 (8.0%)	6 (8.7%)	10 (8.4%)	15 (10.9%)
Grade 1	3 (6.0%)	1 (1.4%)	4 (3.4%)	6 (4.3%)
Grade 2	1 (2.0%)	4 (5.8%)	5 (4.2%)	8 (5.8%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Retching	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Nausea and vomiting symptoms	2 (14.3%)	5 (33.3%)	7 (24.1%)	11 (34.4%)
Grade 1	2 (14.3%)	4 (26.7%)	6 (20.7%)	9 (28.1%)
Grade 2	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 3	0	0	0	1 (3.1%)
Nausea	2 (14.3%)	3 (20.0%)	5 (17.2%)	9 (28.1%)
Grade 1	2 (14.3%)	2 (13.3%)	4 (13.8%)	7 (21.9%)
Grade 2	0	1 (6.7%)	1 (3.4%)	2 (6.3%)
Grade 3	0	0	0	0
Vomiting	1 (7.1%)	2 (13.3%)	3 (10.3%)	4 (12.5%)
Grade 1	1 (7.1%)	2 (13.3%)	3 (10.3%)	3 (9.4%)
Grade 2	0	0	0	0
Grade 3	0	0	0	1 (3.1%)
Retching	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Nausea and vomiting symptoms (cont)				
Retching (cont)				
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Gastrointestinal and abdominal pains (excl oral and throat)	5 (10.0%)	13 (18.8%)	18 (15.1%)	25 (18.1%)
Grade 1	3 (6.0%)	6 (8.7%)	9 (7.6%)	14 (10.1%)
Grade 2	2 (4.0%)	5 (7.2%)	7 (5.9%)	8 (5.8%)
Grade 3	0	2 (2.9%)	2 (1.7%)	3 (2.2%)
Abdominal pain	1 (2.0%)	9 (13.0%)	10 (8.4%)	17 (12.3%)
Grade 1	1 (2.0%)	5 (7.2%)	6 (5.0%)	10 (7.2%)
Grade 2	0	3 (4.3%)	3 (2.5%)	5 (3.6%)
Grade 3	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Abdominal pain upper	4 (8.0%)	5 (7.2%)	9 (7.6%)	12 (8.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Nausea and vomiting symptoms (cont)				
Retching (cont)				
Grade 1	0	0	0	0
Gastrointestinal and abdominal pains (excl oral and throat)	4 (28.6%)	2 (13.3%)	6 (20.7%)	10 (31.3%)
Grade 1	3 (21.4%)	0	3 (10.3%)	5 (15.6%)
Grade 2	0	2 (13.3%)	2 (6.9%)	3 (9.4%)
Grade 3	1 (7.1%)	0	1 (3.4%)	2 (6.3%)
Abdominal pain	3 (21.4%)	2 (13.3%)	5 (17.2%)	9 (28.1%)
Grade 1	2 (14.3%)	0	2 (6.9%)	4 (12.5%)
Grade 2	0	2 (13.3%)	2 (6.9%)	3 (9.4%)
Grade 3	1 (7.1%)	0	1 (3.4%)	2 (6.3%)
Abdominal pain upper	1 (7.1%)	0	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal and abdominal pains (excl oral and throat) (cont)				
Abdominal pain upper (cont)				
Grade 1	2 (4.0%)	1 (1.4%)	3 (2.5%)	6 (4.3%)
Grade 2	2 (4.0%)	3 (4.3%)	5 (4.2%)	5 (3.6%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Abdominal rigidity	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Gastrointestinal atonic and hypomotility disorders NEC	2 (4.0%)	11 (15.9%)	13 (10.9%)	24 (17.4%)
Grade 1	1 (2.0%)	7 (10.1%)	8 (6.7%)	17 (12.3%)
Grade 2	1 (2.0%)	3 (4.3%)	4 (3.4%)	6 (4.3%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal and abdominal pains (excl oral and throat) (cont)				
Abdominal pain upper (cont)				
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Abdominal rigidity	0	0	0	0
Grade 1	0	0	0	0
Gastrointestinal atonic and hypomotility disorders NEC	3 (21.4%)	3 (20.0%)	6 (20.7%)	8 (25.0%)
Grade 1	2 (14.3%)	1 (6.7%)	3 (10.3%)	5 (15.6%)
Grade 2	1 (7.1%)	2 (13.3%)	3 (10.3%)	3 (9.4%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal atonic and hypomotility disorders NEC (cont)				
Constipation	1 (2.0%)	7 (10.1%)	8 (6.7%)	17 (12.3%)
Grade 1	1 (2.0%)	4 (5.8%)	5 (4.2%)	14 (10.1%)
Grade 2	0	2 (2.9%)	2 (1.7%)	2 (1.4%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Gastrooesophageal reflux disease	1 (2.0%)	5 (7.2%)	6 (5.0%)	10 (7.2%)
Grade 1	0	4 (5.8%)	4 (3.4%)	6 (4.3%)
Grade 2	1 (2.0%)	1 (1.4%)	2 (1.7%)	4 (2.9%)
Flatulence, bloating and distension	0	5 (7.2%)	5 (4.2%)	9 (6.5%)
Grade 1	0	4 (5.8%)	4 (3.4%)	6 (4.3%)
Grade 2	0	1 (1.4%)	1 (0.8%)	3 (2.2%)
Abdominal distension	0	4 (5.8%)	4 (3.4%)	7 (5.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal atonic and hypomotility disorders NEC (cont)				
Constipation	3 (21.4%)	3 (20.0%)	6 (20.7%)	8 (25.0%)
Grade 1	2 (14.3%)	1 (6.7%)	3 (10.3%)	5 (15.6%)
Grade 2	1 (7.1%)	2 (13.3%)	3 (10.3%)	3 (9.4%)
Grade 3	0	0	0	0
Gastrooesophageal reflux disease	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	0	0	0	0
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Flatulence, bloating and distension	0	0	0	1 (3.1%)
Grade 1	0	0	0	1 (3.1%)
Grade 2	0	0	0	0
Abdominal distension	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Flatulence, bloating and distension (cont)				
Abdominal distension (cont)				
Grade 1	0	4 (5.8%)	4 (3.4%)	5 (3.6%)
Grade 2	0	0	0	2 (1.4%)
Flatulence	0	1 (1.4%)	1 (0.8%)	3 (2.2%)
Grade 1	0	0	0	2 (1.4%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Gastrointestinal signs and symptoms NEC	1 (2.0%)	4 (5.8%)	5 (4.2%)	9 (6.5%)
Grade 1	1 (2.0%)	3 (4.3%)	4 (3.4%)	8 (5.8%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Abdominal discomfort	1 (2.0%)	2 (2.9%)	3 (2.5%)	6 (4.3%)
Grade 1	1 (2.0%)	2 (2.9%)	3 (2.5%)	6 (4.3%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Flatulence, bloating and distension (cont)				
Abdominal distension (cont)				
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Flatulence	0	0	0	1 (3.1%)
Grade 1	0	0	0	1 (3.1%)
Grade 2	0	0	0	0
Gastrointestinal signs and symptoms NEC	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Abdominal discomfort	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal signs and symptoms NEC (cont)				
Anal incontinence	0	2 (2.9%)	2 (1.7%)	2 (1.4%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Dysphagia	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)
Dyspeptic signs and symptoms	1 (2.0%)	3 (4.3%)	4 (3.4%)	5 (3.6%)
Grade 1	1 (2.0%)	1 (1.4%)	2 (1.7%)	3 (2.2%)
Grade 2	0	2 (2.9%)	2 (1.7%)	2 (1.4%)
Dyspepsia	1 (2.0%)	3 (4.3%)	4 (3.4%)	5 (3.6%)
Grade 1	1 (2.0%)	1 (1.4%)	2 (1.7%)	3 (2.2%)
Grade 2	0	2 (2.9%)	2 (1.7%)	2 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal signs and symptoms NEC (cont)				
Anal incontinence	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Dysphagia	0	0	0	0
Grade 1	0	0	0	0
Dyspeptic signs and symptoms	1 (7.1%)	2 (13.3%)	3 (10.3%)	3 (9.4%)
Grade 1	1 (7.1%)	2 (13.3%)	3 (10.3%)	3 (9.4%)
Grade 2	0	0	0	0
Dyspepsia	1 (7.1%)	2 (13.3%)	3 (10.3%)	3 (9.4%)
Grade 1	1 (7.1%)	2 (13.3%)	3 (10.3%)	3 (9.4%)
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Dyspeptic signs and symptoms (cont)				
Epigastric discomfort	0	0	0	0
Grade 1	0	0	0	0
Intestinal haemorrhages	0	3 (4.3%)	3 (2.5%)	5 (3.6%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Grade 3	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Rectal haemorrhage	0	2 (2.9%)	2 (1.7%)	4 (2.9%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Grade 3	0	0	0	1 (0.7%)
Lower gastrointestinal haemorrhage	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Dyspeptic signs and symptoms (cont)				
Epigastric discomfort	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 1	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Intestinal haemorrhages	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 1	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Rectal haemorrhage	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 1	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Lower gastrointestinal haemorrhage	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Intestinal haemorrhages (cont)				
Small intestinal haemorrhage	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Oral dryness and saliva altered	1 (2.0%)	2 (2.9%)	3 (2.5%)	5 (3.6%)
Grade 1	1 (2.0%)	0	1 (0.8%)	3 (2.2%)
Grade 2	0	2 (2.9%)	2 (1.7%)	2 (1.4%)
Dry mouth	1 (2.0%)	2 (2.9%)	3 (2.5%)	5 (3.6%)
Grade 1	1 (2.0%)	0	1 (0.8%)	3 (2.2%)
Grade 2	0	2 (2.9%)	2 (1.7%)	2 (1.4%)
Peritoneal and retroperitoneal disorders	1 (2.0%)	2 (2.9%)	3 (2.5%)	3 (2.2%)
Grade 2	1 (2.0%)	2 (2.9%)	3 (2.5%)	3 (2.2%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Intestinal haemorrhages (cont)				
Small intestinal haemorrhage	0	0	0	0
Grade 3	0	0	0	0
Oral dryness and saliva altered	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	0	0	0	0
Dry mouth	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	0	0	0	0
Peritoneal and retroperitoneal disorders	2 (14.3%)	0	2 (6.9%)	3 (9.4%)
Grade 2	2 (14.3%)	0	2 (6.9%)	2 (6.3%)
Grade 3	0	0	0	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Peritoneal and retroperitoneal disorders (cont)				
Ascites	1 (2.0%)	2 (2.9%)	3 (2.5%)	3 (2.2%)
Grade 2	1 (2.0%)	2 (2.9%)	3 (2.5%)	3 (2.2%)
Grade 3	0	0	0	0
Haemorrhoids and gastrointestinal varices (excl oesophageal)	0	2 (2.9%)	2 (1.7%)	5 (3.6%)
Grade 1	0	1 (1.4%)	1 (0.8%)	3 (2.2%)
Grade 2	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Haemorrhoids	0	2 (2.9%)	2 (1.7%)	4 (2.9%)
Grade 1	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Grade 2	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Haemorrhoidal haemorrhage	0	0	0	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Peritoneal and retroperitoneal disorders (cont)				
Ascites	2 (14.3%)	0	2 (6.9%)	3 (9.4%)
Grade 2	2 (14.3%)	0	2 (6.9%)	2 (6.3%)
Grade 3	0	0	0	1 (3.1%)
Haemorrhoids and gastrointestinal varices (excl oesophageal)	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Haemorrhoids	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Haemorrhoidal haemorrhage	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Haemorrhoids and gastrointestinal varices (excl oesophageal) (cont)				
Haemorrhoidal haemorrhage (cont)				
Grade 1	0	0	0	1 (0.7%)
Oesophageal varices	1 (2.0%)	2 (2.9%)	3 (2.5%)	3 (2.2%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Varices oesophageal	1 (2.0%)	2 (2.9%)	3 (2.5%)	3 (2.2%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Oral soft tissue haemorrhages	1 (2.0%)	2 (2.9%)	3 (2.5%)	3 (2.2%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Haemorrhoids and gastrointestinal varices (excl oesophageal) (cont)				
Haemorrhoidal haemorrhage (cont)				
Grade 1	0	0	0	0
Oesophageal varices	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Varices oesophageal	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Oral soft tissue haemorrhages	0	1 (6.7%)	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Oral soft tissue haemorrhages (cont) (cont)				
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	0	2 (2.9%)	2 (1.7%)	2 (1.4%)
Mouth haemorrhage	0	2 (2.9%)	2 (1.7%)	2 (1.4%)
Grade 1	0	0	0	0
Grade 2	0	2 (2.9%)	2 (1.7%)	2 (1.4%)
Oral mucosa haematoma	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Stomatitis and ulceration	2 (4.0%)	0	2 (1.7%)	3 (2.2%)
Grade 1	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Oral soft tissue haemorrhages (cont) (cont)				
Grade 1	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 2	0	0	0	0
Mouth haemorrhage	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 1	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 2	0	0	0	0
Oral mucosa haematoma	0	0	0	0
Grade 1	0	0	0	0
Stomatitis and ulceration	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Stomatitis and ulceration (cont)				
Stomatitis	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Aphthous ulcer	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Mouth ulceration	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)
Dental pain and sensation disorders	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Grade 1	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Toothache	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Grade 1	0	1 (1.4%)	1 (0.8%)	2 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Stomatitis and ulceration (cont)				
Stomatitis	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Aphthous ulcer	0	0	0	0
Grade 2	0	0	0	0
Mouth ulceration	0	0	0	0
Grade 1	0	0	0	0
Dental pain and sensation disorders	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 1	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Toothache	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 1	0	1 (6.7%)	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastritis (excl infective)	1 (2.0%)	2 (2.9%)	3 (2.5%)	3 (2.2%)
Grade 1	1 (2.0%)	2 (2.9%)	3 (2.5%)	3 (2.2%)
Gastritis	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Grade 1	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Chronic gastritis	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Non-site specific gastrointestinal haemorrhages	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Grade 1	0	0	0	0
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 4	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Gastrointestinal haemorrhage	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastritis (excl infective)	0	0	0	0
Grade 1	0	0	0	0
Gastritis	0	0	0	0
Grade 1	0	0	0	0
Chronic gastritis	0	0	0	0
Grade 1	0	0	0	0
Non-site specific gastrointestinal haemorrhages	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Gastrointestinal haemorrhage	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Non-site specific gastrointestinal haemorrhages (cont)				
Gastrointestinal haemorrhage (cont)				
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Haematemesis	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 4	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Melaena	0	0	0	0
Grade 1	0	0	0	0
Oral soft tissue disorders NEC	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	0	0	0	0
Cheilitis	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Non-site specific gastrointestinal haemorrhages (cont)				
Gastrointestinal haemorrhage (cont)				
Grade 3	0	0	0	0
Haematemesis	0	0	0	0
Grade 4	0	0	0	0
Melaena	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Oral soft tissue disorders NEC	0	1 (6.7%)	1 (3.4%)	2 (6.3%)
Grade 1	0	0	0	1 (3.1%)
Grade 2	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Cheilitis	0	1 (6.7%)	1 (3.4%)	2 (6.3%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Oral soft tissue disorders NEC (cont)				
Cheilitis (cont)				
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Angina bullosa haemorrhagica	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Oral soft tissue pain and paraesthesia	0	1 (1.4%)	1 (0.8%)	3 (2.2%)
Grade 1	0	0	0	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	0	0	0	1 (0.7%)
Lip pain	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Oral soft tissue disorders NEC (cont)				
Cheilitis (cont)				
Grade 1	0	0	0	1 (3.1%)
Grade 2	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Angina bullosa haemorrhagica	0	0	0	0
Grade 1	0	0	0	0
Oral soft tissue pain and paraesthesia	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Lip pain	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Oral soft tissue pain and paraesthesia (cont)				
Odynophagia	0	0	0	1 (0.7%)
Grade 3	0	0	0	1 (0.7%)
Oral pain	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Anal and rectal pains	0	0	0	2 (1.4%)
Grade 2	0	0	0	2 (1.4%)
Proctalgia	0	0	0	2 (1.4%)
Grade 2	0	0	0	2 (1.4%)
Dental disorders NEC	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Oral soft tissue pain and paraesthesia (cont)				
Odynophagia	0	0	0	0
Grade 3	0	0	0	0
Oral pain	0	0	0	0
Grade 2	0	0	0	0
Anal and rectal pains	0	0	0	0
Grade 2	0	0	0	0
Proctalgia	0	0	0	0
Grade 2	0	0	0	0
Dental disorders NEC	0	2 (13.3%)	2 (6.9%)	2 (6.3%)
Grade 1	0	1 (6.7%)	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Dental disorders NEC (cont)				
(cont)				
Grade 2	0	0	0	0
Periodontal disease	0	0	0	0
Grade 1	0	0	0	0
Tooth impacted	0	0	0	0
Grade 2	0	0	0	0
Gastric and oesophageal haemorrhages	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Gastric haemorrhage	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Dental disorders NEC (cont)				
(cont)				
Grade 2	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Periodontal disease	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 1	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Tooth impacted	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 2	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Gastric and oesophageal haemorrhages	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 3	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Gastric haemorrhage	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastric and oesophageal haemorrhages (cont)				
Oesophageal varices haemorrhage	0	0	0	0
Grade 3	0	0	0	0
Gastric ulcers and perforation	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	0	0	0
Gastric ulcer	0	0	0	0
Grade 2	0	0	0	0
Gastritis erosive	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Gastrointestinal vascular occlusion and infarction	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastric and oesophageal haemorrhages (cont)				
Oesophageal varices haemorrhage	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 3	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Gastric ulcers and perforation	0	0	0	1 (3.1%)
Grade 1	0	0	0	0
Grade 2	0	0	0	1 (3.1%)
Gastric ulcer	0	0	0	1 (3.1%)
Grade 2	0	0	0	1 (3.1%)
Gastritis erosive	0	0	0	0
Grade 1	0	0	0	0
Gastrointestinal vascular occlusion and infarction	0	1 (6.7%)	1 (3.4%)	2 (6.3%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal vascular occlusion and infarction (cont) (cont)				
Grade 5	0	0	0	0
Intestinal infarction	0	0	0	0
Grade 5	0	0	0	0
Mesenteric vein thrombosis	0	0	0	0
Grade 5	0	0	0	0
Oral soft tissue infections	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Angular cheilitis	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal vascular occlusion and infarction (cont) (cont)				
Grade 5	0	1 (6.7%)	1 (3.4%)	2 (6.3%)
Intestinal infarction	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 5	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Mesenteric vein thrombosis	0	0	0	1 (3.1%)
Grade 5	0	0	0	1 (3.1%)
Oral soft tissue infections	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Angular cheilitis	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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SAF-Anemic Analysis Set

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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Colitis (excl infective)	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Colitis	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Cystic pancreatic disorders	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Pancreatic cyst	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Dental and periodontal infections and inflammations	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Colitis (excl infective)	0	0	0	0
Grade 2	0	0	0	0
Colitis	0	0	0	0
Grade 2	0	0	0	0
Cystic pancreatic disorders	0	0	0	0
Grade 1	0	0	0	0
Pancreatic cyst	0	0	0	0
Grade 1	0	0	0	0
Dental and periodontal infections and inflammations	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 1	0	1 (6.7%)	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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SAF-Anemic Analysis Set

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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Dental and periodontal infections and inflammations (cont)				
Dental caries	0	0	0	0
Grade 1	0	0	0	0
Diaphragmatic hernias	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Hiatus hernia	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Diverticula	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Diverticulum	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Dental and periodontal infections and inflammations (cont)				
Dental caries	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 1	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Diaphragmatic hernias	0	0	0	0
Grade 1	0	0	0	0
Hiatus hernia	0	0	0	0
Grade 1	0	0	0	0
Diverticula	0	0	0	0
Grade 2	0	0	0	0
Diverticulum	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Faecal abnormalities NEC	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Abnormal faeces	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Gastrointestinal spastic and hypermotility disorders	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Defaecation urgency	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Gingival disorders, signs and symptoms NEC	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Faecal abnormalities NEC	0	0	0	0
Grade 1	0	0	0	0
Abnormal faeces	0	0	0	0
Grade 1	0	0	0	0
Gastrointestinal spastic and hypermotility disorders	0	0	0	0
Grade 1	0	0	0	0
Defaecation urgency	0	0	0	0
Grade 1	0	0	0	0
Gingival disorders, signs and symptoms NEC	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gingival disorders, signs and symptoms NEC (cont)				
Gingival ulceration	0	0	0	0
Grade 2	0	0	0	0
Gingival haemorrhages	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Gingival bleeding	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Inguinal hernias	0	0	0	0
Grade 2	0	0	0	0
Inguinal hernia	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gingival disorders, signs and symptoms NEC (cont)				
Gingival ulceration	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Gingival haemorrhages	0	0	0	0
Grade 2	0	0	0	0
Gingival bleeding	0	0	0	0
Grade 2	0	0	0	0
Inguinal hernias	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Inguinal hernia	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Pancreatic disorders NEC	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Pancreatic steatosis	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Infections and infestations	26 (52.0%)	40 (58.0%)	66 (55.5%)	83 (60.1%)
Grade 1	1 (2.0%)	7 (10.1%)	8 (6.7%)	14 (10.1%)
Grade 2	12 (24.0%)	17 (24.6%)	29 (24.4%)	30 (21.7%)
Grade 3	7 (14.0%)	13 (18.8%)	20 (16.8%)	28 (20.3%)
Grade 4	3 (6.0%)	1 (1.4%)	4 (3.4%)	5 (3.6%)
Grade 5	3 (6.0%)	2 (2.9%)	5 (4.2%)	6 (4.3%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Pancreatic disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Pancreatic steatosis	0	0	0	0
Grade 1	0	0	0	0
Infections and infestations	11 (78.6%)	12 (80.0%)	23 (79.3%)	24 (75.0%)
Grade 1	3 (21.4%)	2 (13.3%)	5 (17.2%)	5 (15.6%)
Grade 2	4 (28.6%)	7 (46.7%)	11 (37.9%)	12 (37.5%)
Grade 3	4 (28.6%)	3 (20.0%)	7 (24.1%)	7 (21.9%)
Grade 4	0	0	0	0
Grade 5	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Lower respiratory tract and lung infections	11 (22.0%)	12 (17.4%)	23 (19.3%)	29 (21.0%)
Grade 1	0	0	0	0
Grade 2	2 (4.0%)	5 (7.2%)	7 (5.9%)	8 (5.8%)
Grade 3	6 (12.0%)	5 (7.2%)	11 (9.2%)	16 (11.6%)
Grade 4	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Grade 5	2 (4.0%)	1 (1.4%)	3 (2.5%)	3 (2.2%)
Pneumonia	8 (16.0%)	10 (14.5%)	18 (15.1%)	22 (15.9%)
Grade 2	1 (2.0%)	3 (4.3%)	4 (3.4%)	4 (2.9%)
Grade 3	5 (10.0%)	5 (7.2%)	10 (8.4%)	14 (10.1%)
Grade 4	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Grade 5	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Bronchitis	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Grade 1	0	0	0	0
Grade 2	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Lower respiratory tract and lung infections	5 (35.7%)	5 (33.3%)	10 (34.5%)	11 (34.4%)
Grade 1	0	1 (6.7%)	1 (3.4%)	2 (6.3%)
Grade 2	1 (7.1%)	2 (13.3%)	3 (10.3%)	3 (9.4%)
Grade 3	4 (28.6%)	2 (13.3%)	6 (20.7%)	6 (18.8%)
Grade 4	0	0	0	0
Grade 5	0	0	0	0
Pneumonia	4 (28.6%)	2 (13.3%)	6 (20.7%)	6 (18.8%)
Grade 2	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Grade 3	3 (21.4%)	1 (6.7%)	4 (13.8%)	4 (12.5%)
Grade 4	0	0	0	0
Grade 5	0	0	0	0
Bronchitis	2 (14.3%)	4 (26.7%)	6 (20.7%)	6 (18.8%)
Grade 1	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 2	2 (14.3%)	2 (13.3%)	4 (13.8%)	4 (12.5%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Lower respiratory tract and lung infections (cont)				
Bronchitis (cont)				
Grade 3	0	0	0	0
Lower respiratory tract infection	0	1 (1.4%)	1 (0.8%)	3 (2.2%)
Grade 1	0	0	0	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Lung infection	2 (4.0%)	0	2 (1.7%)	3 (2.2%)
Grade 3	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Grade 5	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Upper respiratory tract infections	8 (16.0%)	13 (18.8%)	21 (17.6%)	26 (18.8%)
Grade 1	3 (6.0%)	3 (4.3%)	6 (5.0%)	11 (8.0%)
Grade 2	4 (8.0%)	10 (14.5%)	14 (11.8%)	14 (10.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Lower respiratory tract and lung infections (cont)				
Bronchitis (cont)				
Grade 3	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Lower respiratory tract infection	0	0	0	1 (3.1%)
Grade 1	0	0	0	1 (3.1%)
Grade 2	0	0	0	0
Lung infection	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 3	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 5	0	0	0	0
Upper respiratory tract infections	4 (28.6%)	4 (26.7%)	8 (27.6%)	8 (25.0%)
Grade 1	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Grade 2	3 (21.4%)	3 (20.0%)	6 (20.7%)	6 (18.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Upper respiratory tract infections (cont) (cont)				
Grade 3	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Upper respiratory tract infection	4 (8.0%)	8 (11.6%)	12 (10.1%)	16 (11.6%)
Grade 1	1 (2.0%)	1 (1.4%)	2 (1.7%)	6 (4.3%)
Grade 2	3 (6.0%)	7 (10.1%)	10 (8.4%)	10 (7.2%)
Nasopharyngitis	2 (4.0%)	4 (5.8%)	6 (5.0%)	7 (5.1%)
Grade 1	2 (4.0%)	2 (2.9%)	4 (3.4%)	5 (3.6%)
Grade 2	0	2 (2.9%)	2 (1.7%)	2 (1.4%)
Sinusitis	2 (4.0%)	2 (2.9%)	4 (3.4%)	4 (2.9%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Grade 3	1 (2.0%)	0	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Upper respiratory tract infections (cont)				
(cont)				
Grade 3	0	0	0	0
Upper respiratory tract infection	2 (14.3%)	1 (6.7%)	3 (10.3%)	3 (9.4%)
Grade 1	0	0	0	0
Grade 2	2 (14.3%)	1 (6.7%)	3 (10.3%)	3 (9.4%)
Nasopharyngitis	2 (14.3%)	1 (6.7%)	3 (10.3%)	3 (9.4%)
Grade 1	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Sinusitis	0	2 (13.3%)	2 (6.9%)	2 (6.3%)
Grade 1	0	0	0	0
Grade 2	0	2 (13.3%)	2 (6.9%)	2 (6.3%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Upper respiratory tract infections (cont)				
Laryngitis	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Grade 2	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Tonsillitis	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Pharyngitis	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Urinary tract infections	10 (20.0%)	8 (11.6%)	18 (15.1%)	22 (15.9%)
Grade 1	0	0	0	1 (0.7%)
Grade 2	7 (14.0%)	6 (8.7%)	13 (10.9%)	15 (10.9%)
Grade 3	3 (6.0%)	2 (2.9%)	5 (4.2%)	6 (4.3%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Upper respiratory tract infections (cont)				
Laryngitis	0	0	0	0
Grade 2	0	0	0	0
Tonsillitis	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Grade 1	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Pharyngitis	0	0	0	0
Grade 1	0	0	0	0
Urinary tract infections	1 (7.1%)	2 (13.3%)	3 (10.3%)	3 (9.4%)
Grade 1	0	0	0	0
Grade 2	1 (7.1%)	2 (13.3%)	3 (10.3%)	3 (9.4%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Urinary tract infections (cont)				
Urinary tract infection	8 (16.0%)	7 (10.1%)	15 (12.6%)	18 (13.0%)
Grade 1	0	0	0	1 (0.7%)
Grade 2	5 (10.0%)	6 (8.7%)	11 (9.2%)	13 (9.4%)
Grade 3	3 (6.0%)	1 (1.4%)	4 (3.4%)	4 (2.9%)
Cystitis	3 (6.0%)	0	3 (2.5%)	5 (3.6%)
Grade 2	3 (6.0%)	0	3 (2.5%)	4 (2.9%)
Grade 3	0	0	0	1 (0.7%)
Pyelocystitis	0	0	0	1 (0.7%)
Grade 2	0	0	0	1 (0.7%)
Pyelonephritis	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Urinary tract infections (cont)				
Urinary tract infection	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Grade 1	0	0	0	0
Grade 2	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Grade 3	0	0	0	0
Cystitis	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 2	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 3	0	0	0	0
Pyelocystitis	0	0	0	0
Grade 2	0	0	0	0
Pyelonephritis	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Herpes viral infections	4 (8.0%)	2 (2.9%)	6 (5.0%)	8 (5.8%)
Grade 1	1 (2.0%)	1 (1.4%)	2 (1.7%)	3 (2.2%)
Grade 2	3 (6.0%)	1 (1.4%)	4 (3.4%)	5 (3.6%)
Herpes zoster	2 (4.0%)	0	2 (1.7%)	4 (2.9%)
Grade 1	0	0	0	1 (0.7%)
Grade 2	2 (4.0%)	0	2 (1.7%)	3 (2.2%)
Oral herpes	2 (4.0%)	1 (1.4%)	3 (2.5%)	3 (2.2%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Genital herpes	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Herpes viral infections	1 (7.1%)	3 (20.0%)	4 (13.8%)	5 (15.6%)
Grade 1	0	0	0	0
Grade 2	1 (7.1%)	3 (20.0%)	4 (13.8%)	5 (15.6%)
Herpes zoster	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Oral herpes	0	1 (6.7%)	1 (3.4%)	2 (6.3%)
Grade 1	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 2	0	0	0	1 (3.1%)
Genital herpes	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Herpes viral infections (cont)				
Herpes simplex	0	0	0	0
Grade 2	0	0	0	0
Nasal herpes	0	0	0	0
Grade 2	0	0	0	0
Varicella zoster virus infection	0	0	0	0
Grade 2	0	0	0	0
Infections NEC	2 (4.0%)	2 (2.9%)	4 (3.4%)	7 (5.1%)
Grade 1	0	0	0	1 (0.7%)
Grade 2	2 (4.0%)	1 (1.4%)	3 (2.5%)	4 (2.9%)
Grade 3	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Respiratory tract infection	1 (2.0%)	1 (1.4%)	2 (1.7%)	3 (2.2%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Herpes viral infections (cont)				
Herpes simplex	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Grade 2	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Nasal herpes	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Varicella zoster virus infection	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 2	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Infections NEC	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Respiratory tract infection	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Infections NEC (cont)				
Respiratory tract infection (cont)				
Grade 1	0	0	0	1 (0.7%)
Grade 2	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Localised infection	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Grade 2	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Device related infection	0	0	0	0
Grade 3	0	0	0	0
Infection	0	0	0	1 (0.7%)
Grade 3	0	0	0	1 (0.7%)
Wound infection	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Infections NEC (cont)				
Respiratory tract infection (cont)				
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Localised infection	0	0	0	0
Grade 2	0	0	0	0
Device related infection	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 3	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Infection	0	0	0	0
Grade 3	0	0	0	0
Wound infection	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Abdominal and gastrointestinal infections	1 (2.0%)	1 (1.4%)	2 (1.7%)	3 (2.2%)
Grade 1	0	0	0	0
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 3	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Gastroenteritis	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Anal abscess	0	0	0	1 (0.7%)
Grade 3	0	0	0	1 (0.7%)
Diverticulitis	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Enterocolitis infectious	1 (2.0%)	0	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Abdominal and gastrointestinal infections	1 (7.1%)	2 (13.3%)	3 (10.3%)	4 (12.5%)
Grade 1	0	0	0	1 (3.1%)
Grade 2	1 (7.1%)	2 (13.3%)	3 (10.3%)	3 (9.4%)
Grade 3	0	0	0	0
Gastroenteritis	1 (7.1%)	2 (13.3%)	3 (10.3%)	4 (12.5%)
Grade 1	0	0	0	1 (3.1%)
Grade 2	1 (7.1%)	2 (13.3%)	3 (10.3%)	3 (9.4%)
Anal abscess	0	0	0	0
Grade 3	0	0	0	0
Diverticulitis	0	0	0	0
Grade 3	0	0	0	0
Enterocolitis infectious	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Abdominal and gastrointestinal infections (cont)				
Enterocolitis infectious (cont)				
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Sepsis, bacteraemia, viraemia and fungaemia NEC	3 (6.0%)	2 (2.9%)	5 (4.2%)	7 (5.1%)
Grade 3	1 (2.0%)	1 (1.4%)	2 (1.7%)	3 (2.2%)
Grade 4	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 5	1 (2.0%)	1 (1.4%)	2 (1.7%)	3 (2.2%)
Sepsis	3 (6.0%)	1 (1.4%)	4 (3.4%)	6 (4.3%)
Grade 3	1 (2.0%)	1 (1.4%)	2 (1.7%)	3 (2.2%)
Grade 4	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 5	1 (2.0%)	0	1 (0.8%)	2 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Abdominal and gastrointestinal infections (cont)				
Enterocolitis infectious (cont)				
Grade 2	0	0	0	0
Sepsis, bacteraemia, viraemia and fungaemia NEC	0	0	0	0
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Grade 5	0	0	0	0
Sepsis	0	0	0	0
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Grade 5	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Sepsis, bacteraemia, viraemia and fungaemia NEC (cont)				
Bacteraemia	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 3	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Septic shock	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 5	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Influenza viral infections	1 (2.0%)	4 (5.8%)	5 (4.2%)	6 (4.3%)
Grade 1	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Grade 2	1 (2.0%)	2 (2.9%)	3 (2.5%)	3 (2.2%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Influenza	1 (2.0%)	4 (5.8%)	5 (4.2%)	6 (4.3%)
Grade 1	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Grade 2	1 (2.0%)	2 (2.9%)	3 (2.5%)	3 (2.2%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Sepsis, bacteraemia, viraemia and fungaemia NEC (cont)				
Bacteraemia	0	0	0	0
Grade 3	0	0	0	0
Septic shock	0	0	0	0
Grade 5	0	0	0	0
Influenza viral infections	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Influenza	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Influenza viral infections (cont)				
Influenza (cont)				
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Skin structures and soft tissue infections	1 (2.0%)	0	1 (0.8%)	4 (2.9%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	0	0	0	2 (1.4%)
Grade 3	0	0	0	1 (0.7%)
Skin infection	0	0	0	3 (2.2%)
Grade 2	0	0	0	2 (1.4%)
Grade 3	0	0	0	1 (0.7%)
Folliculitis	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Influenza viral infections (cont)				
Influenza (cont)				
Grade 3	0	0	0	0
Skin structures and soft tissue infections	2 (14.3%)	0	2 (6.9%)	2 (6.3%)
Grade 1	0	0	0	0
Grade 2	2 (14.3%)	0	2 (6.9%)	2 (6.3%)
Grade 3	0	0	0	0
Skin infection	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Folliculitis	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Skin structures and soft tissue infections (cont)				
Infected dermal cyst	0	0	0	0
Grade 2	0	0	0	0
Infected skin ulcer	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Subcutaneous abscess	0	0	0	0
Grade 2	0	0	0	0
Viral infections NEC	2 (4.0%)	3 (4.3%)	5 (4.2%)	5 (3.6%)
Grade 1	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Grade 2	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Skin structures and soft tissue infections (cont)				
Infected dermal cyst	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Infected skin ulcer	0	0	0	0
Grade 1	0	0	0	0
Subcutaneous abscess	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Viral infections NEC	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 1	0	0	0	0
Grade 2	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Viral infections NEC (cont)				
Viral infection	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	0	0	0	0
Gastroenteritis viral	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Pneumonia viral	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Vestibular neuronitis	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Viral uveitis	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Viral infections NEC (cont)				
Viral infection	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 1	0	0	0	0
Grade 2	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Gastroenteritis viral	0	0	0	0
Grade 1	0	0	0	0
Pneumonia viral	0	0	0	0
Grade 3	0	0	0	0
Vestibular neuronitis	0	0	0	0
Grade 2	0	0	0	0
Viral uveitis	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Dental and oral soft tissue infections	0	1 (1.4%)	1 (0.8%)	4 (2.9%)
Grade 1	0	1 (1.4%)	1 (0.8%)	4 (2.9%)
Periodontitis	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)
Gingivitis	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)
Lip infection	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)
Tooth abscess	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Dental and oral soft tissue infections	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Periodontitis	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Gingivitis	0	0	0	0
Grade 1	0	0	0	0
Lip infection	0	0	0	0
Grade 1	0	0	0	0
Tooth abscess	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Bacterial infections NEC	1 (2.0%)	1 (1.4%)	2 (1.7%)	4 (2.9%)
Grade 1	0	0	0	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Cellulitis	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Grade 1	0	0	0	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Gangrene	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 3	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Pneumonia bacterial	0	0	0	1 (0.7%)
Grade 3	0	0	0	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Bacterial infections NEC	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Cellulitis	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Gangrene	0	0	0	0
Grade 3	0	0	0	0
Pneumonia bacterial	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Clostridia infections	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Grade 2	0	0	0	0
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 4	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Clostridium difficile colitis	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Clostridium difficile infection	0	0	0	0
Grade 2	0	0	0	0
Tetanus	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 4	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Ear infections	0	2 (2.9%)	2 (1.7%)	2 (1.4%)
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Clostridia infections	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 2	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Clostridium difficile colitis	0	0	0	0
Grade 3	0	0	0	0
Clostridium difficile infection	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 2	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Tetanus	0	0	0	0
Grade 4	0	0	0	0
Ear infections	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Ear infections (cont)				
(cont)				
Grade 2	0	2 (2.9%)	2 (1.7%)	2 (1.4%)
Ear infection	0	0	0	0
Grade 1	0	0	0	0
Labyrinthitis	0	0	0	0
Grade 1	0	0	0	0
Otitis externa	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Otitis media	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Ear infections (cont)				
(cont)				
Grade 2	0	0	0	0
Ear infection	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Labyrinthitis	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Otitis externa	0	0	0	0
Grade 2	0	0	0	0
Otitis media	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Escherichia infections	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Grade 1	0	0	0	0
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 4	0	0	0	1 (0.7%)
Escherichia urinary tract infection	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	0	0	0
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Escherichia infection	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Escherichia sepsis	0	0	0	1 (0.7%)
Grade 4	0	0	0	1 (0.7%)
Fungal infections NEC	1 (2.0%)	0	1 (0.8%)	2 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Escherichia infections	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Escherichia urinary tract infection	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 3	0	0	0	0
Escherichia infection	0	0	0	0
Grade 2	0	0	0	0
Escherichia sepsis	0	0	0	0
Grade 4	0	0	0	0
Fungal infections NEC	0	0	0	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Fungal infections NEC (cont)				
(cont)				
Grade 1	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Fungal skin infection	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Grade 1	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Fungal infection	0	0	0	0
Grade 1	0	0	0	0
Borrelial infections	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Grade 1	0	0	0	1 (0.7%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Borrelia infection	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Fungal infections NEC (cont)				
(cont)				
Grade 1	0	0	0	1 (3.1%)
Fungal skin infection	0	0	0	0
Grade 1	0	0	0	0
Fungal infection	0	0	0	1 (3.1%)
Grade 1	0	0	0	1 (3.1%)
Borrelial infections	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Borrelia infection	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Borrelial infections (cont)				
Lyme disease	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)
Neuroborreliosis	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Candida infections	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Grade 1	0	0	0	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Gastrointestinal candidiasis	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Oral candidiasis	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Borrelial infections (cont)				
Lyme disease	0	0	0	0
Grade 1	0	0	0	0
Neuroborreliosis	0	0	0	0
Grade 3	0	0	0	0
Candida infections	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Gastrointestinal candidiasis	0	0	0	0
Grade 2	0	0	0	0
Oral candidiasis	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Staphylococcal infections	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Furuncle	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Bordetella infections	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Pertussis	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Eye and eyelid infections	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Eye infection	1 (2.0%)	0	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Staphylococcal infections	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Furuncle	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Bordetella infections	0	0	0	0
Grade 1	0	0	0	0
Pertussis	0	0	0	0
Grade 1	0	0	0	0
Eye and eyelid infections	0	0	0	0
Grade 2	0	0	0	0
Eye infection	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Eye and eyelid infections (cont)				
Eye infection (cont)				
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Male reproductive tract infections	0	0	0	1 (0.7%)
Grade 2	0	0	0	1 (0.7%)
Scrotal abscess	0	0	0	1 (0.7%)
Grade 2	0	0	0	1 (0.7%)
Streptococcal infections	0	0	0	0
Grade 2	0	0	0	0
Erysipelas	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Eye and eyelid infections (cont)				
Eye infection (cont)				
Grade 2	0	0	0	0
Male reproductive tract infections	0	0	0	0
Grade 2	0	0	0	0
Scrotal abscess	0	0	0	0
Grade 2	0	0	0	0
Streptococcal infections	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 2	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Erysipelas	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 2	0	1 (6.7%)	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Tinea infections	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)
Tinea versicolour	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)
Tuberculous infections	0	0	0	0
Grade 2	0	0	0	0
Tuberculosis	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Tinea infections	0	0	0	0
Grade 1	0	0	0	0
Tinea versicolour	0	0	0	0
Grade 1	0	0	0	0
Tuberculous infections	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Tuberculosis	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions	19 (38.0%)	26 (37.7%)	45 (37.8%)	67 (48.6%)
Grade 1	12 (24.0%)	8 (11.6%)	20 (16.8%)	35 (25.4%)
Grade 2	4 (8.0%)	15 (21.7%)	19 (16.0%)	23 (16.7%)
Grade 3	2 (4.0%)	3 (4.3%)	5 (4.2%)	7 (5.1%)
Grade 5	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Asthenic conditions	7 (14.0%)	15 (21.7%)	22 (18.5%)	36 (26.1%)
Grade 1	4 (8.0%)	4 (5.8%)	8 (6.7%)	20 (14.5%)
Grade 2	2 (4.0%)	9 (13.0%)	11 (9.2%)	13 (9.4%)
Grade 3	1 (2.0%)	2 (2.9%)	3 (2.5%)	3 (2.2%)
Fatigue	4 (8.0%)	9 (13.0%)	13 (10.9%)	22 (15.9%)
Grade 1	2 (4.0%)	4 (5.8%)	6 (5.0%)	13 (9.4%)
Grade 2	1 (2.0%)	5 (7.2%)	6 (5.0%)	8 (5.8%)
Grade 3	1 (2.0%)	0	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions	10 (71.4%)	5 (33.3%)	15 (51.7%)	19 (59.4%)
Grade 1	3 (21.4%)	2 (13.3%)	5 (17.2%)	7 (21.9%)
Grade 2	7 (50.0%)	2 (13.3%)	9 (31.0%)	11 (34.4%)
Grade 3	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 5	0	0	0	0
Asthenic conditions	5 (35.7%)	3 (20.0%)	8 (27.6%)	11 (34.4%)
Grade 1	1 (7.1%)	1 (6.7%)	2 (6.9%)	4 (12.5%)
Grade 2	4 (28.6%)	1 (6.7%)	5 (17.2%)	6 (18.8%)
Grade 3	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Fatigue	2 (14.3%)	3 (20.0%)	5 (17.2%)	8 (25.0%)
Grade 1	0	1 (6.7%)	1 (3.4%)	4 (12.5%)
Grade 2	2 (14.3%)	1 (6.7%)	3 (10.3%)	3 (9.4%)
Grade 3	0	1 (6.7%)	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Asthenic conditions (cont)				
Asthenia	3 (6.0%)	5 (7.2%)	8 (6.7%)	11 (8.0%)
Grade 1	2 (4.0%)	0	2 (1.7%)	5 (3.6%)
Grade 2	1 (2.0%)	4 (5.8%)	5 (4.2%)	5 (3.6%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Malaise	0	2 (2.9%)	2 (1.7%)	4 (2.9%)
Grade 1	0	0	0	2 (1.4%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Febrile disorders	5 (10.0%)	3 (4.3%)	8 (6.7%)	15 (10.9%)
Grade 1	3 (6.0%)	3 (4.3%)	6 (5.0%)	11 (8.0%)
Grade 2	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Grade 3	1 (2.0%)	0	1 (0.8%)	2 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Asthenic conditions (cont)				
Asthenia	2 (14.3%)	0	2 (6.9%)	3 (9.4%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	1 (7.1%)	0	1 (3.4%)	2 (6.3%)
Grade 3	0	0	0	0
Malaise	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	0	0	0	0
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 3	0	0	0	0
Febrile disorders	6 (42.9%)	3 (20.0%)	9 (31.0%)	10 (31.3%)
Grade 1	1 (7.1%)	2 (13.3%)	3 (10.3%)	4 (12.5%)
Grade 2	5 (35.7%)	1 (6.7%)	6 (20.7%)	6 (18.8%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Febrile disorders (cont)				
Pyrexia	5 (10.0%)	3 (4.3%)	8 (6.7%)	15 (10.9%)
Grade 1	3 (6.0%)	3 (4.3%)	6 (5.0%)	11 (8.0%)
Grade 2	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Grade 3	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Oedema NEC	5 (10.0%)	3 (4.3%)	8 (6.7%)	12 (8.7%)
Grade 1	4 (8.0%)	2 (2.9%)	6 (5.0%)	8 (5.8%)
Grade 2	1 (2.0%)	1 (1.4%)	2 (1.7%)	4 (2.9%)
Oedema peripheral	5 (10.0%)	2 (2.9%)	7 (5.9%)	11 (8.0%)
Grade 1	4 (8.0%)	1 (1.4%)	5 (4.2%)	8 (5.8%)
Grade 2	1 (2.0%)	1 (1.4%)	2 (1.7%)	3 (2.2%)
Oedema	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Febrile disorders (cont)				
Pyrexia	6 (42.9%)	3 (20.0%)	9 (31.0%)	10 (31.3%)
Grade 1	1 (7.1%)	2 (13.3%)	3 (10.3%)	4 (12.5%)
Grade 2	5 (35.7%)	1 (6.7%)	6 (20.7%)	6 (18.8%)
Grade 3	0	0	0	0
Oedema NEC	3 (21.4%)	1 (6.7%)	4 (13.8%)	6 (18.8%)
Grade 1	2 (14.3%)	1 (6.7%)	3 (10.3%)	4 (12.5%)
Grade 2	1 (7.1%)	0	1 (3.4%)	2 (6.3%)
Oedema peripheral	3 (21.4%)	1 (6.7%)	4 (13.8%)	5 (15.6%)
Grade 1	2 (14.3%)	1 (6.7%)	3 (10.3%)	3 (9.4%)
Grade 2	1 (7.1%)	0	1 (3.4%)	2 (6.3%)
Oedema	0	0	0	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Oedema NEC (cont)				
Oedema (cont)				
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Generalised oedema	0	0	0	1 (0.7%)
Grade 2	0	0	0	1 (0.7%)
General signs and symptoms NEC	4 (8.0%)	4 (5.8%)	8 (6.7%)	11 (8.0%)
Grade 1	2 (4.0%)	3 (4.3%)	5 (4.2%)	7 (5.1%)
Grade 2	1 (2.0%)	1 (1.4%)	2 (1.7%)	3 (2.2%)
Grade 3	0	0	0	0
Grade 5	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Influenza like illness	2 (4.0%)	3 (4.3%)	5 (4.2%)	6 (4.3%)
Grade 1	1 (2.0%)	2 (2.9%)	3 (2.5%)	4 (2.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Oedema NEC (cont)				
Oedema (cont)				
Grade 1	0	0	0	1 (3.1%)
Generalised oedema	0	0	0	0
Grade 2	0	0	0	0
General signs and symptoms NEC	2 (14.3%)	1 (6.7%)	3 (10.3%)	4 (12.5%)
Grade 1	2 (14.3%)	0	2 (6.9%)	3 (9.4%)
Grade 2	0	0	0	0
Grade 3	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 5	0	0	0	0
Influenza like illness	0	0	0	1 (3.1%)
Grade 1	0	0	0	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
General signs and symptoms NEC (cont)				
Influenza like illness (cont)				
Grade 2	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Peripheral swelling	1 (2.0%)	1 (1.4%)	2 (1.7%)	5 (3.6%)
Grade 1	1 (2.0%)	1 (1.4%)	2 (1.7%)	4 (2.9%)
Grade 2	0	0	0	1 (0.7%)
Crepitations	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)
General physical health deterioration	0	0	0	0
Grade 3	0	0	0	0
Multiple organ dysfunction syndrome	1 (2.0%)	0	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
General signs and symptoms NEC (cont)				
Influenza like illness (cont)				
Grade 2	0	0	0	0
Peripheral swelling	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	0	0	0	0
Crepitations	0	0	0	0
Grade 1	0	0	0	0
General physical health deterioration	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 3	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Multiple organ dysfunction syndrome	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
General signs and symptoms NEC (cont)				
Multiple organ dysfunction syndrome (cont)				
Grade 5	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Swelling	0	0	0	0
Grade 1	0	0	0	0
Xerosis	0	0	0	0
Grade 1	0	0	0	0
Pain and discomfort NEC	1 (2.0%)	3 (4.3%)	4 (3.4%)	10 (7.2%)
Grade 1	1 (2.0%)	1 (1.4%)	2 (1.7%)	6 (4.3%)
Grade 2	0	1 (1.4%)	1 (0.8%)	3 (2.2%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
General signs and symptoms NEC (cont)				
Multiple organ dysfunction syndrome (cont)				
Grade 5	0	0	0	0
Swelling	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Xerosis	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Pain and discomfort NEC	0	1 (6.7%)	1 (3.4%)	2 (6.3%)
Grade 1	0	1 (6.7%)	1 (3.4%)	2 (6.3%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Pain and discomfort NEC (cont)				
Chest pain	1 (2.0%)	2 (2.9%)	3 (2.5%)	6 (4.3%)
Grade 1	1 (2.0%)	0	1 (0.8%)	4 (2.9%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Pain	0	0	0	2 (1.4%)
Grade 1	0	0	0	1 (0.7%)
Grade 2	0	0	0	1 (0.7%)
Facial pain	0	0	0	1 (0.7%)
Grade 2	0	0	0	1 (0.7%)
Non-cardiac chest pain	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Pain and discomfort NEC (cont)				
Chest pain	0	1 (6.7%)	1 (3.4%)	2 (6.3%)
Grade 1	0	1 (6.7%)	1 (3.4%)	2 (6.3%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Pain	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Facial pain	0	0	0	0
Grade 2	0	0	0	0
Non-cardiac chest pain	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Feelings and sensations NEC	2 (4.0%)	2 (2.9%)	4 (3.4%)	5 (3.6%)
Grade 1	2 (4.0%)	2 (2.9%)	4 (3.4%)	5 (3.6%)
Chills	1 (2.0%)	1 (1.4%)	2 (1.7%)	3 (2.2%)
Grade 1	1 (2.0%)	1 (1.4%)	2 (1.7%)	3 (2.2%)
Early satiety	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Feeling hot	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Healing abnormal NEC	0	2 (2.9%)	2 (1.7%)	2 (1.4%)
Grade 2	0	2 (2.9%)	2 (1.7%)	2 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Feelings and sensations NEC	0	0	0	0
Grade 1	0	0	0	0
Chills	0	0	0	0
Grade 1	0	0	0	0
Early satiety	0	0	0	0
Grade 1	0	0	0	0
Feeling hot	0	0	0	0
Grade 1	0	0	0	0
Healing abnormal NEC	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Healing abnormal NEC (cont)				
Impaired healing	0	2 (2.9%)	2 (1.7%)	2 (1.4%)
Grade 2	0	2 (2.9%)	2 (1.7%)	2 (1.4%)
Mucosal findings abnormal	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 3	0	0	0	1 (0.7%)
Mucosal inflammation	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 3	0	0	0	1 (0.7%)
Death and sudden death	0	0	0	1 (0.7%)
Grade 5	0	0	0	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Healing abnormal NEC (cont)				
Impaired healing	0	0	0	0
Grade 2	0	0	0	0
Mucosal findings abnormal	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Mucosal inflammation	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Death and sudden death	0	0	0	0
Grade 5	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Death and sudden death (cont)				
Sudden death	0	0	0	1 (0.7%)
Grade 5	0	0	0	1 (0.7%)
Gait disturbances	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)
Gait disturbance	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)
Implant and catheter site reactions	0	0	0	0
Grade 2	0	0	0	0
Catheter site pain	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Death and sudden death (cont)				
Sudden death	0	0	0	0
Grade 5	0	0	0	0
Gait disturbances	0	0	0	0
Grade 1	0	0	0	0
Gait disturbance	0	0	0	0
Grade 1	0	0	0	0
Implant and catheter site reactions	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 2	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Catheter site pain	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 2	0	1 (6.7%)	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Withdrawal and rebound effects	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Drug withdrawal syndrome	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Blood and lymphatic system disorders	19 (38.0%)	32 (46.4%)	51 (42.9%)	69 (50.0%)
Grade 1	1 (2.0%)	4 (5.8%)	5 (4.2%)	9 (6.5%)
Grade 2	3 (6.0%)	11 (15.9%)	14 (11.8%)	17 (12.3%)
Grade 3	13 (26.0%)	13 (18.8%)	26 (21.8%)	35 (25.4%)
Grade 4	2 (4.0%)	3 (4.3%)	5 (4.2%)	7 (5.1%)
Grade 5	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Withdrawal and rebound effects	0	0	0	0
Grade 2	0	0	0	0
Drug withdrawal syndrome	0	0	0	0
Grade 2	0	0	0	0
Blood and lymphatic system disorders	5 (35.7%)	6 (40.0%)	11 (37.9%)	16 (50.0%)
Grade 1	1 (7.1%)	0	1 (3.4%)	0
Grade 2	0	3 (20.0%)	3 (10.3%)	8 (25.0%)
Grade 3	2 (14.3%)	3 (20.0%)	5 (17.2%)	5 (15.6%)
Grade 4	2 (14.3%)	0	2 (6.9%)	3 (9.4%)
Grade 5	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Thrombocytopenias	10 (20.0%)	14 (20.3%)	24 (20.2%)	34 (24.6%)
Grade 1	3 (6.0%)	3 (4.3%)	6 (5.0%)	8 (5.8%)
Grade 2	0	2 (2.9%)	2 (1.7%)	4 (2.9%)
Grade 3	7 (14.0%)	7 (10.1%)	14 (11.8%)	18 (13.0%)
Grade 4	0	2 (2.9%)	2 (1.7%)	4 (2.9%)
Thrombocytopenia	10 (20.0%)	14 (20.3%)	24 (20.2%)	34 (24.6%)
Grade 1	3 (6.0%)	3 (4.3%)	6 (5.0%)	8 (5.8%)
Grade 2	0	2 (2.9%)	2 (1.7%)	4 (2.9%)
Grade 3	7 (14.0%)	7 (10.1%)	14 (11.8%)	18 (13.0%)
Grade 4	0	2 (2.9%)	2 (1.7%)	4 (2.9%)
Anaemias NEC	12 (24.0%)	12 (17.4%)	24 (20.2%)	33 (23.9%)
Grade 2	3 (6.0%)	6 (8.7%)	9 (7.6%)	11 (8.0%)
Grade 3	8 (16.0%)	6 (8.7%)	14 (11.8%)	21 (15.2%)
Grade 4	1 (2.0%)	0	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Thrombocytopenias	2 (14.3%)	2 (13.3%)	4 (13.8%)	9 (28.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	0
Grade 2	0	0	0	4 (12.5%)
Grade 3	0	2 (13.3%)	2 (6.9%)	3 (9.4%)
Grade 4	1 (7.1%)	0	1 (3.4%)	2 (6.3%)
Thrombocytopenia	2 (14.3%)	2 (13.3%)	4 (13.8%)	9 (28.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	0
Grade 2	0	0	0	4 (12.5%)
Grade 3	0	2 (13.3%)	2 (6.9%)	3 (9.4%)
Grade 4	1 (7.1%)	0	1 (3.4%)	2 (6.3%)
Anaemias NEC	4 (28.6%)	3 (20.0%)	7 (24.1%)	8 (25.0%)
Grade 2	0	3 (20.0%)	3 (10.3%)	4 (12.5%)
Grade 3	2 (14.3%)	0	2 (6.9%)	2 (6.3%)
Grade 4	2 (14.3%)	0	2 (6.9%)	2 (6.3%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Anaemias NEC (cont)				
Anaemia	12 (24.0%)	12 (17.4%)	24 (20.2%)	33 (23.9%)
Grade 2	3 (6.0%)	6 (8.7%)	9 (7.6%)	11 (8.0%)
Grade 3	8 (16.0%)	6 (8.7%)	14 (11.8%)	21 (15.2%)
Grade 4	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Leukocytoses NEC	2 (4.0%)	6 (8.7%)	8 (6.7%)	9 (6.5%)
Grade 1	1 (2.0%)	3 (4.3%)	4 (3.4%)	5 (3.6%)
Grade 2	0	3 (4.3%)	3 (2.5%)	3 (2.2%)
Grade 3	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Leukocytosis	2 (4.0%)	6 (8.7%)	8 (6.7%)	9 (6.5%)
Grade 1	1 (2.0%)	3 (4.3%)	4 (3.4%)	5 (3.6%)
Grade 2	0	3 (4.3%)	3 (2.5%)	3 (2.2%)
Grade 3	1 (2.0%)	0	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Anaemias NEC (cont)				
Anaemia	4 (28.6%)	3 (20.0%)	7 (24.1%)	8 (25.0%)
Grade 2	0	3 (20.0%)	3 (10.3%)	4 (12.5%)
Grade 3	2 (14.3%)	0	2 (6.9%)	2 (6.3%)
Grade 4	2 (14.3%)	0	2 (6.9%)	2 (6.3%)
Leukocytoses NEC	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 3	0	0	0	0
Leukocytosis	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Leukocytoses NEC (cont)				
Neutrophilia	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Neutropenias	2 (4.0%)	3 (4.3%)	5 (4.2%)	9 (6.5%)
Grade 1	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Grade 3	1 (2.0%)	2 (2.9%)	3 (2.5%)	5 (3.6%)
Grade 4	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Neutropenia	2 (4.0%)	3 (4.3%)	5 (4.2%)	8 (5.8%)
Grade 1	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Grade 3	1 (2.0%)	2 (2.9%)	3 (2.5%)	4 (2.9%)
Grade 4	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Febrile neutropenia	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Grade 3	1 (2.0%)	0	1 (0.8%)	2 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Leukocytoses NEC (cont)				
Neutrophilia	0	0	0	0
Grade 1	0	0	0	0
Neutropenias	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Neutropenia	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Febrile neutropenia	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Leukopenias NEC	0	2 (2.9%)	2 (1.7%)	4 (2.9%)
Grade 1	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	0	0	0	1 (0.7%)
Grade 4	0	0	0	0
Leukopenia	0	1 (1.4%)	1 (0.8%)	3 (2.2%)
Grade 1	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Grade 3	0	0	0	1 (0.7%)
Lymphopenia	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 4	0	0	0	0
Spleen disorders	2 (4.0%)	1 (1.4%)	3 (2.5%)	4 (2.9%)
Grade 3	2 (4.0%)	0	2 (1.7%)	3 (2.2%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Leukopenias NEC	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Grade 4	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Leukopenia	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	0	0	0	0
Grade 3	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Lymphopenia	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	0	0	0	0
Grade 4	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Spleen disorders	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Spleen disorders (cont)				
(cont)				
Grade 5	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Splenomegaly	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Grade 3	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Splenic haematoma	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 5	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Splenic infarction	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 3	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Thrombocytoses	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Spleen disorders (cont)				
(cont)				
Grade 5	0	0	0	0
Splenomegaly	0	0	0	0
Grade 3	0	0	0	0
Splenic haematoma	0	0	0	0
Grade 5	0	0	0	0
Splenic infarction	0	0	0	0
Grade 3	0	0	0	0
Thrombocytoses	0	2 (13.3%)	2 (6.9%)	2 (6.3%)
Grade 1	0	0	0	0
Grade 2	0	1 (6.7%)	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Thrombocytoses (cont)				
(cont)				
Grade 3	0	0	0	0
Thrombocytosis	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Bleeding tendencies	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Grade 1	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Increased tendency to bruise	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Grade 1	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Anaemias haemolytic NEC	1 (2.0%)	0	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Thrombocytoses (cont)				
(cont)				
Grade 3	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Thrombocytosis	0	2 (13.3%)	2 (6.9%)	2 (6.3%)
Grade 1	0	0	0	0
Grade 2	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 3	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Bleeding tendencies	0	0	0	0
Grade 1	0	0	0	0
Increased tendency to bruise	0	0	0	0
Grade 1	0	0	0	0
Anaemias haemolytic NEC	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Anaemias haemolytic NEC (cont)				
(cont)				
Grade 4	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Haemolytic anaemia	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 4	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Coagulation factor deficiencies	0	0	0	1 (0.7%)
Grade 2	0	0	0	1 (0.7%)
Hypoprothrombinaemia	0	0	0	1 (0.7%)
Grade 2	0	0	0	1 (0.7%)
Haemolyses NEC	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 3	1 (2.0%)	0	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Anaemias haemolytic NEC (cont)				
(cont)				
Grade 4	0	0	0	0
Haemolytic anaemia	0	0	0	0
Grade 4	0	0	0	0
Coagulation factor deficiencies	0	0	0	0
Grade 2	0	0	0	0
Hypoprothrombinaemia	0	0	0	0
Grade 2	0	0	0	0
Haemolyses NEC	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Haemolyses NEC (cont)				
Haemolysis	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 3	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Respiratory, thoracic and mediastinal disorders	18 (36.0%)	27 (39.1%)	45 (37.8%)	62 (44.9%)
Grade 1	9 (18.0%)	12 (17.4%)	21 (17.6%)	31 (22.5%)
Grade 2	5 (10.0%)	10 (14.5%)	15 (12.6%)	19 (13.8%)
Grade 3	1 (2.0%)	5 (7.2%)	6 (5.0%)	7 (5.1%)
Grade 4	2 (4.0%)	0	2 (1.7%)	4 (2.9%)
Grade 5	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Coughing and associated symptoms	6 (12.0%)	12 (17.4%)	18 (15.1%)	29 (21.0%)
Grade 1	4 (8.0%)	7 (10.1%)	11 (9.2%)	20 (14.5%)
Grade 2	2 (4.0%)	3 (4.3%)	5 (4.2%)	7 (5.1%)
Grade 3	0	2 (2.9%)	2 (1.7%)	2 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Haemolyses NEC (cont)				
Haemolysis	0	0	0	0
Grade 3	0	0	0	0
Respiratory, thoracic and mediastinal disorders	8 (57.1%)	9 (60.0%)	17 (58.6%)	19 (59.4%)
Grade 1	3 (21.4%)	3 (20.0%)	6 (20.7%)	7 (21.9%)
Grade 2	5 (35.7%)	3 (20.0%)	8 (27.6%)	9 (28.1%)
Grade 3	0	2 (13.3%)	2 (6.9%)	2 (6.3%)
Grade 4	0	0	0	0
Grade 5	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Coughing and associated symptoms	7 (50.0%)	4 (26.7%)	11 (37.9%)	12 (37.5%)
Grade 1	4 (28.6%)	3 (20.0%)	7 (24.1%)	7 (21.9%)
Grade 2	3 (21.4%)	1 (6.7%)	4 (13.8%)	5 (15.6%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Coughing and associated symptoms (cont)				
Cough	5 (10.0%)	12 (17.4%)	17 (14.3%)	27 (19.6%)
Grade 1	4 (8.0%)	7 (10.1%)	11 (9.2%)	20 (14.5%)
Grade 2	1 (2.0%)	3 (4.3%)	4 (3.4%)	5 (3.6%)
Grade 3	0	2 (2.9%)	2 (1.7%)	2 (1.4%)
Productive cough	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Grade 1	0	0	0	1 (0.7%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Haemoptysis	0	0	0	1 (0.7%)
Grade 2	0	0	0	1 (0.7%)
Breathing abnormalities	4 (8.0%)	7 (10.1%)	11 (9.2%)	23 (16.7%)
Grade 1	3 (6.0%)	3 (4.3%)	6 (5.0%)	16 (11.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Coughing and associated symptoms (cont)				
Cough	7 (50.0%)	4 (26.7%)	11 (37.9%)	12 (37.5%)
Grade 1	4 (28.6%)	3 (20.0%)	7 (24.1%)	7 (21.9%)
Grade 2	3 (21.4%)	1 (6.7%)	4 (13.8%)	5 (15.6%)
Grade 3	0	0	0	0
Productive cough	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Haemoptysis	0	0	0	0
Grade 2	0	0	0	0
Breathing abnormalities	3 (21.4%)	4 (26.7%)	7 (24.1%)	11 (34.4%)
Grade 1	2 (14.3%)	1 (6.7%)	3 (10.3%)	7 (21.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Breathing abnormalities (cont) (cont)				
Grade 2	1 (2.0%)	1 (1.4%)	2 (1.7%)	4 (2.9%)
Grade 3	0	3 (4.3%)	3 (2.5%)	3 (2.2%)
Dyspnoea	4 (8.0%)	5 (7.2%)	9 (7.6%)	18 (13.0%)
Grade 1	3 (6.0%)	1 (1.4%)	4 (3.4%)	11 (8.0%)
Grade 2	1 (2.0%)	1 (1.4%)	2 (1.7%)	4 (2.9%)
Grade 3	0	3 (4.3%)	3 (2.5%)	3 (2.2%)
Dyspnoea exertional	0	1 (1.4%)	1 (0.8%)	4 (2.9%)
Grade 1	0	1 (1.4%)	1 (0.8%)	4 (2.9%)
Hypoventilation	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Breathing abnormalities (cont) (cont)				
Grade 2	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Grade 3	0	2 (13.3%)	2 (6.9%)	2 (6.3%)
Dyspnoea	2 (14.3%)	4 (26.7%)	6 (20.7%)	8 (25.0%)
Grade 1	1 (7.1%)	1 (6.7%)	2 (6.9%)	4 (12.5%)
Grade 2	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Grade 3	0	2 (13.3%)	2 (6.9%)	2 (6.3%)
Dyspnoea exertional	1 (7.1%)	0	1 (3.4%)	3 (9.4%)
Grade 1	1 (7.1%)	0	1 (3.4%)	3 (9.4%)
Hypoventilation	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Breathing abnormalities (cont)				
Tachypnoea	0	0	0	0
Grade 1	0	0	0	0
Nasal disorders NEC	4 (8.0%)	1 (1.4%)	5 (4.2%)	8 (5.8%)
Grade 1	3 (6.0%)	1 (1.4%)	4 (3.4%)	5 (3.6%)
Grade 2	1 (2.0%)	0	1 (0.8%)	3 (2.2%)
Epistaxis	4 (8.0%)	1 (1.4%)	5 (4.2%)	8 (5.8%)
Grade 1	3 (6.0%)	1 (1.4%)	4 (3.4%)	5 (3.6%)
Grade 2	1 (2.0%)	0	1 (0.8%)	3 (2.2%)
Nasal dryness	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Breathing abnormalities (cont)				
Tachypnoea	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Nasal disorders NEC	2 (14.3%)	2 (13.3%)	4 (13.8%)	4 (12.5%)
Grade 1	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Grade 2	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Epistaxis	1 (7.1%)	2 (13.3%)	3 (10.3%)	3 (9.4%)
Grade 1	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 2	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Nasal dryness	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Upper respiratory tract signs and symptoms	1 (2.0%)	2 (2.9%)	3 (2.5%)	7 (5.1%)
Grade 1	1 (2.0%)	1 (1.4%)	2 (1.7%)	6 (4.3%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Dysphonia	1 (2.0%)	1 (1.4%)	2 (1.7%)	4 (2.9%)
Grade 1	1 (2.0%)	0	1 (0.8%)	3 (2.2%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Rhinorrhoea	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)
Oropharyngeal discomfort	0	0	0	0
Grade 1	0	0	0	0
Oropharyngeal pain	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Upper respiratory tract signs and symptoms	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Grade 1	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Grade 2	0	0	0	0
Dysphonia	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Rhinorrhoea	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Oropharyngeal discomfort	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 1	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Oropharyngeal pain	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Upper respiratory tract signs and symptoms (cont)				
Oropharyngeal pain (cont)				
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Throat tightness	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)
Bronchospasm and obstruction	1 (2.0%)	2 (2.9%)	3 (2.5%)	4 (2.9%)
Grade 1	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	0	0	0	1 (0.7%)
Bronchitis chronic	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Upper respiratory tract signs and symptoms (cont)				
Oropharyngeal pain (cont)				
Grade 1	0	0	0	0
Throat tightness	0	0	0	0
Grade 1	0	0	0	0
Bronchospasm and obstruction	3 (21.4%)	0	3 (10.3%)	3 (9.4%)
Grade 1	2 (14.3%)	0	2 (6.9%)	2 (6.3%)
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 3	0	0	0	0
Bronchitis chronic	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Bronchospasm and obstruction (cont)				
Chronic obstructive pulmonary disease	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	0	0	0	1 (0.7%)
Wheezing	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Asthma	0	0	0	0
Grade 2	0	0	0	0
Pneumothorax and pleural effusions NEC	1 (2.0%)	2 (2.9%)	3 (2.5%)	3 (2.2%)
Grade 1	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Bronchospasm and obstruction (cont)				
Chronic obstructive pulmonary disease	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Wheezing	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Asthma	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Pneumothorax and pleural effusions NEC	0	2 (13.3%)	2 (6.9%)	2 (6.3%)
Grade 1	0	0	0	0
Grade 2	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 3	0	1 (6.7%)	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Pneumothorax and pleural effusions NEC (cont)				
Pleural effusion	1 (2.0%)	2 (2.9%)	3 (2.5%)	3 (2.2%)
Grade 1	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	0	0	0	0
Lower respiratory tract signs and symptoms	1 (2.0%)	0	1 (0.8%)	3 (2.2%)
Grade 1	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Grade 2	0	0	0	1 (0.7%)
Rales	0	0	0	2 (1.4%)
Grade 1	0	0	0	1 (0.7%)
Grade 2	0	0	0	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Pneumothorax and pleural effusions NEC (cont)				
Pleural effusion	0	2 (13.3%)	2 (6.9%)	2 (6.3%)
Grade 1	0	0	0	0
Grade 2	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 3	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Lower respiratory tract signs and symptoms	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	0	0	0	0
Rales	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Lower respiratory tract signs and symptoms (cont)				
Hiccups	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Respiratory failures (excl neonatal)	2 (4.0%)	0	2 (1.7%)	3 (2.2%)
Grade 3	0	0	0	0
Grade 4	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Grade 5	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Respiratory failure	2 (4.0%)	0	2 (1.7%)	3 (2.2%)
Grade 3	0	0	0	0
Grade 4	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Grade 5	1 (2.0%)	0	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Lower respiratory tract signs and symptoms (cont)				
Hiccups	0	0	0	0
Grade 1	0	0	0	0
Respiratory failures (excl neonatal)	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 3	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 4	0	0	0	0
Grade 5	0	0	0	0
Respiratory failure	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 3	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 4	0	0	0	0
Grade 5	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Lower respiratory tract inflammatory and immunologic conditions	1 (2.0%)	2 (2.9%)	3 (2.5%)	3 (2.2%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Alveolitis	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Pneumonia aspiration	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 3	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Pulmonary granuloma	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Lower respiratory tract inflammatory and immunologic conditions	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Alveolitis	0	0	0	0
Grade 2	0	0	0	0
Pneumonia aspiration	0	0	0	0
Grade 3	0	0	0	0
Pulmonary granuloma	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Pulmonary thrombotic and embolic conditions	2 (4.0%)	0	2 (1.7%)	2 (1.4%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 3	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 5	0	0	0	0
Pulmonary embolism	2 (4.0%)	0	2 (1.7%)	2 (1.4%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 3	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 5	0	0	0	0
Conditions associated with abnormal gas exchange	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Grade 4	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Hypoxia	1 (2.0%)	0	1 (0.8%)	2 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Pulmonary thrombotic and embolic conditions	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Grade 5	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Pulmonary embolism	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Grade 5	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Conditions associated with abnormal gas exchange	0	0	0	0
Grade 4	0	0	0	0
Hypoxia	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Conditions associated with abnormal gas exchange (cont)				
Hypoxia (cont)				
Grade 4	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Grade 2	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Laryngeal inflammation	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Reflux laryngitis	0	0	0	1 (0.7%)
Grade 2	0	0	0	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Conditions associated with abnormal gas exchange (cont)				
Hypoxia (cont)				
Grade 4	0	0	0	0
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)	0	0	0	0
Grade 2	0	0	0	0
Laryngeal inflammation	0	0	0	0
Grade 2	0	0	0	0
Reflux laryngitis	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Parenchymal lung disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Emphysema	0	0	0	0
Grade 1	0	0	0	0
Lung consolidation	0	0	0	0
Grade 2	0	0	0	0
Pleural infections and inflammations	0	2 (2.9%)	2 (1.7%)	2 (1.4%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Pleurisy	0	2 (2.9%)	2 (1.7%)	2 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Parenchymal lung disorders NEC	2 (14.3%)	0	2 (6.9%)	2 (6.3%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Emphysema	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Lung consolidation	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Pleural infections and inflammations	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Pleurisy	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Pleural infections and inflammations (cont)				
Pleurisy (cont)				
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Paranasal sinus disorders (excl infections and neoplasms)	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Sinus congestion	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Pharyngeal disorders (excl infections and neoplasms)	0	0	0	1 (0.7%)
Grade 3	0	0	0	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Pleural infections and inflammations (cont)				
Pleurisy (cont)				
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Paranasal sinus disorders (excl infections and neoplasms)	0	0	0	0
Grade 1	0	0	0	0
Sinus congestion	0	0	0	0
Grade 1	0	0	0	0
Pharyngeal disorders (excl infections and neoplasms)	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Pharyngeal disorders (excl infections and neoplasms) (cont)				
Pharyngeal ulceration	0	0	0	1 (0.7%)
Grade 3	0	0	0	1 (0.7%)
Pulmonary oedemas	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Pulmonary oedema	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Respiratory tract disorders NEC	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Lung disorder	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Pharyngeal disorders (excl infections and neoplasms) (cont)				
Pharyngeal ulceration	0	0	0	0
Grade 3	0	0	0	0
Pulmonary oedemas	0	0	0	0
Grade 2	0	0	0	0
Pulmonary oedema	0	0	0	0
Grade 2	0	0	0	0
Respiratory tract disorders NEC	0	0	0	0
Grade 2	0	0	0	0
Lung disorder	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Respiratory tract disorders NEC (cont)				
Lung disorder (cont)				
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Nervous system disorders	17 (34.0%)	27 (39.1%)	44 (37.0%)	60 (43.5%)
Grade 1	8 (16.0%)	12 (17.4%)	20 (16.8%)	28 (20.3%)
Grade 2	3 (6.0%)	11 (15.9%)	14 (11.8%)	19 (13.8%)
Grade 3	5 (10.0%)	4 (5.8%)	9 (7.6%)	12 (8.7%)
Grade 4	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 5	0	0	0	0
Neurological signs and symptoms NEC	3 (6.0%)	13 (18.8%)	16 (13.4%)	29 (21.0%)
Grade 1	2 (4.0%)	10 (14.5%)	12 (10.1%)	22 (15.9%)
Grade 2	1 (2.0%)	2 (2.9%)	3 (2.5%)	5 (3.6%)
Grade 3	0	1 (1.4%)	1 (0.8%)	2 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Respiratory tract disorders NEC (cont)				
Lung disorder (cont)				
Grade 2	0	0	0	0
Nervous system disorders	10 (71.4%)	5 (33.3%)	15 (51.7%)	19 (59.4%)
Grade 1	5 (35.7%)	4 (26.7%)	9 (31.0%)	11 (34.4%)
Grade 2	2 (14.3%)	0	2 (6.9%)	4 (12.5%)
Grade 3	2 (14.3%)	1 (6.7%)	3 (10.3%)	3 (9.4%)
Grade 4	0	0	0	0
Grade 5	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Neurological signs and symptoms NEC	4 (28.6%)	1 (6.7%)	5 (17.2%)	6 (18.8%)
Grade 1	4 (28.6%)	0	4 (13.8%)	5 (15.6%)
Grade 2	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Neurological signs and symptoms NEC (cont)				
Dizziness	2 (4.0%)	13 (18.8%)	15 (12.6%)	28 (20.3%)
Grade 1	2 (4.0%)	10 (14.5%)	12 (10.1%)	23 (16.7%)
Grade 2	0	2 (2.9%)	2 (1.7%)	4 (2.9%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Presyncope	1 (2.0%)	0	1 (0.8%)	3 (2.2%)
Grade 1	0	0	0	1 (0.7%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 3	0	0	0	1 (0.7%)
Peripheral neuropathies NEC	8 (16.0%)	10 (14.5%)	18 (15.1%)	23 (16.7%)
Grade 1	5 (10.0%)	4 (5.8%)	9 (7.6%)	13 (9.4%)
Grade 2	1 (2.0%)	5 (7.2%)	6 (5.0%)	7 (5.1%)
Grade 3	2 (4.0%)	1 (1.4%)	3 (2.5%)	3 (2.2%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Neurological signs and symptoms NEC (cont)				
Dizziness	4 (28.6%)	1 (6.7%)	5 (17.2%)	6 (18.8%)
Grade 1	4 (28.6%)	0	4 (13.8%)	5 (15.6%)
Grade 2	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 3	0	0	0	0
Presyncope	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Peripheral neuropathies NEC	1 (7.1%)	3 (20.0%)	4 (13.8%)	8 (25.0%)
Grade 1	0	2 (13.3%)	2 (6.9%)	4 (12.5%)
Grade 2	1 (7.1%)	0	1 (3.4%)	3 (9.4%)
Grade 3	0	1 (6.7%)	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Peripheral neuropathies NEC (cont)				
Peripheral sensory neuropathy	7 (14.0%)	10 (14.5%)	17 (14.3%)	22 (15.9%)
Grade 1	5 (10.0%)	4 (5.8%)	9 (7.6%)	13 (9.4%)
Grade 2	1 (2.0%)	5 (7.2%)	6 (5.0%)	7 (5.1%)
Grade 3	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Neuropathy peripheral	0	0	0	0
Grade 2	0	0	0	0
Peripheral sensorimotor neuropathy	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 3	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Paraesthesias and dysaesthesias	2 (4.0%)	6 (8.7%)	8 (6.7%)	13 (9.4%)
Grade 1	2 (4.0%)	2 (2.9%)	4 (3.4%)	9 (6.5%)
Grade 2	0	4 (5.8%)	4 (3.4%)	4 (2.9%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Peripheral neuropathies NEC (cont)				
Peripheral sensory neuropathy	0	3 (20.0%)	3 (10.3%)	7 (21.9%)
Grade 1	0	2 (13.3%)	2 (6.9%)	4 (12.5%)
Grade 2	0	0	0	2 (6.3%)
Grade 3	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Neuropathy peripheral	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Peripheral sensorimotor neuropathy	0	0	0	0
Grade 3	0	0	0	0
Paraesthesias and dysaesthesias	4 (28.6%)	1 (6.7%)	5 (17.2%)	5 (15.6%)
Grade 1	2 (14.3%)	1 (6.7%)	3 (10.3%)	3 (9.4%)
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 3	1 (7.1%)	0	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Paraesthesias and dysaesthesias (cont)				
Paraesthesia	1 (2.0%)	4 (5.8%)	5 (4.2%)	10 (7.2%)
Grade 1	1 (2.0%)	1 (1.4%)	2 (1.7%)	7 (5.1%)
Grade 2	0	3 (4.3%)	3 (2.5%)	3 (2.2%)
Grade 3	0	0	0	0
Hypoaesthesia	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Burning sensation	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Dysaesthesia	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Paraesthesias and dysaesthesias (cont)				
Paraesthesia	2 (14.3%)	1 (6.7%)	3 (10.3%)	3 (9.4%)
Grade 1	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Grade 2	0	0	0	0
Grade 3	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Hypoaesthesia	4 (28.6%)	1 (6.7%)	5 (17.2%)	5 (15.6%)
Grade 1	3 (21.4%)	1 (6.7%)	4 (13.8%)	4 (12.5%)
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Burning sensation	0	0	0	0
Grade 2	0	0	0	0
Dysaesthesia	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Headaches NEC	1 (2.0%)	4 (5.8%)	5 (4.2%)	9 (6.5%)
Grade 1	1 (2.0%)	2 (2.9%)	3 (2.5%)	6 (4.3%)
Grade 2	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Headache	1 (2.0%)	3 (4.3%)	4 (3.4%)	8 (5.8%)
Grade 1	1 (2.0%)	1 (1.4%)	2 (1.7%)	5 (3.6%)
Grade 2	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Sinus headache	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Disturbances in consciousness NEC	2 (4.0%)	2 (2.9%)	4 (3.4%)	7 (5.1%)
Grade 1	0	0	0	1 (0.7%)
Grade 2	0	2 (2.9%)	2 (1.7%)	2 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Headaches NEC	1 (7.1%)	0	1 (3.4%)	7 (21.9%)
Grade 1	1 (7.1%)	0	1 (3.4%)	5 (15.6%)
Grade 2	0	0	0	2 (6.3%)
Grade 3	0	0	0	0
Headache	1 (7.1%)	0	1 (3.4%)	7 (21.9%)
Grade 1	1 (7.1%)	0	1 (3.4%)	5 (15.6%)
Grade 2	0	0	0	2 (6.3%)
Grade 3	0	0	0	0
Sinus headache	0	0	0	0
Grade 1	0	0	0	0
Disturbances in consciousness NEC	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Grade 1	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Disturbances in consciousness NEC (cont) (cont)				
Grade 3	2 (4.0%)	0	2 (1.7%)	4 (2.9%)
Syncope	1 (2.0%)	1 (1.4%)	2 (1.7%)	4 (2.9%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	1 (2.0%)	0	1 (0.8%)	3 (2.2%)
Somnolence	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Grade 1	0	0	0	1 (0.7%)
Grade 3	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Lethargy	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Disturbances in consciousness NEC (cont) (cont)				
Grade 3	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Syncope	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Somnolence	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 1	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 3	0	0	0	0
Lethargy	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	0	0	0	0
Grade 3	1 (7.1%)	0	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Coordination and balance disturbances	1 (2.0%)	2 (2.9%)	3 (2.5%)	5 (3.6%)
Grade 1	0	2 (2.9%)	2 (1.7%)	4 (2.9%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Balance disorder	1 (2.0%)	1 (1.4%)	2 (1.7%)	4 (2.9%)
Grade 1	0	1 (1.4%)	1 (0.8%)	3 (2.2%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Ataxia	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Sensory abnormalities NEC	1 (2.0%)	2 (2.9%)	3 (2.5%)	5 (3.6%)
Grade 1	1 (2.0%)	2 (2.9%)	3 (2.5%)	5 (3.6%)
Dysgeusia	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Coordination and balance disturbances	2 (14.3%)	0	2 (6.9%)	2 (6.3%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Balance disorder	2 (14.3%)	0	2 (6.9%)	2 (6.3%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Ataxia	0	0	0	0
Grade 1	0	0	0	0
Sensory abnormalities NEC	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Grade 1	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Dysgeusia	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Grade 1	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Sensory abnormalities NEC (cont)				
Sensory disturbance	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Grade 1	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Taste disorder	0	0	0	2 (1.4%)
Grade 1	0	0	0	2 (1.4%)
Ageusia	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Restless legs syndrome	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Sensory abnormalities NEC (cont)				
Sensory disturbance	0	0	0	0
Grade 1	0	0	0	0
Taste disorder	0	0	0	0
Grade 1	0	0	0	0
Ageusia	0	0	0	0
Grade 1	0	0	0	0
Restless legs syndrome	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Central nervous system haemorrhages and cerebrovascular accidents	3 (6.0%)	0	3 (2.5%)	4 (2.9%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	0	0	0	1 (0.7%)
Grade 3	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 4	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 5	0	0	0	0
Cerebrovascular accident	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	0	0	0	0
Grade 4	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Cerebellar stroke	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 3	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Cerebral ischaemia	0	0	0	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Central nervous system haemorrhages and cerebrovascular accidents	2 (14.3%)	0	2 (6.9%)	2 (6.3%)
Grade 1	0	0	0	0
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Grade 5	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Cerebrovascular accident	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 4	0	0	0	0
Cerebellar stroke	0	0	0	0
Grade 3	0	0	0	0
Cerebral ischaemia	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Central nervous system haemorrhages and cerebrovascular accidents (cont)				
Cerebral ischaemia (cont)				
Grade 2	0	0	0	1 (0.7%)
Haemorrhagic stroke	0	0	0	0
Grade 5	0	0	0	0
Lacunar infarction	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Memory loss (excl dementia)	1 (2.0%)	3 (4.3%)	4 (3.4%)	6 (4.3%)
Grade 1	0	1 (1.4%)	1 (0.8%)	3 (2.2%)
Grade 2	1 (2.0%)	2 (2.9%)	3 (2.5%)	3 (2.2%)
Amnesia	1 (2.0%)	2 (2.9%)	3 (2.5%)	4 (2.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Central nervous system haemorrhages and cerebrovascular accidents (cont)				
Cerebral ischaemia (cont)				
Grade 2	0	0	0	0
Haemorrhagic stroke	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 5	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Lacunar infarction	0	0	0	0
Grade 1	0	0	0	0
Memory loss (excl dementia)	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Amnesia	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Memory loss (excl dementia) (cont)				
Amnesia (cont)				
Grade 1	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Grade 2	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Memory impairment	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Grade 1	0	0	0	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Central nervous system vascular disorders NEC	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	0	0	0
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Cerebral microangiopathy	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Memory loss (excl dementia) (cont)				
Amnesia (cont)				
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Memory impairment	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Central nervous system vascular disorders NEC	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	0	0	0	0
Cerebral microangiopathy	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Central nervous system vascular disorders NEC (cont)				
Cerebrovascular insufficiency	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Transient cerebrovascular events	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Transient ischaemic attack	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Dementia (excl Alzheimer's type)	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Central nervous system vascular disorders NEC (cont)				
Cerebrovascular insufficiency	0	0	0	0
Grade 2	0	0	0	0
Transient cerebrovascular events	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Transient ischaemic attack	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Dementia (excl Alzheimer's type)	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Dementia (excl Alzheimer's type) (cont)				
Dementia	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Demyelinating disorders NEC	0	0	0	0
Grade 2	0	0	0	0
Demyelination	0	0	0	0
Grade 2	0	0	0	0
Encephalopathies NEC	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Leukoencephalopathy	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Dementia (excl Alzheimer's type) (cont)				
Dementia	0	0	0	0
Grade 2	0	0	0	0
Demyelinating disorders NEC	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 2	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Demyelination	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 2	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Encephalopathies NEC	0	0	0	0
Grade 2	0	0	0	0
Leukoencephalopathy	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Lumbar spinal cord and nerve root disorders	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Sciatica	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Muscle tone abnormal	0	0	0	0
Grade 1	0	0	0	0
Myotonia	0	0	0	0
Grade 1	0	0	0	0
Parkinson's disease and parkinsonism	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Parkinson's disease	1 (2.0%)	0	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Lumbar spinal cord and nerve root disorders	0	0	0	0
Grade 2	0	0	0	0
Sciatica	0	0	0	0
Grade 2	0	0	0	0
Muscle tone abnormal	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 1	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Myotonia	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 1	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Parkinson's disease and parkinsonism	0	0	0	0
Grade 2	0	0	0	0
Parkinson's disease	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Parkinson's disease and parkinsonism (cont)				
Parkinson's disease (cont)				
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Structural brain disorders NEC	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Cerebral atrophy	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Tremor (excl congenital)	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Tremor	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Parkinson's disease and parkinsonism (cont)				
Parkinson's disease (cont)				
Grade 2	0	0	0	0
Structural brain disorders NEC	0	0	0	0
Grade 2	0	0	0	0
Cerebral atrophy	0	0	0	0
Grade 2	0	0	0	0
Tremor (excl congenital)	0	0	0	0
Grade 1	0	0	0	0
Tremor	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders	20 (40.0%)	31 (44.9%)	51 (42.9%)	64 (46.4%)
Grade 1	8 (16.0%)	12 (17.4%)	20 (16.8%)	23 (16.7%)
Grade 2	4 (8.0%)	15 (21.7%)	19 (16.0%)	24 (17.4%)
Grade 3	5 (10.0%)	3 (4.3%)	8 (6.7%)	11 (8.0%)
Grade 4	3 (6.0%)	1 (1.4%)	4 (3.4%)	6 (4.3%)
Disorders of purine metabolism	6 (12.0%)	6 (8.7%)	12 (10.1%)	16 (11.6%)
Grade 1	1 (2.0%)	4 (5.8%)	5 (4.2%)	7 (5.1%)
Grade 2	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Grade 3	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 4	3 (6.0%)	1 (1.4%)	4 (3.4%)	6 (4.3%)
Hyperuricaemia	4 (8.0%)	5 (7.2%)	9 (7.6%)	13 (9.4%)
Grade 1	1 (2.0%)	4 (5.8%)	5 (4.2%)	7 (5.1%)
Grade 4	3 (6.0%)	1 (1.4%)	4 (3.4%)	6 (4.3%)
Gout	2 (4.0%)	1 (1.4%)	3 (2.5%)	3 (2.2%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders	6 (42.9%)	4 (26.7%)	10 (34.5%)	14 (43.8%)
Grade 1	2 (14.3%)	1 (6.7%)	3 (10.3%)	4 (12.5%)
Grade 2	3 (21.4%)	2 (13.3%)	5 (17.2%)	6 (18.8%)
Grade 3	1 (7.1%)	0	1 (3.4%)	3 (9.4%)
Grade 4	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Disorders of purine metabolism	0	3 (20.0%)	3 (10.3%)	5 (15.6%)
Grade 1	0	2 (13.3%)	2 (6.9%)	3 (9.4%)
Grade 2	0	0	0	1 (3.1%)
Grade 3	0	0	0	0
Grade 4	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Hyperuricaemia	0	3 (20.0%)	3 (10.3%)	4 (12.5%)
Grade 1	0	2 (13.3%)	2 (6.9%)	3 (9.4%)
Grade 4	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Gout	0	0	0	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Disorders of purine metabolism (cont)				
Gout (cont)				
Grade 2	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Grade 3	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Water soluble vitamin deficiencies	6 (12.0%)	7 (10.1%)	13 (10.9%)	17 (12.3%)
Grade 1	2 (4.0%)	4 (5.8%)	6 (5.0%)	7 (5.1%)
Grade 2	4 (8.0%)	3 (4.3%)	7 (5.9%)	10 (7.2%)
Vitamin B1 deficiency	5 (10.0%)	7 (10.1%)	12 (10.1%)	16 (11.6%)
Grade 1	1 (2.0%)	4 (5.8%)	5 (4.2%)	6 (4.3%)
Grade 2	4 (8.0%)	3 (4.3%)	7 (5.9%)	10 (7.2%)
Vitamin B complex deficiency	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Disorders of purine metabolism (cont)				
Gout (cont)				
Grade 2	0	0	0	1 (3.1%)
Grade 3	0	0	0	0
Water soluble vitamin deficiencies	2 (14.3%)	1 (6.7%)	3 (10.3%)	4 (12.5%)
Grade 1	0	0	0	1 (3.1%)
Grade 2	2 (14.3%)	1 (6.7%)	3 (10.3%)	3 (9.4%)
Vitamin B1 deficiency	2 (14.3%)	1 (6.7%)	3 (10.3%)	3 (9.4%)
Grade 1	0	0	0	0
Grade 2	2 (14.3%)	1 (6.7%)	3 (10.3%)	3 (9.4%)
Vitamin B complex deficiency	0	0	0	1 (3.1%)
Grade 1	0	0	0	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Potassium imbalance	7 (14.0%)	4 (5.8%)	11 (9.2%)	14 (10.1%)
Grade 1	3 (6.0%)	3 (4.3%)	6 (5.0%)	5 (3.6%)
Grade 2	0	1 (1.4%)	1 (0.8%)	4 (2.9%)
Grade 3	4 (8.0%)	0	4 (3.4%)	5 (3.6%)
Hyperkalaemia	6 (12.0%)	1 (1.4%)	7 (5.9%)	9 (6.5%)
Grade 1	2 (4.0%)	1 (1.4%)	3 (2.5%)	2 (1.4%)
Grade 2	0	0	0	2 (1.4%)
Grade 3	4 (8.0%)	0	4 (3.4%)	5 (3.6%)
Hypokalaemia	2 (4.0%)	3 (4.3%)	5 (4.2%)	6 (4.3%)
Grade 1	1 (2.0%)	2 (2.9%)	3 (2.5%)	3 (2.2%)
Grade 2	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Grade 3	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Appetite disorders	5 (10.0%)	5 (7.2%)	10 (8.4%)	14 (10.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Potassium imbalance	2 (14.3%)	0	2 (6.9%)	4 (12.5%)
Grade 1	1 (7.1%)	0	1 (3.4%)	2 (6.3%)
Grade 2	0	0	0	1 (3.1%)
Grade 3	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Hyperkalaemia	2 (14.3%)	0	2 (6.9%)	2 (6.3%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	0	0	0	0
Grade 3	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Hypokalaemia	0	0	0	2 (6.3%)
Grade 1	0	0	0	1 (3.1%)
Grade 2	0	0	0	1 (3.1%)
Grade 3	0	0	0	0
Appetite disorders	1 (7.1%)	2 (13.3%)	3 (10.3%)	3 (9.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Appetite disorders (cont)				
(cont)				
Grade 1	4 (8.0%)	3 (4.3%)	7 (5.9%)	10 (7.2%)
Grade 2	1 (2.0%)	2 (2.9%)	3 (2.5%)	4 (2.9%)
Decreased appetite	5 (10.0%)	5 (7.2%)	10 (8.4%)	14 (10.1%)
Grade 1	4 (8.0%)	3 (4.3%)	7 (5.9%)	10 (7.2%)
Grade 2	1 (2.0%)	2 (2.9%)	3 (2.5%)	4 (2.9%)
Magnesium metabolism disorders	1 (2.0%)	1 (1.4%)	2 (1.7%)	5 (3.6%)
Grade 1	0	1 (1.4%)	1 (0.8%)	3 (2.2%)
Grade 2	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Hypomagnesaemia	1 (2.0%)	1 (1.4%)	2 (1.7%)	5 (3.6%)
Grade 1	0	1 (1.4%)	1 (0.8%)	3 (2.2%)
Grade 2	1 (2.0%)	0	1 (0.8%)	2 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Appetite disorders (cont)				
(cont)				
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	0	2 (13.3%)	2 (6.9%)	2 (6.3%)
Decreased appetite	1 (7.1%)	2 (13.3%)	3 (10.3%)	3 (9.4%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	0	2 (13.3%)	2 (6.9%)	2 (6.3%)
Magnesium metabolism disorders	0	0	0	2 (6.3%)
Grade 1	0	0	0	2 (6.3%)
Grade 2	0	0	0	0
Hypomagnesaemia	0	0	0	2 (6.3%)
Grade 1	0	0	0	2 (6.3%)
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Calcium metabolism disorders	1 (2.0%)	2 (2.9%)	3 (2.5%)	5 (3.6%)
Grade 2	1 (2.0%)	2 (2.9%)	3 (2.5%)	5 (3.6%)
Hypocalcaemia	1 (2.0%)	1 (1.4%)	2 (1.7%)	4 (2.9%)
Grade 2	1 (2.0%)	1 (1.4%)	2 (1.7%)	4 (2.9%)
Hypercalcaemia	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Diabetes mellitus (incl subtypes)	0	4 (5.8%)	4 (3.4%)	4 (2.9%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	3 (4.3%)	3 (2.5%)	3 (2.2%)
Diabetes mellitus	0	4 (5.8%)	4 (3.4%)	4 (2.9%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	3 (4.3%)	3 (2.5%)	3 (2.2%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Calcium metabolism disorders	0	0	0	1 (3.1%)
Grade 2	0	0	0	1 (3.1%)
Hypocalcaemia	0	0	0	1 (3.1%)
Grade 2	0	0	0	1 (3.1%)
Hypercalcaemia	0	0	0	0
Grade 2	0	0	0	0
Diabetes mellitus (incl subtypes)	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Diabetes mellitus	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Fat soluble vitamin deficiencies and disorders	1 (2.0%)	1 (1.4%)	2 (1.7%)	3 (2.2%)
Grade 1	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Vitamin D deficiency	1 (2.0%)	1 (1.4%)	2 (1.7%)	3 (2.2%)
Grade 1	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Vitamin K deficiency	0	0	0	0
Grade 1	0	0	0	0
Hyperglycaemic conditions NEC	1 (2.0%)	2 (2.9%)	3 (2.5%)	4 (2.9%)
Grade 1	0	0	0	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Fat soluble vitamin deficiencies and disorders	0	0	0	1 (3.1%)
Grade 1	0	0	0	1 (3.1%)
Grade 2	0	0	0	0
Vitamin D deficiency	0	0	0	1 (3.1%)
Grade 1	0	0	0	1 (3.1%)
Grade 2	0	0	0	0
Vitamin K deficiency	0	0	0	1 (3.1%)
Grade 1	0	0	0	1 (3.1%)
Hyperglycaemic conditions NEC	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Hyperglycaemic conditions NEC (cont)				
Hyperglycaemia	1 (2.0%)	2 (2.9%)	3 (2.5%)	4 (2.9%)
Grade 1	0	0	0	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Iron excess	0	1 (1.4%)	1 (0.8%)	3 (2.2%)
Grade 1	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Grade 2	0	0	0	0
Grade 3	0	0	0	1 (0.7%)
Iron overload	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	0	0	0
Grade 3	0	0	0	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Hyperglycaemic conditions NEC (cont)				
Hyperglycaemia	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Iron excess	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	0	0	0	0
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 3	0	0	0	0
Iron overload	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	0	0	0	0
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Iron excess (cont)				
Haemosiderosis	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)
Total fluid volume decreased	1 (2.0%)	1 (1.4%)	2 (1.7%)	3 (2.2%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Dehydration	1 (2.0%)	1 (1.4%)	2 (1.7%)	3 (2.2%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Protein metabolism disorders NEC	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Grade 1	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Iron excess (cont)				
Haemosiderosis	0	0	0	0
Grade 1	0	0	0	0
Total fluid volume decreased	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 2	0	0	0	0
Grade 3	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Dehydration	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 2	0	0	0	0
Grade 3	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Protein metabolism disorders NEC	0	0	0	1 (3.1%)
Grade 1	0	0	0	0
Grade 2	0	0	0	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Protein metabolism disorders NEC (cont)				
Hypoalbuminaemia	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Grade 1	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Grade 2	0	0	0	0
Sodium imbalance	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Grade 3	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Hyponatraemia	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Grade 3	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Hypernatraemia	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Hypoglycaemic conditions NEC	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Protein metabolism disorders NEC (cont)				
Hypoalbuminaemia	0	0	0	1 (3.1%)
Grade 1	0	0	0	0
Grade 2	0	0	0	1 (3.1%)
Sodium imbalance	0	0	0	1 (3.1%)
Grade 3	0	0	0	1 (3.1%)
Hyponatraemia	0	0	0	1 (3.1%)
Grade 3	0	0	0	1 (3.1%)
Hypernatraemia	0	0	0	0
Grade 2	0	0	0	0
Hypoglycaemic conditions NEC	0	0	0	1 (3.1%)
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Hypoglycaemic conditions NEC (cont)				
(cont)				
Grade 3	0	0	0	0
Hypoglycaemia	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	0	0	0	0
Total fluid volume increased	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	0	0	0	0
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Fluid overload	0	0	0	0
Grade 1	0	0	0	0
Fluid retention	1 (2.0%)	0	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Hypoglycaemic conditions NEC (cont)				
(cont)				
Grade 3	0	0	0	1 (3.1%)
Hypoglycaemia	0	0	0	1 (3.1%)
Grade 2	0	0	0	0
Grade 3	0	0	0	1 (3.1%)
Total fluid volume increased	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	0	0	0	0
Fluid overload	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Fluid retention	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Total fluid volume increased (cont)				
Fluid retention (cont)				
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Electrolyte imbalance NEC	0	0	0	0
Grade 1	0	0	0	0
Electrolyte imbalance	0	0	0	0
Grade 1	0	0	0	0
Elevated triglycerides	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Hypertriglyceridaemia	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Total fluid volume increased (cont)				
Fluid retention (cont)				
Grade 2	0	0	0	0
Electrolyte imbalance NEC	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 1	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Electrolyte imbalance	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 1	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Elevated triglycerides	0	0	0	0
Grade 3	0	0	0	0
Hypertriglyceridaemia	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
General nutritional disorders NEC	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Abnormal loss of weight	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Iron deficiencies	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Iron deficiency	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Lipid metabolism and deposit disorders NEC	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Dyslipidaemia	1 (2.0%)	0	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
General nutritional disorders NEC	0	0	0	0
Grade 2	0	0	0	0
Abnormal loss of weight	0	0	0	0
Grade 2	0	0	0	0
Iron deficiencies	0	0	0	0
Grade 2	0	0	0	0
Iron deficiency	0	0	0	0
Grade 2	0	0	0	0
Lipid metabolism and deposit disorders NEC	0	0	0	0
Grade 2	0	0	0	0
Dyslipidaemia	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Lipid metabolism and deposit disorders NEC (cont)				
Dyslipidaemia (cont)				
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Phosphorus metabolism disorders	0	0	0	0
Grade 3	0	0	0	0
Hypophosphataemia	0	0	0	0
Grade 3	0	0	0	0
Skin and subcutaneous tissue disorders	16 (32.0%)	19 (27.5%)	35 (29.4%)	46 (33.3%)
Grade 1	10 (20.0%)	14 (20.3%)	24 (20.2%)	33 (23.9%)
Grade 2	5 (10.0%)	5 (7.2%)	10 (8.4%)	12 (8.7%)
Grade 3	1 (2.0%)	0	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Lipid metabolism and deposit disorders NEC (cont)				
Dyslipidaemia (cont)				
Grade 2	0	0	0	0
Phosphorus metabolism disorders	0	0	0	1 (3.1%)
Grade 3	0	0	0	1 (3.1%)
Hypophosphataemia	0	0	0	1 (3.1%)
Grade 3	0	0	0	1 (3.1%)
Skin and subcutaneous tissue disorders	8 (57.1%)	6 (40.0%)	14 (48.3%)	16 (50.0%)
Grade 1	7 (50.0%)	4 (26.7%)	11 (37.9%)	12 (37.5%)
Grade 2	1 (7.1%)	1 (6.7%)	2 (6.9%)	3 (9.4%)
Grade 3	0	1 (6.7%)	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Rashes, eruptions and exanthems NEC	5 (10.0%)	6 (8.7%)	11 (9.2%)	15 (10.9%)
Grade 1	4 (8.0%)	6 (8.7%)	10 (8.4%)	14 (10.1%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Rash	5 (10.0%)	3 (4.3%)	8 (6.7%)	10 (7.2%)
Grade 1	4 (8.0%)	3 (4.3%)	7 (5.9%)	9 (6.5%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Rash maculo-papular	0	1 (1.4%)	1 (0.8%)	3 (2.2%)
Grade 1	0	1 (1.4%)	1 (0.8%)	3 (2.2%)
Rash generalised	0	0	0	0
Grade 1	0	0	0	0
Rash macular	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Grade 1	0	1 (1.4%)	1 (0.8%)	2 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Rashes, eruptions and exanthems NEC	3 (21.4%)	3 (20.0%)	6 (20.7%)	8 (25.0%)
Grade 1	3 (21.4%)	3 (20.0%)	6 (20.7%)	7 (21.9%)
Grade 2	0	0	0	1 (3.1%)
Rash	2 (14.3%)	2 (13.3%)	4 (13.8%)	6 (18.8%)
Grade 1	2 (14.3%)	2 (13.3%)	4 (13.8%)	5 (15.6%)
Grade 2	0	0	0	1 (3.1%)
Rash maculo-papular	0	0	0	0
Grade 1	0	0	0	0
Rash generalised	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Grade 1	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Rash macular	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Rashes, eruptions and exanthems NEC (cont)				
Rash papular	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Apocrine and eccrine gland disorders	4 (8.0%)	7 (10.1%)	11 (9.2%)	14 (10.1%)
Grade 1	4 (8.0%)	5 (7.2%)	9 (7.6%)	12 (8.7%)
Grade 2	0	2 (2.9%)	2 (1.7%)	2 (1.4%)
Night sweats	4 (8.0%)	3 (4.3%)	7 (5.9%)	10 (7.2%)
Grade 1	4 (8.0%)	1 (1.4%)	5 (4.2%)	8 (5.8%)
Grade 2	0	2 (2.9%)	2 (1.7%)	2 (1.4%)
Hyperhidrosis	0	4 (5.8%)	4 (3.4%)	4 (2.9%)
Grade 1	0	4 (5.8%)	4 (3.4%)	4 (2.9%)
Cold sweat	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Rashes, eruptions and exanthems NEC (cont)				
Rash papular	0	0	0	0
Grade 1	0	0	0	0
Apocrine and eccrine gland disorders	3 (21.4%)	1 (6.7%)	4 (13.8%)	5 (15.6%)
Grade 1	3 (21.4%)	1 (6.7%)	4 (13.8%)	5 (15.6%)
Grade 2	0	0	0	0
Night sweats	3 (21.4%)	1 (6.7%)	4 (13.8%)	5 (15.6%)
Grade 1	3 (21.4%)	1 (6.7%)	4 (13.8%)	5 (15.6%)
Grade 2	0	0	0	0
Hyperhidrosis	0	0	0	0
Grade 1	0	0	0	0
Cold sweat	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Apocrine and eccrine gland disorders (cont)				
Cold sweat (cont)				
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Pruritus NEC	1 (2.0%)	7 (10.1%)	8 (6.7%)	10 (7.2%)
Grade 1	0	6 (8.7%)	6 (5.0%)	8 (5.8%)
Grade 2	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Pruritus	1 (2.0%)	7 (10.1%)	8 (6.7%)	9 (6.5%)
Grade 1	0	6 (8.7%)	6 (5.0%)	7 (5.1%)
Grade 2	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Pruritus generalised	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)
Purpura and related conditions	2 (4.0%)	1 (1.4%)	3 (2.5%)	6 (4.3%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Apocrine and eccrine gland disorders (cont)				
Cold sweat (cont)				
Grade 1	0	0	0	0
Pruritus NEC	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Grade 1	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Pruritus	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Grade 1	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Pruritus generalised	0	0	0	0
Grade 1	0	0	0	0
Purpura and related conditions	1 (7.1%)	0	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Purpura and related conditions (cont)				
(cont)				
Grade 1	1 (2.0%)	1 (1.4%)	2 (1.7%)	5 (3.6%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Ecchymosis	1 (2.0%)	1 (1.4%)	2 (1.7%)	3 (2.2%)
Grade 1	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Petechiae	0	0	0	2 (1.4%)
Grade 1	0	0	0	2 (1.4%)
Purpura	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Dermal and epidermal conditions NEC	2 (4.0%)	0	2 (1.7%)	3 (2.2%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Purpura and related conditions (cont)				
(cont)				
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	0	0	0	0
Ecchymosis	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Petechiae	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Purpura	0	0	0	0
Grade 1	0	0	0	0
Dermal and epidermal conditions NEC	1 (7.1%)	0	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Dermal and epidermal conditions NEC (cont)				
(cont)				
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Dermatosis	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Papule	0	0	0	0
Grade 1	0	0	0	0
Skin disorder	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Skin fragility	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Dermal and epidermal conditions NEC (cont)				
(cont)				
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	0	0	0	0
Dermatosis	0	0	0	0
Grade 2	0	0	0	0
Papule	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Skin disorder	0	0	0	0
Grade 1	0	0	0	0
Skin fragility	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Dermal and epidermal conditions NEC (cont)				
Skin lesion	0	0	0	1 (0.7%)
Grade 2	0	0	0	1 (0.7%)
Dermatitis and eczema	2 (4.0%)	0	2 (1.7%)	4 (2.9%)
Grade 1	1 (2.0%)	0	1 (0.8%)	3 (2.2%)
Grade 3	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Dermatitis contact	0	0	0	2 (1.4%)
Grade 1	0	0	0	2 (1.4%)
Dermatitis	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Dermatitis allergic	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 3	1 (2.0%)	0	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Dermal and epidermal conditions NEC (cont)				
Skin lesion	0	0	0	0
Grade 2	0	0	0	0
Dermatitis and eczema	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Dermatitis contact	0	0	0	0
Grade 1	0	0	0	0
Dermatitis	0	0	0	0
Grade 1	0	0	0	0
Dermatitis allergic	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Erythemas	1 (2.0%)	1 (1.4%)	2 (1.7%)	3 (2.2%)
Grade 1	0	0	0	1 (0.7%)
Grade 2	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Erythema	1 (2.0%)	1 (1.4%)	2 (1.7%)	3 (2.2%)
Grade 1	0	0	0	1 (0.7%)
Grade 2	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Alopecias	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)
Alopecia	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)
Bullous conditions	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Erythemas	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Erythema	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Alopecias	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 1	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Alopecia	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 1	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Bullous conditions	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Bullous conditions (cont)				
(cont)				
Grade 2	0	0	0	0
Blister	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)
Grade 2	0	0	0	0
Blood blister	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)
Dermatitis ascribed to specific agent	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 3	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Drug eruption	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Bullous conditions (cont)				
(cont)				
Grade 2	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Blister	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 1	0	0	0	0
Grade 2	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Blood blister	0	0	0	0
Grade 1	0	0	0	0
Dermatitis ascribed to specific agent	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 3	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Drug eruption	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 3	0	1 (6.7%)	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Dermatitis ascribed to specific agent (cont)				
Toxic skin eruption	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 3	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Hyperkeratoses	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	0	0	1 (0.7%)
Hyperkeratosis	0	0	0	1 (0.7%)
Grade 2	0	0	0	1 (0.7%)
Lichenoid keratosis	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Dermatitis ascribed to specific agent (cont)				
Toxic skin eruption	0	0	0	0
Grade 3	0	0	0	0
Hyperkeratoses	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Hyperkeratosis	0	0	0	0
Grade 2	0	0	0	0
Lichenoid keratosis	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Nail and nail bed conditions (excl infections and infestations)	0	0	0	1 (0.7%)
Grade 1	0	0	0	0
Grade 2	0	0	0	1 (0.7%)
Ingrowing nail	0	0	0	1 (0.7%)
Grade 2	0	0	0	1 (0.7%)
Nail discolouration	0	0	0	0
Grade 1	0	0	0	0
Skin preneoplastic conditions NEC	2 (4.0%)	0	2 (1.7%)	2 (1.4%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Actinic keratosis	2 (4.0%)	0	2 (1.7%)	2 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Nail and nail bed conditions (excl infections and infestations)	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 1	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 2	0	0	0	0
Ingrowing nail	0	0	0	0
Grade 2	0	0	0	0
Nail discolouration	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 1	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Skin preneoplastic conditions NEC	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Actinic keratosis	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Skin preneoplastic conditions NEC (cont)				
Actinic keratosis (cont)				
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Exfoliative conditions	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Skin exfoliation	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Skin cysts and polyps	0	0	0	0
Grade 1	0	0	0	0
Dermal cyst	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Skin preneoplastic conditions NEC (cont)				
Actinic keratosis (cont)				
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Exfoliative conditions	0	0	0	0
Grade 1	0	0	0	0
Skin exfoliation	0	0	0	0
Grade 1	0	0	0	0
Skin cysts and polyps	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Dermal cyst	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Skin haemorrhages	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Skin haemorrhage	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Skin vasculitides	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Hypersensitivity vasculitis	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Telangiectasia and related conditions	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)
Telangiectasia	0	0	0	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Skin haemorrhages	0	0	0	0
Grade 2	0	0	0	0
Skin haemorrhage	0	0	0	0
Grade 2	0	0	0	0
Skin vasculitides	0	0	0	0
Grade 2	0	0	0	0
Hypersensitivity vasculitis	0	0	0	0
Grade 2	0	0	0	0
Telangiectasia and related conditions	0	0	0	0
Grade 1	0	0	0	0
Telangiectasia	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Telangiectasia and related conditions (cont)				
Telangiectasia (cont)				
Grade 1	0	0	0	1 (0.7%)
Musculoskeletal and connective tissue disorders	11 (22.0%)	24 (34.8%)	35 (29.4%)	46 (33.3%)
Grade 1	3 (6.0%)	9 (13.0%)	12 (10.1%)	19 (13.8%)
Grade 2	8 (16.0%)	13 (18.8%)	21 (17.6%)	24 (17.4%)
Grade 3	0	2 (2.9%)	2 (1.7%)	3 (2.2%)
Musculoskeletal and connective tissue pain and discomfort	8 (16.0%)	14 (20.3%)	22 (18.5%)	31 (22.5%)
Grade 1	2 (4.0%)	6 (8.7%)	8 (6.7%)	15 (10.9%)
Grade 2	6 (12.0%)	8 (11.6%)	14 (11.8%)	15 (10.9%)
Grade 3	0	0	0	1 (0.7%)
Pain in extremity	4 (8.0%)	4 (5.8%)	8 (6.7%)	15 (10.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Telangiectasia and related conditions (cont)				
Telangiectasia (cont)				
Grade 1	0	0	0	0
Musculoskeletal and connective tissue disorders	5 (35.7%)	6 (40.0%)	11 (37.9%)	15 (46.9%)
Grade 1	1 (7.1%)	2 (13.3%)	3 (10.3%)	5 (15.6%)
Grade 2	4 (28.6%)	3 (20.0%)	7 (24.1%)	9 (28.1%)
Grade 3	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Musculoskeletal and connective tissue pain and discomfort	4 (28.6%)	5 (33.3%)	9 (31.0%)	11 (34.4%)
Grade 1	2 (14.3%)	2 (13.3%)	4 (13.8%)	5 (15.6%)
Grade 2	2 (14.3%)	3 (20.0%)	5 (17.2%)	6 (18.8%)
Grade 3	0	0	0	0
Pain in extremity	3 (21.4%)	2 (13.3%)	5 (17.2%)	6 (18.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Musculoskeletal and connective tissue pain and discomfort (cont)				
Pain in extremity (cont)				
Grade 1	0	3 (4.3%)	3 (2.5%)	9 (6.5%)
Grade 2	4 (8.0%)	1 (1.4%)	5 (4.2%)	6 (4.3%)
Back pain	3 (6.0%)	8 (11.6%)	11 (9.2%)	15 (10.9%)
Grade 1	2 (4.0%)	3 (4.3%)	5 (4.2%)	8 (5.8%)
Grade 2	1 (2.0%)	5 (7.2%)	6 (5.0%)	6 (4.3%)
Grade 3	0	0	0	1 (0.7%)
Musculoskeletal pain	1 (2.0%)	2 (2.9%)	3 (2.5%)	5 (3.6%)
Grade 1	0	1 (1.4%)	1 (0.8%)	3 (2.2%)
Grade 2	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Musculoskeletal and connective tissue pain and discomfort (cont)				
Pain in extremity (cont)				
Grade 1	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Grade 2	2 (14.3%)	1 (6.7%)	3 (10.3%)	4 (12.5%)
Back pain	1 (7.1%)	3 (20.0%)	4 (13.8%)	5 (15.6%)
Grade 1	1 (7.1%)	1 (6.7%)	2 (6.9%)	3 (9.4%)
Grade 2	0	2 (13.3%)	2 (6.9%)	2 (6.3%)
Grade 3	0	0	0	0
Musculoskeletal pain	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Musculoskeletal and connective tissue pain and discomfort (cont)				
Flank pain	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)
Musculoskeletal chest pain	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)
Neck pain	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Bone related signs and symptoms	2 (4.0%)	4 (5.8%)	6 (5.0%)	10 (7.2%)
Grade 1	1 (2.0%)	2 (2.9%)	3 (2.5%)	6 (4.3%)
Grade 2	1 (2.0%)	2 (2.9%)	3 (2.5%)	4 (2.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Musculoskeletal and connective tissue pain and discomfort (cont)				
Flank pain	0	0	0	0
Grade 1	0	0	0	0
Musculoskeletal chest pain	0	0	0	0
Grade 1	0	0	0	0
Neck pain	0	0	0	0
Grade 2	0	0	0	0
Bone related signs and symptoms	2 (14.3%)	0	2 (6.9%)	2 (6.3%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Bone related signs and symptoms (cont)				
Bone pain	1 (2.0%)	3 (4.3%)	4 (3.4%)	6 (4.3%)
Grade 1	0	1 (1.4%)	1 (0.8%)	3 (2.2%)
Grade 2	1 (2.0%)	2 (2.9%)	3 (2.5%)	3 (2.2%)
Pain in jaw	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Grade 1	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Spinal pain	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	0	0	1 (0.7%)
Joint related signs and symptoms	2 (4.0%)	2 (2.9%)	4 (3.4%)	6 (4.3%)
Grade 1	0	0	0	1 (0.7%)
Grade 2	2 (4.0%)	2 (2.9%)	4 (3.4%)	5 (3.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Bone related signs and symptoms (cont)				
Bone pain	2 (14.3%)	0	2 (6.9%)	2 (6.3%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Pain in jaw	0	0	0	0
Grade 1	0	0	0	0
Spinal pain	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Joint related signs and symptoms	2 (14.3%)	2 (13.3%)	4 (13.8%)	4 (12.5%)
Grade 1	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Grade 2	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Joint related signs and symptoms (cont)				
Arthralgia	2 (4.0%)	2 (2.9%)	4 (3.4%)	6 (4.3%)
Grade 1	0	0	0	1 (0.7%)
Grade 2	2 (4.0%)	2 (2.9%)	4 (3.4%)	5 (3.6%)
Joint effusion	0	0	0	0
Grade 2	0	0	0	0
Joint swelling	0	0	0	0
Grade 2	0	0	0	0
Muscle related signs and symptoms NEC	0	3 (4.3%)	3 (2.5%)	3 (2.2%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Joint related signs and symptoms (cont)				
Arthralgia	2 (14.3%)	2 (13.3%)	4 (13.8%)	4 (12.5%)
Grade 1	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Grade 2	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Joint effusion	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 2	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Joint swelling	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Muscle related signs and symptoms NEC	0	0	0	2 (6.3%)
Grade 1	0	0	0	2 (6.3%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Muscle related signs and symptoms NEC (cont)				
Muscle spasms	0	2 (2.9%)	2 (1.7%)	2 (1.4%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Muscle haemorrhage	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Arthropathies NEC	2 (4.0%)	1 (1.4%)	3 (2.5%)	3 (2.2%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Arthritis	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Muscle related signs and symptoms NEC (cont)				
Muscle spasms	0	0	0	2 (6.3%)
Grade 1	0	0	0	2 (6.3%)
Grade 2	0	0	0	0
Muscle haemorrhage	0	0	0	0
Grade 3	0	0	0	0
Arthropathies NEC	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Arthritis	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Arthropathies NEC (cont)				
Arthritis (cont)				
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Arthritis reactive	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Muscle pains	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	0	0	1 (0.7%)
Myalgia	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	0	0	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Arthropathies NEC (cont)				
Arthritis (cont)				
Grade 3	0	0	0	0
Arthritis reactive	0	0	0	0
Grade 2	0	0	0	0
Muscle pains	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	0	0	0	0
Myalgia	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Muscle weakness conditions	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Muscular weakness	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Bone disorders NEC	0	2 (2.9%)	2 (1.7%)	2 (1.4%)
Grade 1	0	2 (2.9%)	2 (1.7%)	2 (1.4%)
Bone lesion	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Osteosclerosis	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Muscle weakness conditions	2 (14.3%)	0	2 (6.9%)	2 (6.3%)
Grade 2	2 (14.3%)	0	2 (6.9%)	2 (6.3%)
Muscular weakness	2 (14.3%)	0	2 (6.9%)	2 (6.3%)
Grade 2	2 (14.3%)	0	2 (6.9%)	2 (6.3%)
Bone disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Bone lesion	0	0	0	0
Grade 1	0	0	0	0
Osteosclerosis	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Musculoskeletal and connective tissue conditions NEC	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	0	0	0
Mobility decreased	0	0	0	0
Grade 2	0	0	0	0
Musculoskeletal stiffness	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Osteoarthropathies	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Musculoskeletal and connective tissue conditions NEC	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	0	0	0	0
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Mobility decreased	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Musculoskeletal stiffness	0	0	0	0
Grade 1	0	0	0	0
Osteoarthropathies	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 1	0	0	0	0
Grade 3	0	1 (6.7%)	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Osteoarthropathies (cont)				
Osteoarthritis	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 3	0	0	0	0
Soft tissue disorders NEC	0	0	0	2 (1.4%)
Grade 1	0	0	0	2 (1.4%)
Groin pain	0	0	0	2 (1.4%)
Grade 1	0	0	0	2 (1.4%)
Bursal disorders	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)
Bursal fluid accumulation	0	0	0	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Osteoarthropathies (cont)				
Osteoarthritis	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 1	0	0	0	0
Grade 3	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Soft tissue disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Groin pain	0	0	0	0
Grade 1	0	0	0	0
Bursal disorders	0	0	0	0
Grade 1	0	0	0	0
Bursal fluid accumulation	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Bursal disorders (cont)				
Bursal fluid accumulation (cont)				
Grade 1	0	0	0	1 (0.7%)
Cartilage disorders	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Costochondritis	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Crystal arthropathic disorders	0	0	0	0
Grade 2	0	0	0	0
Chondrocalcinosis pyrophosphate	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Bursal disorders (cont)				
Bursal fluid accumulation (cont)				
Grade 1	0	0	0	0
Cartilage disorders	0	0	0	0
Grade 2	0	0	0	0
Costochondritis	0	0	0	0
Grade 2	0	0	0	0
Crystal arthropathic disorders	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Chondrocalcinosis pyrophosphate	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Crystal arthropathic disorders (cont)				
Gouty arthritis	0	0	0	0
Grade 2	0	0	0	0
Intervertebral disc disorders NEC	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Intervertebral disc protrusion	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Joint related disorders NEC	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Rotator cuff syndrome	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Crystal arthropathic disorders (cont)				
Gouty arthritis	0	0	0	1 (3.1%)
Grade 2	0	0	0	1 (3.1%)
Intervertebral disc disorders NEC	0	0	0	0
Grade 2	0	0	0	0
Intervertebral disc protrusion	0	0	0	0
Grade 2	0	0	0	0
Joint related disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Rotator cuff syndrome	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Metabolic bone disorders	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Osteoporosis	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Musculoskeletal and connective tissue infections and inflammations NEC	0	0	0	0
Grade 1	0	0	0	0
Fasciitis	0	0	0	0
Grade 1	0	0	0	0
Tendon disorders	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Metabolic bone disorders	0	0	0	0
Grade 2	0	0	0	0
Osteoporosis	0	0	0	0
Grade 2	0	0	0	0
Musculoskeletal and connective tissue infections and inflammations NEC	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 1	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Fasciitis	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 1	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Tendon disorders	0	0	0	1 (3.1%)
Grade 2	0	0	0	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Tendon disorders (cont)				
Tendonitis	0	0	0	0
Grade 2	0	0	0	0
Investigations	13 (26.0%)	16 (23.2%)	29 (24.4%)	40 (29.0%)
Grade 1	2 (4.0%)	7 (10.1%)	9 (7.6%)	12 (8.7%)
Grade 2	7 (14.0%)	9 (13.0%)	16 (13.4%)	19 (13.8%)
Grade 3	3 (6.0%)	0	3 (2.5%)	7 (5.1%)
Grade 4	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Liver function analyses	4 (8.0%)	8 (11.6%)	12 (10.1%)	20 (14.5%)
Grade 1	0	2 (2.9%)	2 (1.7%)	5 (3.6%)
Grade 2	2 (4.0%)	6 (8.7%)	8 (6.7%)	9 (6.5%)
Grade 3	2 (4.0%)	0	2 (1.7%)	6 (4.3%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Tendon disorders (cont)				
Tendonitis	0	0	0	1 (3.1%)
Grade 2	0	0	0	1 (3.1%)
Investigations	4 (28.6%)	2 (13.3%)	6 (20.7%)	9 (28.1%)
Grade 1	2 (14.3%)	1 (6.7%)	3 (10.3%)	5 (15.6%)
Grade 2	1 (7.1%)	1 (6.7%)	2 (6.9%)	3 (9.4%)
Grade 3	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 4	0	0	0	0
Liver function analyses	1 (7.1%)	0	1 (3.4%)	3 (9.4%)
Grade 1	1 (7.1%)	0	1 (3.4%)	2 (6.3%)
Grade 2	0	0	0	1 (3.1%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Liver function analyses (cont)				
Alanine aminotransferase increased	2 (4.0%)	4 (5.8%)	6 (5.0%)	12 (8.7%)
Grade 1	1 (2.0%)	3 (4.3%)	4 (3.4%)	6 (4.3%)
Grade 2	1 (2.0%)	1 (1.4%)	2 (1.7%)	3 (2.2%)
Grade 3	0	0	0	3 (2.2%)
Gamma-glutamyltransferase increased	1 (2.0%)	4 (5.8%)	5 (4.2%)	9 (6.5%)
Grade 1	0	1 (1.4%)	1 (0.8%)	3 (2.2%)
Grade 2	1 (2.0%)	3 (4.3%)	4 (3.4%)	5 (3.6%)
Grade 3	0	0	0	1 (0.7%)
Aspartate aminotransferase increased	1 (2.0%)	3 (4.3%)	4 (3.4%)	7 (5.1%)
Grade 1	1 (2.0%)	3 (4.3%)	4 (3.4%)	6 (4.3%)
Grade 3	0	0	0	1 (0.7%)
Blood bilirubin increased	1 (2.0%)	2 (2.9%)	3 (2.5%)	3 (2.2%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Liver function analyses (cont)				
Alanine aminotransferase increased	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Gamma-glutamyltransferase increased	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Aspartate aminotransferase increased	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Blood bilirubin increased	0	0	0	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Liver function analyses (cont)				
Blood bilirubin increased (cont)				
Grade 2	0	2 (2.9%)	2 (1.7%)	2 (1.4%)
Grade 3	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Transaminases increased	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Liver function test abnormal	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 3	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Renal function analyses	7 (14.0%)	5 (7.2%)	12 (10.1%)	14 (10.1%)
Grade 1	3 (6.0%)	3 (4.3%)	6 (5.0%)	7 (5.1%)
Grade 2	4 (8.0%)	2 (2.9%)	6 (5.0%)	7 (5.1%)
Blood creatinine increased	5 (10.0%)	4 (5.8%)	9 (7.6%)	10 (7.2%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Liver function analyses (cont)				
Blood bilirubin increased (cont)				
Grade 2	0	0	0	1 (3.1%)
Grade 3	0	0	0	0
Transaminases increased	0	0	0	1 (3.1%)
Grade 1	0	0	0	1 (3.1%)
Liver function test abnormal	0	0	0	0
Grade 3	0	0	0	0
Renal function analyses	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Blood creatinine increased	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Renal function analyses (cont)				
Blood creatinine increased (cont)				
Grade 1	3 (6.0%)	2 (2.9%)	5 (4.2%)	6 (4.3%)
Grade 2	2 (4.0%)	2 (2.9%)	4 (3.4%)	4 (2.9%)
Creatinine renal clearance decreased	2 (4.0%)	1 (1.4%)	3 (2.5%)	4 (2.9%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	2 (4.0%)	0	2 (1.7%)	3 (2.2%)
Physical examination procedures and organ system status	2 (4.0%)	2 (2.9%)	4 (3.4%)	8 (5.8%)
Grade 1	0	2 (2.9%)	2 (1.7%)	6 (4.3%)
Grade 2	2 (4.0%)	0	2 (1.7%)	2 (1.4%)
Grade 3	0	0	0	0
Weight decreased	1 (2.0%)	1 (1.4%)	2 (1.7%)	4 (2.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Renal function analyses (cont)				
Blood creatinine increased (cont)				
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Creatinine renal clearance decreased	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Physical examination procedures and organ system status	2 (14.3%)	0	2 (6.9%)	3 (9.4%)
Grade 1	1 (7.1%)	0	1 (3.4%)	2 (6.3%)
Grade 2	0	0	0	0
Grade 3	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Weight decreased	2 (14.3%)	0	2 (6.9%)	2 (6.3%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Physical examination procedures and organ system status (cont)				
Weight decreased (cont)				
Grade 1	0	1 (1.4%)	1 (0.8%)	3 (2.2%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 3	0	0	0	0
Weight increased	1 (2.0%)	1 (1.4%)	2 (1.7%)	3 (2.2%)
Grade 1	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Lymph node palpable	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)
Coagulation and bleeding analyses	0	3 (4.3%)	3 (2.5%)	3 (2.2%)
Grade 1	0	3 (4.3%)	3 (2.5%)	3 (2.2%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Physical examination procedures and organ system status (cont)				
Weight decreased (cont)				
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	0	0	0	0
Grade 3	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Weight increased	0	0	0	1 (3.1%)
Grade 1	0	0	0	1 (3.1%)
Grade 2	0	0	0	0
Lymph node palpable	0	0	0	0
Grade 1	0	0	0	0
Coagulation and bleeding analyses	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Coagulation and bleeding analyses (cont)				
Activated partial thromboplastin time prolonged	0	2 (2.9%)	2 (1.7%)	2 (1.4%)
Grade 1	0	2 (2.9%)	2 (1.7%)	2 (1.4%)
International normalised ratio increased	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Prothrombin time prolonged	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
ECG investigations	1 (2.0%)	0	1 (0.8%)	3 (2.2%)
Grade 1	0	0	0	1 (0.7%)
Grade 4	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Electrocardiogram QT prolonged	1 (2.0%)	0	1 (0.8%)	2 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Coagulation and bleeding analyses (cont)				
Activated partial thromboplastin time prolonged	0	0	0	0
Grade 1	0	0	0	0
International normalised ratio increased	0	0	0	0
Grade 1	0	0	0	0
Prothrombin time prolonged	0	0	0	0
Grade 1	0	0	0	0
ECG investigations	0	0	0	0
Grade 1	0	0	0	0
Grade 4	0	0	0	0
Electrocardiogram QT prolonged	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
ECG investigations (cont)				
Electrocardiogram QT prolonged (cont)				
Grade 4	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Electrocardiogram ST segment depression	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)
Mineral and electrolyte analyses	1 (2.0%)	1 (1.4%)	2 (1.7%)	3 (2.2%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Blood bicarbonate decreased	0	0	0	1 (0.7%)
Grade 2	0	0	0	1 (0.7%)
Blood chloride increased	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
ECG investigations (cont)				
Electrocardiogram QT prolonged (cont)				
Grade 4	0	0	0	0
Electrocardiogram ST segment depression	0	0	0	0
Grade 1	0	0	0	0
Mineral and electrolyte analyses	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Blood bicarbonate decreased	0	0	0	0
Grade 2	0	0	0	0
Blood chloride increased	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Mineral and electrolyte analyses (cont)				
Serum ferritin increased	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Tissue enzyme analyses NEC	0	1 (1.4%)	1 (0.8%)	3 (2.2%)
Grade 1	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Grade 2	0	0	0	1 (0.7%)
Blood alkaline phosphatase increased	0	0	0	2 (1.4%)
Grade 1	0	0	0	1 (0.7%)
Grade 2	0	0	0	1 (0.7%)
Blood lactate dehydrogenase increased	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Protein analyses NEC	1 (2.0%)	0	1 (0.8%)	2 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Mineral and electrolyte analyses (cont)				
Serum ferritin increased	0	0	0	0
Grade 2	0	0	0	0
Tissue enzyme analyses NEC	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Blood alkaline phosphatase increased	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Blood lactate dehydrogenase increased	0	0	0	0
Grade 1	0	0	0	0
Protein analyses NEC	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Protein analyses NEC (cont)				
(cont)				
Grade 1	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Protein total increased	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Grade 1	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Vitamin analyses	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Blood folate decreased	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Vitamin B1 decreased	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Protein analyses NEC (cont)				
(cont)				
Grade 1	0	0	0	0
Protein total increased	0	0	0	0
Grade 1	0	0	0	0
Vitamin analyses	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Blood folate decreased	0	0	0	0
Grade 2	0	0	0	0
Vitamin B1 decreased	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Autoimmunity analyses	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Antiphospholipid antibodies positive	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Blood gas and acid base analyses	0	0	0	0
Grade 1	0	0	0	0
Blood lactic acid increased	0	0	0	0
Grade 1	0	0	0	0
Haematological analyses NEC	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Blast cell count increased	1 (2.0%)	0	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Autoimmunity analyses	0	0	0	0
Grade 2	0	0	0	0
Antiphospholipid antibodies positive	0	0	0	0
Grade 2	0	0	0	0
Blood gas and acid base analyses	0	0	0	1 (3.1%)
Grade 1	0	0	0	1 (3.1%)
Blood lactic acid increased	0	0	0	1 (3.1%)
Grade 1	0	0	0	1 (3.1%)
Haematological analyses NEC	0	0	0	0
Grade 1	0	0	0	0
Blast cell count increased	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Haematological analyses NEC (cont)				
Blast cell count increased (cont)				
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Reproductive organ and breast imaging procedures	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Computerised tomogram pelvis abnormal	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Respiratory tract and thoracic imaging procedures	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Chest X-ray abnormal	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Haematological analyses NEC (cont)				
Blast cell count increased (cont)				
Grade 1	0	0	0	0
Reproductive organ and breast imaging procedures	0	0	0	0
Grade 1	0	0	0	0
Computerised tomogram pelvis abnormal	0	0	0	0
Grade 1	0	0	0	0
Respiratory tract and thoracic imaging procedures	0	0	0	0
Grade 1	0	0	0	0
Chest X-ray abnormal	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Respiratory tract and thoracic imaging procedures (cont)				
Chest X-ray abnormal (cont)				
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Skeletal and cardiac muscle analyses	0	0	0	0
Grade 1	0	0	0	0
Blood creatine phosphokinase increased	0	0	0	0
Grade 1	0	0	0	0
Vascular tests NEC (incl blood pressure)	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 3	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Blood pressure increased	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 3	1 (2.0%)	0	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Respiratory tract and thoracic imaging procedures (cont)				
Chest X-ray abnormal (cont)				
Grade 1	0	0	0	0
Skeletal and cardiac muscle analyses	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 1	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Blood creatine phosphokinase increased	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 1	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Vascular tests NEC (incl blood pressure)	0	0	0	0
Grade 3	0	0	0	0
Blood pressure increased	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders	10 (20.0%)	15 (21.7%)	25 (21.0%)	34 (24.6%)
Grade 1	4 (8.0%)	2 (2.9%)	6 (5.0%)	10 (7.2%)
Grade 2	3 (6.0%)	6 (8.7%)	9 (7.6%)	10 (7.2%)
Grade 3	2 (4.0%)	6 (8.7%)	8 (6.7%)	10 (7.2%)
Grade 4	0	0	0	1 (0.7%)
Grade 5	1 (2.0%)	1 (1.4%)	2 (1.7%)	3 (2.2%)
Renal failure and impairment	6 (12.0%)	8 (11.6%)	14 (11.8%)	19 (13.8%)
Grade 1	2 (4.0%)	0	2 (1.7%)	4 (2.9%)
Grade 2	1 (2.0%)	4 (5.8%)	5 (4.2%)	5 (3.6%)
Grade 3	2 (4.0%)	3 (4.3%)	5 (4.2%)	6 (4.3%)
Grade 4	0	0	0	1 (0.7%)
Grade 5	1 (2.0%)	1 (1.4%)	2 (1.7%)	3 (2.2%)
Acute kidney injury	2 (4.0%)	3 (4.3%)	5 (4.2%)	7 (5.1%)
Grade 1	1 (2.0%)	0	1 (0.8%)	3 (2.2%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders	7 (50.0%)	1 (6.7%)	8 (27.6%)	10 (31.3%)
Grade 1	3 (21.4%)	1 (6.7%)	4 (13.8%)	6 (18.8%)
Grade 2	2 (14.3%)	0	2 (6.9%)	2 (6.3%)
Grade 3	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 4	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 5	0	0	0	0
Renal failure and impairment	4 (28.6%)	0	4 (13.8%)	4 (12.5%)
Grade 1	2 (14.3%)	0	2 (6.9%)	2 (6.3%)
Grade 2	2 (14.3%)	0	2 (6.9%)	2 (6.3%)
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Grade 5	0	0	0	0
Acute kidney injury	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal failure and impairment (cont)				
Acute kidney injury (cont)				
Grade 3	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Grade 5	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Chronic kidney disease	3 (6.0%)	2 (2.9%)	5 (4.2%)	6 (4.3%)
Grade 2	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Grade 3	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Grade 4	0	0	0	1 (0.7%)
Grade 5	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Renal failure	0	3 (4.3%)	3 (2.5%)	4 (2.9%)
Grade 2	0	2 (2.9%)	2 (1.7%)	2 (1.4%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 5	0	0	0	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal failure and impairment (cont)				
Acute kidney injury (cont)				
Grade 3	0	0	0	0
Grade 5	0	0	0	0
Chronic kidney disease	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Grade 5	0	0	0	0
Renal failure	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 3	0	0	0	0
Grade 5	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal failure and impairment (cont)				
Renal impairment	1 (2.0%)	0	1 (0.8%)	3 (2.2%)
Grade 1	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Grade 2	0	0	0	0
Grade 3	0	0	0	1 (0.7%)
Bladder and urethral symptoms	1 (2.0%)	2 (2.9%)	3 (2.5%)	6 (4.3%)
Grade 1	0	2 (2.9%)	2 (1.7%)	2 (1.4%)
Grade 2	1 (2.0%)	0	1 (0.8%)	3 (2.2%)
Grade 3	0	0	0	1 (0.7%)
Dysuria	1 (2.0%)	1 (1.4%)	2 (1.7%)	3 (2.2%)
Grade 1	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Pollakiuria	0	0	0	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal failure and impairment (cont)				
Renal impairment	2 (14.3%)	0	2 (6.9%)	2 (6.3%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 3	0	0	0	0
Bladder and urethral symptoms	0	0	0	2 (6.3%)
Grade 1	0	0	0	2 (6.3%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Dysuria	0	0	0	1 (3.1%)
Grade 1	0	0	0	1 (3.1%)
Grade 2	0	0	0	0
Pollakiuria	0	0	0	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Bladder and urethral symptoms (cont)				
Pollakiuria (cont)				
Grade 1	0	0	0	0
Grade 3	0	0	0	1 (0.7%)
Micturition disorder	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Urinary incontinence	0	0	0	1 (0.7%)
Grade 2	0	0	0	1 (0.7%)
Urinary retention	0	0	0	1 (0.7%)
Grade 2	0	0	0	1 (0.7%)
Urinary abnormalities	2 (4.0%)	2 (2.9%)	4 (3.4%)	5 (3.6%)
Grade 1	1 (2.0%)	0	1 (0.8%)	2 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Bladder and urethral symptoms (cont)				
Pollakiuria (cont)				
Grade 1	0	0	0	1 (3.1%)
Grade 3	0	0	0	0
Micturition disorder	0	0	0	0
Grade 1	0	0	0	0
Urinary incontinence	0	0	0	0
Grade 2	0	0	0	0
Urinary retention	0	0	0	0
Grade 2	0	0	0	0
Urinary abnormalities	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Urinary abnormalities (cont)				
(cont)				
Grade 2	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Haematuria	1 (2.0%)	2 (2.9%)	3 (2.5%)	4 (2.9%)
Grade 1	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Chromaturia	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)
Proteinuria	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Urinary abnormalities (cont)				
(cont)				
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Haematuria	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Chromaturia	0	0	0	0
Grade 1	0	0	0	0
Proteinuria	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Urinary tract signs and symptoms NEC	1 (2.0%)	2 (2.9%)	3 (2.5%)	5 (3.6%)
Grade 1	1 (2.0%)	0	1 (0.8%)	3 (2.2%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Nocturia	1 (2.0%)	0	1 (0.8%)	3 (2.2%)
Grade 1	1 (2.0%)	0	1 (0.8%)	3 (2.2%)
Renal colic	0	2 (2.9%)	2 (1.7%)	2 (1.4%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Renal lithiasis	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Grade 1	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Nephrolithiasis	0	1 (1.4%)	1 (0.8%)	2 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Urinary tract signs and symptoms NEC	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 1	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Nocturia	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 1	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Renal colic	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Renal lithiasis	0	0	0	0
Grade 1	0	0	0	0
Nephrolithiasis	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal lithiasis (cont)				
Nephrolithiasis (cont)				
Grade 1	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Nephropathies and tubular disorders NEC	0	0	0	0
Grade 4	0	0	0	0
Nephropathy	0	0	0	0
Grade 4	0	0	0	0
Renal disorders NEC	0	0	0	0
Grade 3	0	0	0	0
Renal disorder	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal lithiasis (cont)				
Nephrolithiasis (cont)				
Grade 1	0	0	0	0
Nephropathies and tubular disorders NEC	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 4	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Nephropathy	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 4	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Renal disorders NEC	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 3	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Renal disorder	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 3	1 (7.1%)	0	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal hypertension and related conditions	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Hypertensive nephropathy	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Renal neoplasms	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Renal cyst	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Renal vascular and ischaemic conditions	0	0	0	0
Grade 2	0	0	0	0
Renal tubular necrosis	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal hypertension and related conditions	0	0	0	0
Grade 3	0	0	0	0
Hypertensive nephropathy	0	0	0	0
Grade 3	0	0	0	0
Renal neoplasms	0	0	0	0
Grade 1	0	0	0	0
Renal cyst	0	0	0	0
Grade 1	0	0	0	0
Renal vascular and ischaemic conditions	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Renal tubular necrosis	1 (7.1%)	0	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal vascular and ischaemic conditions (cont)				
Renal tubular necrosis (cont)				
Grade 2	0	0	0	0
Vascular disorders	10 (20.0%)	13 (18.8%)	23 (19.3%)	34 (24.6%)
Grade 1	3 (6.0%)	4 (5.8%)	7 (5.9%)	12 (8.7%)
Grade 2	4 (8.0%)	5 (7.2%)	9 (7.6%)	12 (8.7%)
Grade 3	3 (6.0%)	4 (5.8%)	7 (5.9%)	10 (7.2%)
Vascular hypotensive disorders	2 (4.0%)	3 (4.3%)	5 (4.2%)	15 (10.9%)
Grade 1	0	0	0	5 (3.6%)
Grade 2	0	3 (4.3%)	3 (2.5%)	6 (4.3%)
Grade 3	2 (4.0%)	0	2 (1.7%)	4 (2.9%)
Hypotension	2 (4.0%)	2 (2.9%)	4 (3.4%)	14 (10.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal vascular and ischaemic conditions (cont)				
Renal tubular necrosis (cont)				
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Vascular disorders	4 (28.6%)	3 (20.0%)	7 (24.1%)	9 (28.1%)
Grade 1	2 (14.3%)	1 (6.7%)	3 (10.3%)	5 (15.6%)
Grade 2	1 (7.1%)	2 (13.3%)	3 (10.3%)	3 (9.4%)
Grade 3	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Vascular hypotensive disorders	1 (7.1%)	1 (6.7%)	2 (6.9%)	3 (9.4%)
Grade 1	0	1 (6.7%)	1 (3.4%)	2 (6.3%)
Grade 2	0	0	0	0
Grade 3	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Hypotension	1 (7.1%)	1 (6.7%)	2 (6.9%)	3 (9.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Vascular hypotensive disorders (cont)				
Hypotension (cont)				
Grade 1	0	0	0	5 (3.6%)
Grade 2	0	2 (2.9%)	2 (1.7%)	5 (3.6%)
Grade 3	2 (4.0%)	0	2 (1.7%)	4 (2.9%)
Orthostatic hypotension	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Vascular hypertensive disorders NEC	5 (10.0%)	6 (8.7%)	11 (9.2%)	12 (8.7%)
Grade 1	0	2 (2.9%)	2 (1.7%)	2 (1.4%)
Grade 2	4 (8.0%)	1 (1.4%)	5 (4.2%)	5 (3.6%)
Grade 3	1 (2.0%)	3 (4.3%)	4 (3.4%)	5 (3.6%)
Hypertension	5 (10.0%)	6 (8.7%)	11 (9.2%)	12 (8.7%)
Grade 1	0	2 (2.9%)	2 (1.7%)	2 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Vascular hypotensive disorders (cont)				
Hypotension (cont)				
Grade 1	0	1 (6.7%)	1 (3.4%)	2 (6.3%)
Grade 2	0	0	0	0
Grade 3	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Orthostatic hypotension	0	0	0	0
Grade 2	0	0	0	0
Vascular hypertensive disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Hypertension	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Vascular hypertensive disorders NEC (cont)				
Hypertension (cont)				
Grade 2	4 (8.0%)	1 (1.4%)	5 (4.2%)	5 (3.6%)
Grade 3	1 (2.0%)	3 (4.3%)	4 (3.4%)	5 (3.6%)
Peripheral vascular disorders NEC	1 (2.0%)	1 (1.4%)	2 (1.7%)	4 (2.9%)
Grade 1	1 (2.0%)	1 (1.4%)	2 (1.7%)	3 (2.2%)
Grade 2	0	0	0	1 (0.7%)
Flushing	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	0	0	1 (0.7%)
Hot flush	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Grade 1	1 (2.0%)	0	1 (0.8%)	2 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Vascular hypertensive disorders NEC (cont)				
Hypertension (cont)				
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Peripheral vascular disorders NEC	0	1 (6.7%)	1 (3.4%)	4 (12.5%)
Grade 1	0	1 (6.7%)	1 (3.4%)	4 (12.5%)
Grade 2	0	0	0	0
Flushing	0	0	0	3 (9.4%)
Grade 1	0	0	0	3 (9.4%)
Grade 2	0	0	0	0
Hot flush	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 1	0	1 (6.7%)	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Haemorrhages NEC	1 (2.0%)	1 (1.4%)	2 (1.7%)	3 (2.2%)
Grade 1	1 (2.0%)	1 (1.4%)	2 (1.7%)	3 (2.2%)
Grade 2	0	0	0	0
Haematoma	1 (2.0%)	1 (1.4%)	2 (1.7%)	3 (2.2%)
Grade 1	1 (2.0%)	1 (1.4%)	2 (1.7%)	3 (2.2%)
Grade 2	0	0	0	0
Aortic necrosis and vascular insufficiency	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Aortic stenosis	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	0	0	0
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Haemorrhages NEC	2 (14.3%)	1 (6.7%)	3 (10.3%)	3 (9.4%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Haematoma	2 (14.3%)	1 (6.7%)	3 (10.3%)	3 (9.4%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Aortic necrosis and vascular insufficiency	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	0	0	0	0
Aortic stenosis	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Aortic necrosis and vascular insufficiency (cont)				
Aortic arteriosclerosis	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Non-site specific necrosis and vascular insufficiency NEC	0	2 (2.9%)	2 (1.7%)	2 (1.4%)
Grade 1	0	2 (2.9%)	2 (1.7%)	2 (1.4%)
Arteriosclerosis	0	2 (2.9%)	2 (1.7%)	2 (1.4%)
Grade 1	0	2 (2.9%)	2 (1.7%)	2 (1.4%)
Peripheral embolism and thrombosis	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Aortic necrosis and vascular insufficiency (cont)				
Aortic arteriosclerosis	0	0	0	0
Grade 1	0	0	0	0
Non-site specific necrosis and vascular insufficiency NEC	0	0	0	0
Grade 1	0	0	0	0
Arteriosclerosis	0	0	0	0
Grade 1	0	0	0	0
Peripheral embolism and thrombosis	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Peripheral embolism and thrombosis (cont)				
Deep vein thrombosis	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Thrombophlebitis superficial	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Peripheral vasoconstriction, necrosis and vascular insufficiency	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)
Grade 2	0	0	0	0
Peripheral arterial occlusive disease	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Peripheral embolism and thrombosis (cont)				
Deep vein thrombosis	0	0	0	0
Grade 3	0	0	0	0
Thrombophlebitis superficial	0	0	0	0
Grade 2	0	0	0	0
Peripheral vasoconstriction, necrosis and vascular insufficiency	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 1	0	0	0	0
Grade 2	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Peripheral arterial occlusive disease	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 1	0	0	0	0
Grade 2	0	1 (6.7%)	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Non-site specific vascular disorders NEC	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)
Poor venous access	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)
Phlebitis NEC	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Phlebitis	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Non-site specific vascular disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Poor venous access	0	0	0	0
Grade 1	0	0	0	0
Phlebitis NEC	0	0	0	0
Grade 1	0	0	0	0
Phlebitis	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders	9 (18.0%)	10 (14.5%)	19 (16.0%)	29 (21.0%)
Grade 1	3 (6.0%)	3 (4.3%)	6 (5.0%)	8 (5.8%)
Grade 2	3 (6.0%)	1 (1.4%)	4 (3.4%)	6 (4.3%)
Grade 3	2 (4.0%)	5 (7.2%)	7 (5.9%)	12 (8.7%)
Grade 4	0	0	0	1 (0.7%)
Grade 5	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Supraventricular arrhythmias	6 (12.0%)	5 (7.2%)	11 (9.2%)	16 (11.6%)
Grade 1	3 (6.0%)	0	3 (2.5%)	4 (2.9%)
Grade 2	2 (4.0%)	1 (1.4%)	3 (2.5%)	5 (3.6%)
Grade 3	1 (2.0%)	4 (5.8%)	5 (4.2%)	7 (5.1%)
Atrial fibrillation	5 (10.0%)	5 (7.2%)	10 (8.4%)	14 (10.1%)
Grade 1	2 (4.0%)	0	2 (1.7%)	3 (2.2%)
Grade 2	2 (4.0%)	1 (1.4%)	3 (2.5%)	4 (2.9%)
Grade 3	1 (2.0%)	4 (5.8%)	5 (4.2%)	7 (5.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders	3 (21.4%)	3 (20.0%)	6 (20.7%)	6 (18.8%)
Grade 1	1 (7.1%)	0	1 (3.4%)	0
Grade 2	0	0	0	1 (3.1%)
Grade 3	2 (14.3%)	3 (20.0%)	5 (17.2%)	5 (15.6%)
Grade 4	0	0	0	0
Grade 5	0	0	0	0
Supraventricular arrhythmias	2 (14.3%)	0	2 (6.9%)	3 (9.4%)
Grade 1	0	0	0	0
Grade 2	0	0	0	1 (3.1%)
Grade 3	2 (14.3%)	0	2 (6.9%)	2 (6.3%)
Atrial fibrillation	1 (7.1%)	0	1 (3.4%)	2 (6.3%)
Grade 1	0	0	0	0
Grade 2	0	0	0	1 (3.1%)
Grade 3	1 (7.1%)	0	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Supraventricular arrhythmias (cont)				
Atrial flutter	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Sinus bradycardia	0	0	0	0
Grade 3	0	0	0	0
Supraventricular extrasystoles	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Supraventricular tachycardia	0	0	0	1 (0.7%)
Grade 2	0	0	0	1 (0.7%)
Heart failures NEC	2 (4.0%)	2 (2.9%)	4 (3.4%)	7 (5.1%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Supraventricular arrhythmias (cont)				
Atrial flutter	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Sinus bradycardia	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 3	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Supraventricular extrasystoles	0	0	0	0
Grade 1	0	0	0	0
Supraventricular tachycardia	0	0	0	0
Grade 2	0	0	0	0
Heart failures NEC	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Grade 1	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Heart failures NEC (cont)				
(cont)				
Grade 3	1 (2.0%)	0	1 (0.8%)	4 (2.9%)
Grade 5	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Cardiac failure	2 (4.0%)	2 (2.9%)	4 (3.4%)	6 (4.3%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 3	1 (2.0%)	0	1 (0.8%)	3 (2.2%)
Grade 5	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Cardiac failure congestive	0	0	0	1 (0.7%)
Grade 3	0	0	0	1 (0.7%)
Ischaemic coronary artery disorders	0	2 (2.9%)	2 (1.7%)	3 (2.2%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Heart failures NEC (cont)				
(cont)				
Grade 3	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Grade 5	0	0	0	0
Cardiac failure	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 5	0	0	0	0
Cardiac failure congestive	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 3	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Ischaemic coronary artery disorders	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Ischaemic coronary artery disorders (cont) (cont)				
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 4	0	0	0	1 (0.7%)
Angina pectoris	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	0	0	0	1 (0.7%)
Acute myocardial infarction	0	0	0	1 (0.7%)
Grade 4	0	0	0	1 (0.7%)
Myocardial infarction	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Cardiac signs and symptoms NEC	0	1 (1.4%)	1 (0.8%)	2 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Ischaemic coronary artery disorders (cont) (cont)				
Grade 3	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 4	0	0	0	0
Angina pectoris	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 1	0	0	0	0
Grade 3	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Acute myocardial infarction	0	0	0	0
Grade 4	0	0	0	0
Myocardial infarction	0	0	0	0
Grade 3	0	0	0	0
Cardiac signs and symptoms NEC	1 (7.1%)	0	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Cardiac signs and symptoms NEC (cont) (cont)				
Grade 1	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Palpitations	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Grade 1	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Rate and rhythm disorders NEC	0	0	0	2 (1.4%)
Grade 1	0	0	0	1 (0.7%)
Grade 2	0	0	0	1 (0.7%)
Grade 3	0	0	0	0
Tachycardia	0	0	0	1 (0.7%)
Grade 2	0	0	0	1 (0.7%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Cardiac signs and symptoms NEC (cont) (cont)				
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Palpitations	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Rate and rhythm disorders NEC	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Tachycardia	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	0	0	0	0
Grade 3	1 (7.1%)	0	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Rate and rhythm disorders NEC (cont)				
Bradycardia	0	0	0	0
Grade 1	0	0	0	0
Extrasystoles	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)
Cardiac conduction disorders	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 3	0	0	0	1 (0.7%)
Atrioventricular block complete	0	0	0	1 (0.7%)
Grade 3	0	0	0	1 (0.7%)
Atrioventricular block first degree	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Rate and rhythm disorders NEC (cont)				
Bradycardia	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Extrasystoles	0	0	0	0
Grade 1	0	0	0	0
Cardiac conduction disorders	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Atrioventricular block complete	0	0	0	0
Grade 3	0	0	0	0
Atrioventricular block first degree	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Mitral valvular disorders	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 3	0	0	0	0
Mitral valve incompetence	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 3	0	0	0	0
Cardiac valve disorders NEC	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Cardiac valve disease	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Cardiomyopathies	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Mitral valvular disorders	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 2	0	0	0	0
Grade 3	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Mitral valve incompetence	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 2	0	0	0	0
Grade 3	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Cardiac valve disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Cardiac valve disease	0	0	0	0
Grade 1	0	0	0	0
Cardiomyopathies	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 3	1 (7.1%)	0	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Cardiomyopathies (cont)				
Cardiomyopathy	0	0	0	0
Grade 3	0	0	0	0
Myocardial disorders NEC	0	0	0	1 (0.7%)
Grade 2	0	0	0	1 (0.7%)
Cardiomegaly	0	0	0	1 (0.7%)
Grade 2	0	0	0	1 (0.7%)
Pericardial disorders NEC	0	0	0	1 (0.7%)
Grade 3	0	0	0	1 (0.7%)
Pericardial effusion	0	0	0	1 (0.7%)
Grade 3	0	0	0	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Cardiomyopathies (cont)				
Cardiomyopathy	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 3	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Myocardial disorders NEC	0	0	0	0
Grade 2	0	0	0	0
Cardiomegaly	0	0	0	0
Grade 2	0	0	0	0
Pericardial disorders NEC	0	0	0	0
Grade 3	0	0	0	0
Pericardial effusion	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Ventricular arrhythmias and cardiac arrest	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 5	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Cardiac arrest	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 5	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Injury, poisoning and procedural complications	8 (16.0%)	9 (13.0%)	17 (14.3%)	25 (18.1%)
Grade 1	5 (10.0%)	3 (4.3%)	8 (6.7%)	12 (8.7%)
Grade 2	2 (4.0%)	5 (7.2%)	7 (5.9%)	10 (7.2%)
Grade 3	1 (2.0%)	1 (1.4%)	2 (1.7%)	3 (2.2%)
Grade 5	0	0	0	0
Skin injuries NEC	2 (4.0%)	4 (5.8%)	6 (5.0%)	12 (8.7%)
Grade 1	2 (4.0%)	3 (4.3%)	5 (4.2%)	10 (7.2%)
Grade 2	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Ventricular arrhythmias and cardiac arrest	0	0	0	0
Grade 5	0	0	0	0
Cardiac arrest	0	0	0	0
Grade 5	0	0	0	0
Injury, poisoning and procedural complications	5 (35.7%)	3 (20.0%)	8 (27.6%)	9 (28.1%)
Grade 1	4 (28.6%)	0	4 (13.8%)	5 (15.6%)
Grade 2	0	0	0	0
Grade 3	1 (7.1%)	2 (13.3%)	3 (10.3%)	3 (9.4%)
Grade 5	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Skin injuries NEC	3 (21.4%)	0	3 (10.3%)	5 (15.6%)
Grade 1	2 (14.3%)	0	2 (6.9%)	4 (12.5%)
Grade 2	0	0	0	0
Grade 3	1 (7.1%)	0	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Skin injuries NEC (cont)				
Contusion	2 (4.0%)	2 (2.9%)	4 (3.4%)	10 (7.2%)
Grade 1	2 (4.0%)	2 (2.9%)	4 (3.4%)	9 (6.5%)
Grade 2	0	0	0	1 (0.7%)
Skin abrasion	0	0	0	0
Grade 1	0	0	0	0
Skin injury	0	0	0	0
Grade 3	0	0	0	0
Skin laceration	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Subcutaneous haematoma	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Skin injuries NEC (cont)				
Contusion	2 (14.3%)	0	2 (6.9%)	3 (9.4%)
Grade 1	2 (14.3%)	0	2 (6.9%)	3 (9.4%)
Grade 2	0	0	0	0
Skin abrasion	0	0	0	1 (3.1%)
Grade 1	0	0	0	1 (3.1%)
Skin injury	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 3	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Skin laceration	0	0	0	0
Grade 2	0	0	0	0
Subcutaneous haematoma	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Skin injuries NEC (cont)				
Subcutaneous haematoma (cont)				
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Non-site specific injuries NEC	3 (6.0%)	3 (4.3%)	6 (5.0%)	10 (7.2%)
Grade 1	3 (6.0%)	1 (1.4%)	4 (3.4%)	8 (5.8%)
Grade 2	0	2 (2.9%)	2 (1.7%)	2 (1.4%)
Grade 5	0	0	0	0
Fall	2 (4.0%)	3 (4.3%)	5 (4.2%)	9 (6.5%)
Grade 1	2 (4.0%)	1 (1.4%)	3 (2.5%)	7 (5.1%)
Grade 2	0	2 (2.9%)	2 (1.7%)	2 (1.4%)
Grade 5	0	0	0	0
Wound	1 (2.0%)	0	1 (0.8%)	2 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Skin injuries NEC (cont)				
Subcutaneous haematoma (cont)				
Grade 1	0	0	0	0
Non-site specific injuries NEC	1 (7.1%)	3 (20.0%)	4 (13.8%)	4 (12.5%)
Grade 1	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 2	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Grade 5	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Fall	1 (7.1%)	3 (20.0%)	4 (13.8%)	4 (12.5%)
Grade 1	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 2	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Grade 5	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Wound	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Non-site specific injuries NEC (cont)				
Wound (cont)				
Grade 1	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Site specific injuries NEC	2 (4.0%)	2 (2.9%)	4 (3.4%)	7 (5.1%)
Grade 1	1 (2.0%)	1 (1.4%)	2 (1.7%)	4 (2.9%)
Grade 2	1 (2.0%)	1 (1.4%)	2 (1.7%)	3 (2.2%)
Limb injury	2 (4.0%)	1 (1.4%)	3 (2.5%)	5 (3.6%)
Grade 1	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Grade 2	1 (2.0%)	1 (1.4%)	2 (1.7%)	3 (2.2%)
Head injury	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Non-site specific injuries NEC (cont)				
Wound (cont)				
Grade 1	0	0	0	0
Site specific injuries NEC	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Limb injury	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Head injury	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Site specific injuries NEC (cont)				
Limb crushing injury	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)
Non-site specific procedural complications	0	1 (1.4%)	1 (0.8%)	4 (2.9%)
Grade 1	0	0	0	1 (0.7%)
Grade 2	0	0	0	1 (0.7%)
Grade 3	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Post procedural haemorrhage	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Procedural pain	0	0	0	1 (0.7%)
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Site specific injuries NEC (cont)				
Limb crushing injury	0	0	0	0
Grade 1	0	0	0	0
Non-site specific procedural complications	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	0	0	0	0
Grade 3	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Post procedural haemorrhage	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 3	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Procedural pain	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 2	0	1 (6.7%)	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Non-site specific procedural complications (cont)				
Procedural pain (cont)				
Grade 3	0	0	0	1 (0.7%)
Post procedural complication	0	0	0	1 (0.7%)
Grade 2	0	0	0	1 (0.7%)
Post procedural contusion	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)
Post procedural inflammation	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Spinal fractures and dislocations	2 (4.0%)	1 (1.4%)	3 (2.5%)	3 (2.2%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Non-site specific procedural complications (cont)				
Procedural pain (cont)				
Grade 3	0	0	0	0
Post procedural complication	0	0	0	0
Grade 2	0	0	0	0
Post procedural contusion	0	0	0	0
Grade 1	0	0	0	0
Post procedural inflammation	0	0	0	0
Grade 3	0	0	0	0
Spinal fractures and dislocations	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Spinal fractures and dislocations (cont) (cont)				
Grade 2	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Grade 3	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Spinal compression fracture	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Spinal fracture	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Gastrointestinal and hepatobiliary procedural complications	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Spinal fractures and dislocations (cont) (cont)				
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Spinal compression fracture	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Spinal fracture	0	0	0	0
Grade 2	0	0	0	0
Gastrointestinal and hepatobiliary procedural complications	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Gastrointestinal and hepatobiliary procedural complications (cont) (cont)				
Grade 2	0	0	0	0
Dental restoration failure	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Procedural nausea	0	0	0	0
Grade 2	0	0	0	0
Cerebral injuries NEC	0	0	0	0
Grade 1	0	0	0	0
Subdural haemorrhage	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Gastrointestinal and hepatobiliary procedural complications (cont) (cont)				
Grade 2	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Dental restoration failure	0	0	0	0
Grade 1	0	0	0	0
Procedural nausea	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 2	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Cerebral injuries NEC	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Subdural haemorrhage	1 (7.1%)	0	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Cerebral injuries NEC (cont)				
Subdural haemorrhage (cont)				
Grade 1	0	0	0	0
Chest and respiratory tract injuries NEC	0	0	0	0
Grade 3	0	0	0	0
Traumatic haemothorax	0	0	0	0
Grade 3	0	0	0	0
Limb fractures and dislocations	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Patella fracture	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Cerebral injuries NEC (cont)				
Subdural haemorrhage (cont)				
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Chest and respiratory tract injuries NEC	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 3	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Traumatic haemothorax	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 3	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Limb fractures and dislocations	0	0	0	0
Grade 2	0	0	0	0
Patella fracture	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Muscle, tendon and ligament injuries	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Muscle strain	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Skull fractures, facial bone fractures and dislocations	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Facial bones fracture	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Transfusion related complications	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Muscle, tendon and ligament injuries	0	0	0	0
Grade 2	0	0	0	0
Muscle strain	0	0	0	0
Grade 2	0	0	0	0
Skull fractures, facial bone fractures and dislocations	0	0	0	0
Grade 1	0	0	0	0
Facial bones fracture	0	0	0	0
Grade 1	0	0	0	0
Transfusion related complications	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Transfusion related complications (cont)				
Febrile nonhaemolytic transfusion reaction	0	0	0	0
Grade 1	0	0	0	0
Eye disorders	9 (18.0%)	6 (8.7%)	15 (12.6%)	21 (15.2%)
Grade 1	8 (16.0%)	5 (7.2%)	13 (10.9%)	18 (13.0%)
Grade 2	0	0	0	1 (0.7%)
Grade 3	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Grade 4	0	0	0	0
Cataract conditions	4 (8.0%)	2 (2.9%)	6 (5.0%)	8 (5.8%)
Grade 1	3 (6.0%)	1 (1.4%)	4 (3.4%)	5 (3.6%)
Grade 2	0	0	0	1 (0.7%)
Grade 3	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Transfusion related complications (cont)				
Febrile nonhaemolytic transfusion reaction	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Eye disorders	5 (35.7%)	3 (20.0%)	8 (27.6%)	10 (31.3%)
Grade 1	2 (14.3%)	2 (13.3%)	4 (13.8%)	6 (18.8%)
Grade 2	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 3	2 (14.3%)	0	2 (6.9%)	2 (6.3%)
Grade 4	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Cataract conditions	2 (14.3%)	1 (6.7%)	3 (10.3%)	3 (9.4%)
Grade 1	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Grade 2	0	0	0	0
Grade 3	1 (7.1%)	0	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Cataract conditions (cont)				
Cataract cortical	1 (2.0%)	1 (1.4%)	2 (1.7%)	3 (2.2%)
Grade 1	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Grade 2	0	0	0	1 (0.7%)
Grade 3	0	0	0	0
Cataract nuclear	3 (6.0%)	0	3 (2.5%)	3 (2.2%)
Grade 1	2 (4.0%)	0	2 (1.7%)	2 (1.4%)
Grade 2	0	0	0	0
Grade 3	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Cataract	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Grade 1	0	0	0	1 (0.7%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Cataract subcapsular	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Cataract conditions (cont)				
Cataract cortical	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Grade 1	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 2	0	0	0	0
Grade 3	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Cataract nuclear	2 (14.3%)	0	2 (6.9%)	2 (6.3%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 3	0	0	0	0
Cataract	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Cataract subcapsular	1 (7.1%)	0	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Cataract conditions (cont)				
Cataract subcapsular (cont)				
Grade 1	0	0	0	0
Visual disorders NEC	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Grade 1	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Grade 3	0	0	0	0
Vision blurred	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)
Grade 3	0	0	0	0
Diplopia	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Cataract conditions (cont)				
Cataract subcapsular (cont)				
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Visual disorders NEC	1 (7.1%)	1 (6.7%)	2 (6.9%)	4 (12.5%)
Grade 1	0	1 (6.7%)	1 (3.4%)	3 (9.4%)
Grade 3	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Vision blurred	1 (7.1%)	1 (6.7%)	2 (6.9%)	4 (12.5%)
Grade 1	0	1 (6.7%)	1 (3.4%)	3 (9.4%)
Grade 3	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Diplopia	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Conjunctival and corneal bleeding and vascular disorders	2 (4.0%)	1 (1.4%)	3 (2.5%)	3 (2.2%)
Grade 1	2 (4.0%)	1 (1.4%)	3 (2.5%)	3 (2.2%)
Grade 2	0	0	0	0
Conjunctival haemorrhage	2 (4.0%)	1 (1.4%)	3 (2.5%)	3 (2.2%)
Grade 1	2 (4.0%)	1 (1.4%)	3 (2.5%)	3 (2.2%)
Grade 2	0	0	0	0
Lacrimation disorders	0	1 (1.4%)	1 (0.8%)	3 (2.2%)
Grade 1	0	1 (1.4%)	1 (0.8%)	3 (2.2%)
Dry eye	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Lacrimation increased	0	0	0	2 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Conjunctival and corneal bleeding and vascular disorders	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	0	0	0	0
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Conjunctival haemorrhage	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	0	0	0	0
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Lacrimation disorders	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Dry eye	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Lacrimation increased	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Lacrimation disorders (cont)				
Lacrimation increased (cont)				
Grade 1	0	0	0	2 (1.4%)
Retinal bleeding and vascular disorders (excl retinopathy)	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Grade 1	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Retinal haemorrhage	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Grade 1	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Choroid and vitreous structural change, deposit and degeneration	0	0	0	0
Grade 1	0	0	0	0
Hyalosis asteroid	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Lacrimation disorders (cont)				
Lacrimation increased (cont)				
Grade 1	0	0	0	0
Retinal bleeding and vascular disorders (excl retinopathy)	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Retinal haemorrhage	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Choroid and vitreous structural change, deposit and degeneration	1 (7.1%)	0	1 (3.4%)	2 (6.3%)
Grade 1	1 (7.1%)	0	1 (3.4%)	2 (6.3%)
Hyalosis asteroid	0	0	0	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Choroid and vitreous structural change, deposit and degeneration (cont)				
Hyalosis asteroid (cont)				
Grade 1	0	0	0	0
Vitreous floaters	0	0	0	0
Grade 1	0	0	0	0
Corneal infections, oedemas and inflammations	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Keratitis	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Choroid and vitreous structural change, deposit and degeneration (cont)				
Hyalosis asteroid (cont)				
Grade 1	0	0	0	1 (3.1%)
Vitreous floaters	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Corneal infections, oedemas and inflammations	0	1 (6.7%)	1 (3.4%)	2 (6.3%)
Grade 1	0	0	0	1 (3.1%)
Grade 2	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Keratitis	0	1 (6.7%)	1 (3.4%)	2 (6.3%)
Grade 1	0	0	0	1 (3.1%)
Grade 2	0	1 (6.7%)	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Lid, lash and lacrimal infections, irritations and inflammations	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Erythema of eyelid	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Eyelid oedema	0	0	0	0
Grade 1	0	0	0	0
Ocular bleeding and vascular disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Grade 4	0	0	0	0
Eye haemorrhage	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Lid, lash and lacrimal infections, irritations and inflammations	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 1	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Erythema of eyelid	0	0	0	0
Grade 1	0	0	0	0
Eyelid oedema	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 1	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Ocular bleeding and vascular disorders NEC	2 (14.3%)	0	2 (6.9%)	2 (6.3%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 4	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Eye haemorrhage	2 (14.3%)	0	2 (6.9%)	2 (6.3%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Ocular bleeding and vascular disorders NEC (cont)				
Eye haemorrhage (cont)				
Grade 4	0	0	0	0
Ocular disorders NEC	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)
Grade 3	0	0	0	0
Eye pain	0	0	0	0
Grade 3	0	0	0	0
Periorbital oedema	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Ocular bleeding and vascular disorders NEC (cont)				
Eye haemorrhage (cont)				
Grade 4	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Ocular disorders NEC	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	0	0	0	0
Grade 3	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Eye pain	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 3	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Periorbital oedema	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Retinal structural change, deposit and degeneration	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)
Grade 3	0	0	0	0
Macular degeneration	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)
Retinal detachment	0	0	0	0
Grade 3	0	0	0	0
Visual impairment and blindness (excl colour blindness)	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Grade 1	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Visual acuity reduced	0	0	0	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Retinal structural change, deposit and degeneration	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	0	0	0	0
Grade 3	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Macular degeneration	0	0	0	0
Grade 1	0	0	0	0
Retinal detachment	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 3	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Visual impairment and blindness (excl colour blindness)	0	0	0	0
Grade 1	0	0	0	0
Visual acuity reduced	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Visual impairment and blindness (excl colour blindness) (cont)				
Visual acuity reduced (cont)				
Grade 1	0	0	0	1 (0.7%)
Visual impairment	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Eyelid movement disorders	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Eyelid ptosis	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Visual impairment and blindness (excl colour blindness) (cont)				
Visual acuity reduced (cont)				
Grade 1	0	0	0	0
Visual impairment	0	0	0	0
Grade 1	0	0	0	0
Eyelid movement disorders	0	0	0	0
Grade 1	0	0	0	0
Eyelid ptosis	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	11 (22.0%)	9 (13.0%)	20 (16.8%)	22 (15.9%)
Grade 1	1 (2.0%)	4 (5.8%)	5 (4.2%)	5 (3.6%)
Grade 2	3 (6.0%)	2 (2.9%)	5 (4.2%)	5 (3.6%)
Grade 3	6 (12.0%)	2 (2.9%)	8 (6.7%)	9 (6.5%)
Grade 4	0	0	0	1 (0.7%)
Grade 5	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Leukaemias acute myeloid	4 (8.0%)	1 (1.4%)	5 (4.2%)	5 (3.6%)
Grade 3	4 (8.0%)	1 (1.4%)	5 (4.2%)	5 (3.6%)
Grade 4	0	0	0	0
Acute myeloid leukaemia	3 (6.0%)	1 (1.4%)	4 (3.4%)	4 (2.9%)
Grade 3	3 (6.0%)	1 (1.4%)	4 (3.4%)	4 (2.9%)
Grade 4	0	0	0	0
Transformation to acute myeloid leukaemia	1 (2.0%)	0	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (21.4%)	2 (13.3%)	5 (17.2%)	6 (18.8%)
Grade 1	2 (14.3%)	0	2 (6.9%)	2 (6.3%)
Grade 2	0	0	0	0
Grade 3	1 (7.1%)	2 (13.3%)	3 (10.3%)	3 (9.4%)
Grade 4	0	0	0	1 (3.1%)
Grade 5	0	0	0	0
Leukaemias acute myeloid	0	0	0	1 (3.1%)
Grade 3	0	0	0	0
Grade 4	0	0	0	1 (3.1%)
Acute myeloid leukaemia	0	0	0	1 (3.1%)
Grade 3	0	0	0	0
Grade 4	0	0	0	1 (3.1%)
Transformation to acute myeloid leukaemia	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-ol.pdf 29AUG2023: 9:42

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Leukaemias acute myeloid (cont)				
Transformation to acute myeloid leukaemia (cont)				
Grade 3	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Skin neoplasms malignant and unspecified (excl melanoma)	3 (6.0%)	3 (4.3%)	6 (5.0%)	6 (4.3%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	3 (6.0%)	2 (2.9%)	5 (4.2%)	5 (3.6%)
Basal cell carcinoma	2 (4.0%)	1 (1.4%)	3 (2.5%)	3 (2.2%)
Grade 2	2 (4.0%)	1 (1.4%)	3 (2.5%)	3 (2.2%)
Squamous cell carcinoma of skin	1 (2.0%)	2 (2.9%)	3 (2.5%)	3 (2.2%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Leukaemias acute myeloid (cont)				
Transformation to acute myeloid leukaemia (cont)				
Grade 3	0	0	0	0
Skin neoplasms malignant and unspecified (excl melanoma)	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Basal cell carcinoma	0	0	0	0
Grade 2	0	0	0	0
Squamous cell carcinoma of skin	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Skin neoplasms malignant and unspecified (excl melanoma) (cont)				
Squamous cell carcinoma of skin (cont)				
Grade 2	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Bowen's disease	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Skin neoplasms benign	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Seborrhoeic keratosis	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Skin papilloma	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Skin neoplasms malignant and unspecified (excl melanoma) (cont)				
Squamous cell carcinoma of skin (cont)				
Grade 2	0	0	0	0
Bowen's disease	0	0	0	0
Grade 2	0	0	0	0
Skin neoplasms benign	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Seborrhoeic keratosis	0	0	0	0
Grade 1	0	0	0	0
Skin papilloma	1 (7.1%)	0	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Skin neoplasms benign (cont)				
Skin papilloma (cont)				
Grade 1	0	0	0	0
Uterine neoplasms malignant NEC	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Grade 3	0	0	0	1 (0.7%)
Grade 5	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Uterine cancer	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Grade 3	0	0	0	1 (0.7%)
Grade 5	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Bone neoplasms benign (excl cysts)	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Skin neoplasms benign (cont)				
Skin papilloma (cont)				
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Uterine neoplasms malignant NEC	0	0	0	0
Grade 3	0	0	0	0
Grade 5	0	0	0	0
Uterine cancer	0	0	0	0
Grade 3	0	0	0	0
Grade 5	0	0	0	0
Bone neoplasms benign (excl cysts)	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Bone neoplasms benign (excl cysts) (cont)				
Haemangioma of bone	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Colorectal neoplasms malignant	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 3	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Rectal cancer	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 3	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Histiocytoses	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Langerhans cell sarcoma	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Bone neoplasms benign (excl cysts) (cont)				
Haemangioma of bone	0	0	0	0
Grade 1	0	0	0	0
Colorectal neoplasms malignant	0	0	0	0
Grade 3	0	0	0	0
Rectal cancer	0	0	0	0
Grade 3	0	0	0	0
Histiocytoses	0	0	0	0
Grade 3	0	0	0	0
Langerhans cell sarcoma	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Leukaemias chronic myeloid	0	0	0	0
Grade 3	0	0	0	0
Chronic myeloid leukaemia	0	0	0	0
Grade 3	0	0	0	0
Myeloproliferative disorders (excl leukaemias)	0	0	0	0
Grade 3	0	0	0	0
Leukoerythroblastosis	0	0	0	0
Grade 3	0	0	0	0
Nasal and paranasal sinus neoplasms benign	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Leukaemias chronic myeloid	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 3	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Chronic myeloid leukaemia	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 3	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Myeloproliferative disorders (excl leukaemias)	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 3	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Leukoerythroblastosis	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 3	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Nasal and paranasal sinus neoplasms benign	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 3	0	1 (6.7%)	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
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Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Nasal and paranasal sinus neoplasms benign (cont)				
Sinonasal papilloma	0	0	0	0
Grade 3	0	0	0	0
Neoplasms malignant site unspecified NEC	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Metastatic squamous cell carcinoma	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Ocular neoplasms malignancy unspecified	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Eyelid tumour	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Nasal and paranasal sinus neoplasms benign (cont)				
Sinonasal papilloma	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 3	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Neoplasms malignant site unspecified NEC	0	0	0	0
Grade 1	0	0	0	0
Metastatic squamous cell carcinoma	0	0	0	0
Grade 1	0	0	0	0
Ocular neoplasms malignancy unspecified	0	0	0	0
Grade 1	0	0	0	0
Eyelid tumour	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Ocular neoplasms malignancy unspecified (cont)				
Eyelid tumour (cont)				
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Oncologic complications and emergencies	0	0	0	0
Grade 1	0	0	0	0
Tumour associated fever	0	0	0	0
Grade 1	0	0	0	0
Ovarian neoplasms malignant (excl germ cell)	0	0	0	1 (0.7%)
Grade 3	0	0	0	1 (0.7%)
Ovarian clear cell carcinoma	0	0	0	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Ocular neoplasms malignancy unspecified (cont)				
Eyelid tumour (cont)				
Grade 1	0	0	0	0
Oncologic complications and emergencies	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Tumour associated fever	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Ovarian neoplasms malignant (excl germ cell)	0	0	0	0
Grade 3	0	0	0	0
Ovarian clear cell carcinoma	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Ovarian neoplasms malignant (excl germ cell) (cont)				
Ovarian clear cell carcinoma (cont)				
Grade 3	0	0	0	1 (0.7%)
Skin melanomas (excl ocular)	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 5	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Malignant melanoma	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 5	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Soft tissue neoplasms benign NEC	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Angiomyolipoma	1 (2.0%)	0	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Ovarian neoplasms malignant (excl germ cell) (cont)				
Ovarian clear cell carcinoma (cont)				
Grade 3	0	0	0	0
Skin melanomas (excl ocular)	0	0	0	0
Grade 5	0	0	0	0
Malignant melanoma	0	0	0	0
Grade 5	0	0	0	0
Soft tissue neoplasms benign NEC	0	0	0	0
Grade 1	0	0	0	0
Angiomyolipoma	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Soft tissue neoplasms benign NEC (cont)				
Angiomyolipoma (cont)				
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Splenic marginal zone lymphomas	0	0	0	1 (0.7%)
Grade 4	0	0	0	1 (0.7%)
Splenic marginal zone lymphoma	0	0	0	1 (0.7%)
Grade 4	0	0	0	1 (0.7%)
Testicular neoplasms malignant	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 3	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Seminoma	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 3	1 (2.0%)	0	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Soft tissue neoplasms benign NEC (cont)				
Angiomyolipoma (cont)				
Grade 1	0	0	0	0
Splenic marginal zone lymphomas	0	0	0	0
Grade 4	0	0	0	0
Splenic marginal zone lymphoma	0	0	0	0
Grade 4	0	0	0	0
Testicular neoplasms malignant	0	0	0	0
Grade 3	0	0	0	0
Seminoma	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Uterine neoplasms benign	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Uterine leiomyoma	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Psychiatric disorders	9 (18.0%)	7 (10.1%)	16 (13.4%)	20 (14.5%)
Grade 1	3 (6.0%)	2 (2.9%)	5 (4.2%)	7 (5.1%)
Grade 2	5 (10.0%)	5 (7.2%)	10 (8.4%)	12 (8.7%)
Grade 3	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Disturbances in initiating and maintaining sleep	5 (10.0%)	3 (4.3%)	8 (6.7%)	9 (6.5%)
Grade 1	3 (6.0%)	1 (1.4%)	4 (3.4%)	5 (3.6%)
Grade 2	2 (4.0%)	2 (2.9%)	4 (3.4%)	4 (2.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Uterine neoplasms benign	0	0	0	0
Grade 1	0	0	0	0
Uterine leiomyoma	0	0	0	0
Grade 1	0	0	0	0
Psychiatric disorders	5 (35.7%)	2 (13.3%)	7 (24.1%)	7 (21.9%)
Grade 1	3 (21.4%)	2 (13.3%)	5 (17.2%)	5 (15.6%)
Grade 2	2 (14.3%)	0	2 (6.9%)	2 (6.3%)
Grade 3	0	0	0	0
Disturbances in initiating and maintaining sleep	2 (14.3%)	1 (6.7%)	3 (10.3%)	3 (9.4%)
Grade 1	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Disturbances in initiating and maintaining sleep (cont)				
Insomnia	5 (10.0%)	3 (4.3%)	8 (6.7%)	9 (6.5%)
Grade 1	3 (6.0%)	1 (1.4%)	4 (3.4%)	5 (3.6%)
Grade 2	2 (4.0%)	2 (2.9%)	4 (3.4%)	4 (2.9%)
Depressive disorders	3 (6.0%)	1 (1.4%)	4 (3.4%)	5 (3.6%)
Grade 1	0	0	0	0
Grade 2	2 (4.0%)	1 (1.4%)	3 (2.5%)	4 (2.9%)
Grade 3	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Depression	3 (6.0%)	1 (1.4%)	4 (3.4%)	5 (3.6%)
Grade 1	0	0	0	0
Grade 2	2 (4.0%)	1 (1.4%)	3 (2.5%)	4 (2.9%)
Grade 3	1 (2.0%)	0	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Disturbances in initiating and maintaining sleep (cont)				
Insomnia	2 (14.3%)	1 (6.7%)	3 (10.3%)	3 (9.4%)
Grade 1	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Depressive disorders	2 (14.3%)	0	2 (6.9%)	2 (6.3%)
Grade 1	2 (14.3%)	0	2 (6.9%)	2 (6.3%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Depression	2 (14.3%)	0	2 (6.9%)	2 (6.3%)
Grade 1	2 (14.3%)	0	2 (6.9%)	2 (6.3%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Anxiety symptoms	3 (6.0%)	0	3 (2.5%)	5 (3.6%)
Grade 1	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Grade 2	2 (4.0%)	0	2 (1.7%)	3 (2.2%)
Anxiety	3 (6.0%)	0	3 (2.5%)	5 (3.6%)
Grade 1	1 (2.0%)	0	1 (0.8%)	2 (1.4%)
Grade 2	2 (4.0%)	0	2 (1.7%)	3 (2.2%)
Confusion and disorientation	2 (4.0%)	2 (2.9%)	4 (3.4%)	5 (3.6%)
Grade 1	2 (4.0%)	1 (1.4%)	3 (2.5%)	4 (2.9%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Confusional state	2 (4.0%)	1 (1.4%)	3 (2.5%)	4 (2.9%)
Grade 1	2 (4.0%)	0	2 (1.7%)	3 (2.2%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Anxiety symptoms	0	0	0	1 (3.1%)
Grade 1	0	0	0	0
Grade 2	0	0	0	1 (3.1%)
Anxiety	0	0	0	1 (3.1%)
Grade 1	0	0	0	0
Grade 2	0	0	0	1 (3.1%)
Confusion and disorientation	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Confusional state	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Confusion and disorientation (cont)				
Disorientation	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Sexual desire disorders	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Libido decreased	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Delusional symptoms	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Delusion	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Confusion and disorientation (cont)				
Disorientation	0	0	0	0
Grade 1	0	0	0	0
Sexual desire disorders	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Libido decreased	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Delusional symptoms	0	0	0	0
Grade 1	0	0	0	0
Delusion	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Delusional symptoms (cont)				
Delusion (cont)				
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Hallucinations (excl sleep-related)	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)
Hallucination	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)
Mental disorders NEC	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)
Mental status changes	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Delusional symptoms (cont)				
Delusion (cont)				
Grade 1	0	0	0	0
Hallucinations (excl sleep-related)	0	0	0	0
Grade 1	0	0	0	0
Hallucination	0	0	0	0
Grade 1	0	0	0	0
Mental disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Mental status changes	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Sleep disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Sleep disorder	0	0	0	0
Grade 1	0	0	0	0
Suicidal and self-injurious behaviour	0	0	0	0
Grade 2	0	0	0	0
Suicidal ideation	0	0	0	0
Grade 2	0	0	0	0
Ear and labyrinth disorders	3 (6.0%)	5 (7.2%)	8 (6.7%)	12 (8.7%)
Grade 1	2 (4.0%)	3 (4.3%)	5 (4.2%)	7 (5.1%)
Grade 2	1 (2.0%)	2 (2.9%)	3 (2.5%)	5 (3.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Sleep disorders NEC	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 1	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Sleep disorder	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 1	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Suicidal and self-injurious behaviour	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Suicidal ideation	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Ear and labyrinth disorders	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Grade 1	0	0	0	0
Grade 2	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Ear and labyrinth disorders (cont)				
Inner ear signs and symptoms	2 (4.0%)	3 (4.3%)	5 (4.2%)	8 (5.8%)
Grade 1	2 (4.0%)	2 (2.9%)	4 (3.4%)	6 (4.3%)
Grade 2	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Vertigo	1 (2.0%)	3 (4.3%)	4 (3.4%)	7 (5.1%)
Grade 1	1 (2.0%)	2 (2.9%)	3 (2.5%)	5 (3.6%)
Grade 2	0	1 (1.4%)	1 (0.8%)	2 (1.4%)
Motion sickness	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Hearing losses	1 (2.0%)	2 (2.9%)	3 (2.5%)	4 (2.9%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	1 (2.0%)	1 (1.4%)	2 (1.7%)	3 (2.2%)
Hypoacusis	0	1 (1.4%)	1 (0.8%)	2 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Ear and labyrinth disorders (cont)				
Inner ear signs and symptoms	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 1	0	0	0	0
Grade 2	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Vertigo	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 1	0	0	0	0
Grade 2	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Motion sickness	0	0	0	0
Grade 1	0	0	0	0
Hearing losses	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	0	0	0	0
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Hypoacusis	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Ear and labyrinth disorders (cont)				
Hearing losses (cont)				
Hypoacusis (cont)				
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	0	0	1 (0.7%)
Deafness	0	0	0	0
Grade 2	0	0	0	0
Deafness unilateral	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Sudden hearing loss	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Ear and labyrinth disorders (cont)				
Hearing losses (cont)				
Hypoacusis (cont)				
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Deafness	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Deafness unilateral	0	0	0	0
Grade 2	0	0	0	0
Sudden hearing loss	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Hepatobiliary disorders	2 (4.0%)	3 (4.3%)	5 (4.2%)	5 (3.6%)
Grade 1	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Grade 2	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Cholecystitis and cholelithiasis	2 (4.0%)	1 (1.4%)	3 (2.5%)	3 (2.2%)
Grade 1	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Cholelithiasis	2 (4.0%)	1 (1.4%)	3 (2.5%)	3 (2.2%)
Grade 1	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Grade 2	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Cholestasis and jaundice	0	0	0	0
Grade 1	0	0	0	0
Ocular icterus	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Hepatobiliary disorders	3 (21.4%)	2 (13.3%)	5 (17.2%)	5 (15.6%)
Grade 1	2 (14.3%)	2 (13.3%)	4 (13.8%)	4 (12.5%)
Grade 2	0	0	0	0
Grade 3	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Cholecystitis and cholelithiasis	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Cholelithiasis	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Cholestasis and jaundice	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Grade 1	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Ocular icterus	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Hepatobiliary disorders (cont)				
Cholestasis and jaundice (cont)				
Ocular icterus (cont)				
Grade 1	0	0	0	0
Hepatic and hepatobiliary disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Liver disorder	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Hepatic vascular disorders	0	2 (2.9%)	2 (1.7%)	2 (1.4%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Hepatobiliary disorders (cont)				
Cholestasis and jaundice (cont)				
Ocular icterus (cont)				
Grade 1	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Hepatic and hepatobiliary disorders NEC	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Grade 1	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 3	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Liver disorder	1 (7.1%)	1 (6.7%)	2 (6.9%)	2 (6.3%)
Grade 1	0	1 (6.7%)	1 (3.4%)	1 (3.1%)
Grade 3	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Hepatic vascular disorders	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Hepatobiliary disorders (cont)				
Hepatic vascular disorders (cont)				
Portal hypertension	0	2 (2.9%)	2 (1.7%)	2 (1.4%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Hepatic enzymes and function abnormalities	0	0	0	0
Grade 1	0	0	0	0
Hepatic function abnormal	0	0	0	0
Grade 1	0	0	0	0
Hepatocellular damage and hepatitis NEC	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Hepatic steatosis	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Hepatobiliary disorders (cont)				
Hepatic vascular disorders (cont)				
Portal hypertension	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Hepatic enzymes and function abnormalities	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Hepatic function abnormal	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Hepatocellular damage and hepatitis NEC	0	0	0	0
Grade 1	0	0	0	0
Hepatic steatosis	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Reproductive system and breast disorders	2 (4.0%)	4 (5.8%)	6 (5.0%)	9 (6.5%)
Grade 1	0	0	0	3 (2.2%)
Grade 2	2 (4.0%)	3 (4.3%)	5 (4.2%)	5 (3.6%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Prostatic neoplasms and hypertrophy	2 (4.0%)	3 (4.3%)	5 (4.2%)	6 (4.3%)
Grade 1	0	0	0	1 (0.7%)
Grade 2	2 (4.0%)	2 (2.9%)	4 (3.4%)	4 (2.9%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Benign prostatic hyperplasia	2 (4.0%)	3 (4.3%)	5 (4.2%)	6 (4.3%)
Grade 1	0	0	0	1 (0.7%)
Grade 2	2 (4.0%)	2 (2.9%)	4 (3.4%)	4 (2.9%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Menopausal effects on the genitourinary tract	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Reproductive system and breast disorders	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Prostatic neoplasms and hypertrophy	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Benign prostatic hyperplasia	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Menopausal effects on the genitourinary tract	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Reproductive system and breast disorders (cont)				
Menopausal effects on the genitourinary tract (cont) (cont)				
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Postmenopausal haemorrhage	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Uterine disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Uterine haemorrhage	0	0	0	0
Grade 1	0	0	0	0
Vulvovaginal disorders NEC	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Reproductive system and breast disorders (cont)				
Menopausal effects on the genitourinary tract (cont) (cont)				
Grade 2	0	0	0	0
Postmenopausal haemorrhage	0	0	0	0
Grade 2	0	0	0	0
Uterine disorders NEC	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Uterine haemorrhage	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Grade 1	1 (7.1%)	0	1 (3.4%)	1 (3.1%)
Vulvovaginal disorders NEC	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Reproductive system and breast disorders (cont)				
Vulvovaginal disorders NEC (cont)				
Vaginal haemorrhage	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)
Vulvovaginal signs and symptoms	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)
Vulvovaginal pain	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)
Endocrine disorders	0	3 (4.3%)	3 (2.5%)	3 (2.2%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Acute and chronic thyroiditis	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Reproductive system and breast disorders (cont)				
Vulvovaginal disorders NEC (cont)				
Vaginal haemorrhage	0	0	0	0
Grade 1	0	0	0	0
Vulvovaginal signs and symptoms	0	0	0	0
Grade 1	0	0	0	0
Vulvovaginal pain	0	0	0	0
Grade 1	0	0	0	0
Endocrine disorders	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Acute and chronic thyroiditis	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Endocrine disorders (cont)				
Acute and chronic thyroiditis (cont)				
(cont)				
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Thyroiditis	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 3	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Thyroid disorders NEC	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Goitre	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 1	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Thyroid hypofunction disorders	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Endocrine disorders (cont)				
Acute and chronic thyroiditis (cont)				
(cont)				
Grade 3	0	0	0	0
Thyroiditis	0	0	0	0
Grade 3	0	0	0	0
Thyroid disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Goitre	0	0	0	0
Grade 1	0	0	0	0
Thyroid hypofunction disorders	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Endocrine disorders (cont)				
Thyroid hypofunction disorders (cont)				
Hypothyroidism	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Immune system disorders	1 (2.0%)	1 (1.4%)	2 (1.7%)	2 (1.4%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Allergies to foods, food additives, drugs and other chemicals	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Drug hypersensitivity	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Grade 1	1 (2.0%)	0	1 (0.8%)	1 (0.7%)
Atopic disorders	0	1 (1.4%)	1 (0.8%)	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Endocrine disorders (cont)				
Thyroid hypofunction disorders (cont)				
Hypothyroidism	0	0	0	0
Grade 2	0	0	0	0
Immune system disorders	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Allergies to foods, food additives, drugs and other chemicals	0	0	0	0
Grade 1	0	0	0	0
Drug hypersensitivity	0	0	0	0
Grade 1	0	0	0	0
Atopic disorders	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	White			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=50)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=69)	OL Phase (Week 24 Onward) Total (N=119)	Overall Exposed to MMB Total (N=138)
Number of Subjects with Any Treatment-Emergent AE	45 (90.0%)	68 (98.6%)	113 (95.0%)	135 (97.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Immune system disorders (cont)				
Atopic disorders (cont)				
(cont)				
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Seasonal allergy	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Grade 2	0	1 (1.4%)	1 (0.8%)	1 (0.7%)
Surgical and medical procedures	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)
Dental and gingival therapeutic procedures	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)
Tooth extraction	0	0	0	1 (0.7%)
Grade 1	0	0	0	1 (0.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0806: TEAEs by SOC, High-Level Term, and PT by Race and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Other Races			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=14)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=15)	OL Phase (Week 24 Onward) Total (N=29)	Overall Exposed to MMB Total (N=32)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	15 (100.0%)	29 (100.0%)	31 (96.9%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Immune system disorders (cont)				
Atopic disorders (cont)				
(cont)				
Grade 2	0	0	0	0
Seasonal allergy	0	0	0	0
Grade 2	0	0	0	0
Surgical and medical procedures	0	0	0	0
Grade 1	0	0	0	0
Dental and gingival therapeutic procedures	0	0	0	0
Grade 1	0	0	0	0
Tooth extraction	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders	25 (50.0%)	23 (41.1%)	48 (45.3%)	8 (20.0%)	26 (53.1%)	34 (38.2%)
Grade 1	18 (36.0%)	12 (21.4%)	30 (28.3%)	6 (15.0%)	10 (20.4%)	16 (18.0%)
Grade 2	4 (8.0%)	9 (16.1%)	13 (12.3%)	2 (5.0%)	11 (22.4%)	13 (14.6%)
Grade 3	3 (6.0%)	1 (1.8%)	4 (3.8%)	0	5 (10.2%)	5 (5.6%)
Grade 4	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 5	0	0	0	0	0	0
Nausea and vomiting symptoms	6 (12.0%)	4 (7.1%)	10 (9.4%)	1 (2.5%)	5 (10.2%)	6 (6.7%)
Grade 1	6 (12.0%)	1 (1.8%)	7 (6.6%)	1 (2.5%)	2 (4.1%)	3 (3.4%)
Grade 2	0	3 (5.4%)	3 (2.8%)	0	3 (6.1%)	3 (3.4%)
Grade 3	0	0	0	0	0	0
Nausea	4 (8.0%)	2 (3.6%)	6 (5.7%)	1 (2.5%)	3 (6.1%)	4 (4.5%)
Grade 1	4 (8.0%)	0	4 (3.8%)	1 (2.5%)	1 (2.0%)	2 (2.2%)
Grade 2	0	2 (3.6%)	2 (1.9%)	0	2 (4.1%)	2 (2.2%)
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders	21 (58.3%)	14 (36.8%)	35 (47.3%)	8 (33.3%)	17 (48.6%)	25 (42.4%)
Grade 1	10 (27.8%)	8 (21.1%)	18 (24.3%)	5 (20.8%)	10 (28.6%)	15 (25.4%)
Grade 2	8 (22.2%)	4 (10.5%)	12 (16.2%)	3 (12.5%)	6 (17.1%)	9 (15.3%)
Grade 3	2 (5.6%)	2 (5.3%)	4 (5.4%)	0	1 (2.9%)	1 (1.7%)
Grade 4	0	0	0	0	0	0
Grade 5	1 (2.8%)	0	1 (1.4%)	0	0	0
Nausea and vomiting symptoms	15 (41.7%)	4 (10.5%)	19 (25.7%)	3 (12.5%)	6 (17.1%)	9 (15.3%)
Grade 1	8 (22.2%)	2 (5.3%)	10 (13.5%)	2 (8.3%)	5 (14.3%)	7 (11.9%)
Grade 2	5 (13.9%)	1 (2.6%)	6 (8.1%)	1 (4.2%)	0	1 (1.7%)
Grade 3	2 (5.6%)	1 (2.6%)	3 (4.1%)	0	1 (2.9%)	1 (1.7%)
Nausea	15 (41.7%)	1 (2.6%)	16 (21.6%)	1 (4.2%)	4 (11.4%)	5 (8.5%)
Grade 1	11 (30.6%)	0	11 (14.9%)	1 (4.2%)	4 (11.4%)	5 (8.5%)
Grade 2	3 (8.3%)	0	3 (4.1%)	0	0	0
Grade 3	1 (2.8%)	1 (2.6%)	2 (2.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Nausea and vomiting symptoms (cont)						
Vomiting	2 (4.0%)	2 (3.6%)	4 (3.8%)	1 (2.5%)	3 (6.1%)	4 (4.5%)
Grade 1	2 (4.0%)	1 (1.8%)	3 (2.8%)	1 (2.5%)	1 (2.0%)	2 (2.2%)
Grade 2	0	1 (1.8%)	1 (0.9%)	0	2 (4.1%)	2 (2.2%)
Grade 3	0	0	0	0	0	0
Retching	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 1	0	0	0	0	1 (2.0%)	1 (1.1%)
Diarrhoea (excl infective)	9 (18.0%)	10 (17.9%)	19 (17.9%)	5 (12.5%)	12 (24.5%)	17 (19.1%)
Grade 1	7 (14.0%)	8 (14.3%)	15 (14.2%)	4 (10.0%)	6 (12.2%)	10 (11.2%)
Grade 2	2 (4.0%)	2 (3.6%)	4 (3.8%)	1 (2.5%)	3 (6.1%)	4 (4.5%)
Grade 3	0	0	0	0	3 (6.1%)	3 (3.4%)
Diarrhoea	9 (18.0%)	10 (17.9%)	19 (17.9%)	5 (12.5%)	12 (24.5%)	17 (19.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Nausea and vomiting symptoms (cont)						
Vomiting	6 (16.7%)	3 (7.9%)	9 (12.2%)	3 (12.5%)	2 (5.7%)	5 (8.5%)
Grade 1	2 (5.6%)	2 (5.3%)	4 (5.4%)	2 (8.3%)	1 (2.9%)	3 (5.1%)
Grade 2	3 (8.3%)	1 (2.6%)	4 (5.4%)	1 (4.2%)	0	1 (1.7%)
Grade 3	1 (2.8%)	0	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Retching	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Diarrhoea (excl infective)	10 (27.8%)	9 (23.7%)	19 (25.7%)	3 (12.5%)	4 (11.4%)	7 (11.9%)
Grade 1	3 (8.3%)	6 (15.8%)	9 (12.2%)	3 (12.5%)	4 (11.4%)	7 (11.9%)
Grade 2	5 (13.9%)	2 (5.3%)	7 (9.5%)	0	0	0
Grade 3	2 (5.6%)	1 (2.6%)	3 (4.1%)	0	0	0
Diarrhoea	10 (27.8%)	9 (23.7%)	19 (25.7%)	3 (12.5%)	4 (11.4%)	7 (11.9%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Diarrhoea (excl infective) (cont)						
Diarrhoea (cont)						
Grade 1	7 (14.0%)	8 (14.3%)	15 (14.2%)	4 (10.0%)	6 (12.2%)	10 (11.2%)
Grade 2	2 (4.0%)	2 (3.6%)	4 (3.8%)	1 (2.5%)	3 (6.1%)	4 (4.5%)
Grade 3	0	0	0	0	3 (6.1%)	3 (3.4%)
Gastrointestinal atonic and hypomotility disorders NEC	12 (24.0%)	4 (7.1%)	16 (15.1%)	1 (2.5%)	7 (14.3%)	8 (9.0%)
Grade 1	11 (22.0%)	3 (5.4%)	14 (13.2%)	1 (2.5%)	4 (8.2%)	5 (5.6%)
Grade 2	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	2 (4.1%)	2 (2.2%)
Grade 3	0	0	0	0	1 (2.0%)	1 (1.1%)
Constipation	9 (18.0%)	3 (5.4%)	12 (11.3%)	1 (2.5%)	3 (6.1%)	4 (4.5%)
Grade 1	9 (18.0%)	2 (3.6%)	11 (10.4%)	1 (2.5%)	1 (2.0%)	2 (2.2%)
Grade 2	0	1 (1.8%)	1 (0.9%)	0	1 (2.0%)	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Diarrhoea (excl infective) (cont)						
Diarrhoea (cont)						
Grade 1	3 (8.3%)	6 (15.8%)	9 (12.2%)	3 (12.5%)	4 (11.4%)	7 (11.9%)
Grade 2	5 (13.9%)	2 (5.3%)	7 (9.5%)	0	0	0
Grade 3	2 (5.6%)	1 (2.6%)	3 (4.1%)	0	0	0
Gastrointestinal atonic and hypomotility disorders NEC	2 (5.6%)	3 (7.9%)	5 (6.8%)	0	3 (8.6%)	3 (5.1%)
Grade 1	1 (2.8%)	2 (5.3%)	3 (4.1%)	0	2 (5.7%)	2 (3.4%)
Grade 2	1 (2.8%)	1 (2.6%)	2 (2.7%)	0	1 (2.9%)	1 (1.7%)
Grade 3	0	0	0	0	0	0
Constipation	2 (5.6%)	3 (7.9%)	5 (6.8%)	0	2 (5.7%)	2 (3.4%)
Grade 1	2 (5.6%)	2 (5.3%)	4 (5.4%)	0	1 (2.9%)	1 (1.7%)
Grade 2	0	1 (2.6%)	1 (1.4%)	0	1 (2.9%)	1 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal atonic and hypomotility disorders NEC (cont)						
Constipation (cont)						
Grade 3	0	0	0	0	1 (2.0%)	1 (1.1%)
Gastrooesophageal reflux disease	3 (6.0%)	1 (1.8%)	4 (3.8%)	0	4 (8.2%)	4 (4.5%)
Grade 1	2 (4.0%)	1 (1.8%)	3 (2.8%)	0	3 (6.1%)	3 (3.4%)
Grade 2	1 (2.0%)	0	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Gastrointestinal and abdominal pains (excl oral and throat)	7 (14.0%)	9 (16.1%)	16 (15.1%)	2 (5.0%)	6 (12.2%)	8 (9.0%)
Grade 1	6 (12.0%)	5 (8.9%)	11 (10.4%)	2 (5.0%)	3 (6.1%)	5 (5.6%)
Grade 2	0	3 (5.4%)	3 (2.8%)	0	3 (6.1%)	3 (3.4%)
Grade 3	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal atonic and hypomotility disorders NEC (cont)						
Constipation (cont)						
Grade 3	0	0	0	0	0	0
Gastrooesophageal reflux disease	1 (2.8%)	0	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 2	1 (2.8%)	0	1 (1.4%)	0	0	0
Gastrointestinal and abdominal pains (excl oral and throat)	6 (16.7%)	3 (7.9%)	9 (12.2%)	1 (4.2%)	3 (8.6%)	4 (6.8%)
Grade 1	2 (5.6%)	2 (5.3%)	4 (5.4%)	0	2 (5.7%)	2 (3.4%)
Grade 2	3 (8.3%)	1 (2.6%)	4 (5.4%)	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 3	1 (2.8%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal and abdominal pains (excl oral and throat) (cont)						
Abdominal pain	5 (10.0%)	8 (14.3%)	13 (12.3%)	1 (2.5%)	4 (8.2%)	5 (5.6%)
Grade 1	4 (8.0%)	5 (8.9%)	9 (8.5%)	1 (2.5%)	2 (4.1%)	3 (3.4%)
Grade 2	0	2 (3.6%)	2 (1.9%)	0	2 (4.1%)	2 (2.2%)
Grade 3	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	0	0
Abdominal pain upper	3 (6.0%)	2 (3.6%)	5 (4.7%)	1 (2.5%)	2 (4.1%)	3 (3.4%)
Grade 1	3 (6.0%)	1 (1.8%)	4 (3.8%)	1 (2.5%)	1 (2.0%)	2 (2.2%)
Grade 2	0	1 (1.8%)	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Abdominal rigidity	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 1	0	0	0	0	1 (2.0%)	1 (1.1%)
Oesophageal pain	0	1 (1.8%)	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal and abdominal pains (excl oral and throat) (cont)						
Abdominal pain	6 (16.7%)	3 (7.9%)	9 (12.2%)	0	2 (5.7%)	2 (3.4%)
Grade 1	2 (5.6%)	2 (5.3%)	4 (5.4%)	0	1 (2.9%)	1 (1.7%)
Grade 2	3 (8.3%)	1 (2.6%)	4 (5.4%)	0	1 (2.9%)	1 (1.7%)
Grade 3	1 (2.8%)	0	1 (1.4%)	0	0	0
Abdominal pain upper	0	0	0	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 2	0	0	0	1 (4.2%)	0	1 (1.7%)
Abdominal rigidity	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Oesophageal pain	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal and abdominal pains (excl oral and throat) (cont)						
Oesophageal pain (cont)						
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0
Flatulence, bloating and distension	3 (6.0%)	4 (7.1%)	7 (6.6%)	0	1 (2.0%)	1 (1.1%)
Grade 1	1 (2.0%)	4 (7.1%)	5 (4.7%)	0	1 (2.0%)	1 (1.1%)
Grade 2	2 (4.0%)	0	2 (1.9%)	0	0	0
Abdominal distension	2 (4.0%)	1 (1.8%)	3 (2.8%)	0	1 (2.0%)	1 (1.1%)
Grade 1	0	1 (1.8%)	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Grade 2	2 (4.0%)	0	2 (1.9%)	0	0	0
Flatulence	2 (4.0%)	4 (7.1%)	6 (5.7%)	0	0	0
Grade 1	2 (4.0%)	4 (7.1%)	6 (5.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal and abdominal pains (excl oral and throat) (cont)						
Oesophageal pain (cont)						
Grade 2	0	0	0	0	0	0
Flatulence, bloating and distension	2 (5.6%)	2 (5.3%)	4 (5.4%)	0	1 (2.9%)	1 (1.7%)
Grade 1	2 (5.6%)	2 (5.3%)	4 (5.4%)	0	0	0
Grade 2	0	0	0	0	1 (2.9%)	1 (1.7%)
Abdominal distension	1 (2.8%)	1 (2.6%)	2 (2.7%)	0	0	0
Grade 1	1 (2.8%)	1 (2.6%)	2 (2.7%)	0	0	0
Grade 2	0	0	0	0	0	0
Flatulence	1 (2.8%)	1 (2.6%)	2 (2.7%)	0	1 (2.9%)	1 (1.7%)
Grade 1	1 (2.8%)	1 (2.6%)	2 (2.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Flatulence, bloating and distension (cont)						
Flatulence (cont)						
Grade 2	0	0	0	0	0	0
Gastrointestinal signs and symptoms NEC	3 (6.0%)	1 (1.8%)	4 (3.8%)	0	1 (2.0%)	1 (1.1%)
Grade 1	3 (6.0%)	0	3 (2.8%)	0	1 (2.0%)	1 (1.1%)
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0
Abdominal discomfort	2 (4.0%)	1 (1.8%)	3 (2.8%)	0	1 (2.0%)	1 (1.1%)
Grade 1	2 (4.0%)	0	2 (1.9%)	0	1 (2.0%)	1 (1.1%)
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0
Dysphagia	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Flatulence, bloating and distension (cont)						
Flatulence (cont)						
Grade 2	0	0	0	0	1 (2.9%)	1 (1.7%)
Gastrointestinal signs and symptoms NEC	1 (2.8%)	0	1 (1.4%)	0	3 (8.6%)	3 (5.1%)
Grade 1	1 (2.8%)	0	1 (1.4%)	0	2 (5.7%)	2 (3.4%)
Grade 2	0	0	0	0	1 (2.9%)	1 (1.7%)
Abdominal discomfort	1 (2.8%)	0	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Grade 1	1 (2.8%)	0	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Grade 2	0	0	0	0	0	0
Dysphagia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal signs and symptoms NEC (cont)						
Anal incontinence	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Haemorrhoids and gastrointestinal varices (excl oesophageal)	2 (4.0%)	0	2 (1.9%)	0	2 (4.1%)	2 (2.2%)
Grade 1	1 (2.0%)	0	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Grade 2	1 (2.0%)	0	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Haemorrhoids	2 (4.0%)	0	2 (1.9%)	0	2 (4.1%)	2 (2.2%)
Grade 1	1 (2.0%)	0	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Grade 2	1 (2.0%)	0	1 (0.9%)	0	1 (2.0%)	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal signs and symptoms NEC (cont)						
Anal incontinence	0	0	0	0	2 (5.7%)	2 (3.4%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 2	0	0	0	0	1 (2.9%)	1 (1.7%)
Haemorrhoids and gastrointestinal varices (excl oesophageal)	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 2	0	0	0	0	0	0
Haemorrhoids	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Haemorrhoids and gastrointestinal varices (excl oesophageal) (cont)						
Haemorrhoidal haemorrhage	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Anal and rectal pains	2 (4.0%)	0	2 (1.9%)	0	0	0
Grade 2	2 (4.0%)	0	2 (1.9%)	0	0	0
Proctalgia	2 (4.0%)	0	2 (1.9%)	0	0	0
Grade 2	2 (4.0%)	0	2 (1.9%)	0	0	0
Intestinal haemorrhages	2 (4.0%)	1 (1.8%)	3 (2.8%)	0	3 (6.1%)	3 (3.4%)
Grade 1	0	1 (1.8%)	1 (0.9%)	0	2 (4.1%)	2 (2.2%)
Grade 2	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 3	1 (2.0%)	0	1 (0.9%)	0	1 (2.0%)	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Haemorrhoids and gastrointestinal varices (excl oesophageal) (cont)						
Haemorrhoidal haemorrhage	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0
Anal and rectal pains	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Proctalgia	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Intestinal haemorrhages	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
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TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Intestinal haemorrhages (cont)						
Rectal haemorrhage	2 (4.0%)	0	2 (1.9%)	0	2 (4.1%)	2 (2.2%)
Grade 1	0	0	0	0	2 (4.1%)	2 (2.2%)
Grade 2	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 3	1 (2.0%)	0	1 (0.9%)	0	0	0
Anal haemorrhage	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0
Lower gastrointestinal haemorrhage	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Small intestinal haemorrhage	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 3	0	0	0	0	1 (2.0%)	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Intestinal haemorrhages (cont)						
Rectal haemorrhage	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Anal haemorrhage	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Lower gastrointestinal haemorrhage	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 2	0	0	0	0	1 (2.9%)	1 (1.7%)
Small intestinal haemorrhage	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Oral dryness and saliva altered	2 (4.0%)	0	2 (1.9%)	1 (2.5%)	2 (4.1%)	3 (3.4%)
Grade 1	2 (4.0%)	0	2 (1.9%)	1 (2.5%)	0	1 (1.1%)
Grade 2	0	0	0	0	2 (4.1%)	2 (2.2%)
Dry mouth	2 (4.0%)	0	2 (1.9%)	1 (2.5%)	2 (4.1%)	3 (3.4%)
Grade 1	2 (4.0%)	0	2 (1.9%)	1 (2.5%)	0	1 (1.1%)
Grade 2	0	0	0	0	2 (4.1%)	2 (2.2%)
Oral soft tissue pain and paraesthesia	2 (4.0%)	0	2 (1.9%)	0	1 (2.0%)	1 (1.1%)
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 3	1 (2.0%)	0	1 (0.9%)	0	0	0
Lip pain	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
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Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Oral dryness and saliva altered	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 1	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 2	0	0	0	0	0	0
Dry mouth	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 1	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 2	0	0	0	0	0	0
Oral soft tissue pain and paraesthesia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Lip pain	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Oral soft tissue pain and paraesthesia (cont)						
Odynophagia	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 3	1 (2.0%)	0	1 (0.9%)	0	0	0
Oral pain	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Dental pain and sensation disorders	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Toothache	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Dyspeptic signs and symptoms	0	1 (1.8%)	1 (0.9%)	1 (2.5%)	1 (2.0%)	2 (2.2%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Oral soft tissue pain and paraesthesia (cont)						
Odynophagia	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Oral pain	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Dental pain and sensation disorders	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Toothache	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Dyspeptic signs and symptoms	1 (2.8%)	1 (2.6%)	2 (2.7%)	1 (4.2%)	2 (5.7%)	3 (5.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Dyspeptic signs and symptoms (cont)						
(cont)						
Grade 1	0	1 (1.8%)	1 (0.9%)	1 (2.5%)	1 (2.0%)	2 (2.2%)
Dyspepsia	0	1 (1.8%)	1 (0.9%)	1 (2.5%)	1 (2.0%)	2 (2.2%)
Grade 1	0	1 (1.8%)	1 (0.9%)	1 (2.5%)	1 (2.0%)	2 (2.2%)
Epigastric discomfort	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Gastric ulcers and perforation	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Gastric ulcer	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
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Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Dyspeptic signs and symptoms (cont)						
(cont)						
Grade 1	1 (2.8%)	1 (2.6%)	2 (2.7%)	1 (4.2%)	2 (5.7%)	3 (5.1%)
Dyspepsia	1 (2.8%)	1 (2.6%)	2 (2.7%)	1 (4.2%)	2 (5.7%)	3 (5.1%)
Grade 1	1 (2.8%)	1 (2.6%)	2 (2.7%)	1 (4.2%)	2 (5.7%)	3 (5.1%)
Epigastric discomfort	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Gastric ulcers and perforation	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 2	1 (2.8%)	0	1 (1.4%)	0	0	0
Gastric ulcer	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 2	1 (2.8%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal vascular occlusion and infarction	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Mesenteric vein thrombosis	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Oral soft tissue disorders NEC	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Cheilitis	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal vascular occlusion and infarction	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 5	1 (2.8%)	0	1 (1.4%)	0	0	0
Mesenteric vein thrombosis	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 5	1 (2.8%)	0	1 (1.4%)	0	0	0
Oral soft tissue disorders NEC	0	1 (2.6%)	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (2.6%)	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Cheilitis	0	1 (2.6%)	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (2.6%)	1 (1.4%)	0	1 (2.9%)	1 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Peritoneal and retroperitoneal disorders	0	1 (1.8%)	1 (0.9%)	1 (2.5%)	1 (2.0%)	2 (2.2%)
Grade 2	0	0	0	1 (2.5%)	1 (2.0%)	2 (2.2%)
Grade 3	0	1 (1.8%)	1 (0.9%)	0	0	0
Ascites	0	1 (1.8%)	1 (0.9%)	1 (2.5%)	1 (2.0%)	2 (2.2%)
Grade 2	0	0	0	1 (2.5%)	1 (2.0%)	2 (2.2%)
Grade 3	0	1 (1.8%)	1 (0.9%)	0	0	0
Stomatitis and ulceration	1 (2.0%)	2 (3.6%)	3 (2.8%)	0	0	0
Grade 1	1 (2.0%)	2 (3.6%)	3 (2.8%)	0	0	0
Grade 2	0	0	0	0	0	0
Mouth ulceration	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	0	0
Grade 1	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Peritoneal and retroperitoneal disorders	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	1 (2.8%)	0	1 (1.4%)	0	0	0
Ascites	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	1 (2.8%)	0	1 (1.4%)	0	0	0
Stomatitis and ulceration	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (2.6%)	1 (1.4%)	0	0	0
Mouth ulceration	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Stomatitis and ulceration (cont)						
Mouth ulceration (cont)						
Grade 2	0	0	0	0	0	0
Stomatitis	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0
Dental and periodontal infections and inflammations	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dental caries	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dental disorders NEC	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
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SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
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Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Stomatitis and ulceration (cont)						
Mouth ulceration (cont)						
Grade 2	0	1 (2.6%)	1 (1.4%)	0	0	0
Stomatitis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dental and periodontal infections and inflammations	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Dental caries	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Dental disorders NEC	0	0	0	0	1 (2.9%)	1 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Dental disorders NEC (cont)						
(cont)						
Grade 1	0	0	0	0	0	0
Periodontal disease	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Gastric and oesophageal haemorrhages	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 3	0	0	0	0	1 (2.0%)	1 (1.1%)
Gastric haemorrhage	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 3	0	0	0	0	1 (2.0%)	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
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Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Dental disorders NEC (cont)						
(cont)						
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Periodontal disease	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Gastric and oesophageal haemorrhages	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Gastric haemorrhage	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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SAF-Anemic Analysis Set

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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal inflammatory disorders NEC	0	2 (3.6%)	2 (1.9%)	0	0	0
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0
Enteritis	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0
Enterocolitis	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0
Gastrointestinal spastic and hypermotility disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
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Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal inflammatory disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Enteritis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Enterocolitis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Gastrointestinal spastic and hypermotility disorders	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal spastic and hypermotility disorders (cont)						
Defaecation urgency	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Gastrointestinal stenosis and obstruction NEC	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 4	0	1 (1.8%)	1 (0.9%)	0	0	0
Ileus	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 4	0	1 (1.8%)	1 (0.9%)	0	0	0
Subileus	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 4	0	1 (1.8%)	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal spastic and hypermotility disorders (cont)						
Defaecation urgency	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Gastrointestinal stenosis and obstruction NEC	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Ileus	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Subileus	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gingival haemorrhages	0	1 (1.8%)	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Gingival bleeding	0	1 (1.8%)	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Non-site specific gastrointestinal haemorrhages	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 3	0	0	0	0	1 (2.0%)	1 (1.1%)
Gastrointestinal haemorrhage	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 3	0	0	0	0	1 (2.0%)	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gingival haemorrhages	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Gingival bleeding	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Non-site specific gastrointestinal haemorrhages	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Gastrointestinal haemorrhage	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Oesophageal varices	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Varices oesophageal	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Oral soft tissue haemorrhages	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 1	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 2	0	0	0	0	0	0
Mouth haemorrhage	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Oesophageal varices	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 1	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 2	0	0	0	0	0	0
Varices oesophageal	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 1	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 2	0	0	0	0	0	0
Oral soft tissue haemorrhages	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (2.9%)	1 (1.7%)
Mouth haemorrhage	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 2	0	0	0	0	1 (2.9%)	1 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Oral soft tissue haemorrhages (cont)						
Oral mucosa haematoma	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 1	0	0	0	1 (2.5%)	0	1 (1.1%)
Oral soft tissue infections	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 2	0	0	0	1 (2.5%)	0	1 (1.1%)
Angular cheilitis	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 2	0	0	0	1 (2.5%)	0	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Oral soft tissue haemorrhages (cont)						
Oral mucosa haematoma	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Oral soft tissue infections	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 2	0	0	0	1 (4.2%)	0	1 (1.7%)
Angular cheilitis	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 2	0	0	0	1 (4.2%)	0	1 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions	24 (48.0%)	30 (53.6%)	54 (50.9%)	10 (25.0%)	12 (24.5%)	22 (24.7%)
Grade 1	18 (36.0%)	18 (32.1%)	36 (34.0%)	6 (15.0%)	5 (10.2%)	11 (12.4%)
Grade 2	5 (10.0%)	12 (21.4%)	17 (16.0%)	4 (10.0%)	7 (14.3%)	11 (12.4%)
Grade 3	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 5	0	0	0	0	0	0
Asthenic conditions	13 (26.0%)	15 (26.8%)	28 (26.4%)	4 (10.0%)	7 (14.3%)	11 (12.4%)
Grade 1	12 (24.0%)	8 (14.3%)	20 (18.9%)	1 (2.5%)	2 (4.1%)	3 (3.4%)
Grade 2	1 (2.0%)	7 (12.5%)	8 (7.5%)	3 (7.5%)	5 (10.2%)	8 (9.0%)
Grade 3	0	0	0	0	0	0
Fatigue	10 (20.0%)	9 (16.1%)	19 (17.9%)	3 (7.5%)	5 (10.2%)	8 (9.0%)
Grade 1	9 (18.0%)	5 (8.9%)	14 (13.2%)	1 (2.5%)	2 (4.1%)	3 (3.4%)
Grade 2	1 (2.0%)	4 (7.1%)	5 (4.7%)	2 (5.0%)	3 (6.1%)	5 (5.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions	14 (38.9%)	15 (39.5%)	29 (39.2%)	7 (29.2%)	9 (25.7%)	16 (27.1%)
Grade 1	8 (22.2%)	10 (26.3%)	18 (24.3%)	5 (20.8%)	4 (11.4%)	9 (15.3%)
Grade 2	4 (11.1%)	4 (10.5%)	8 (10.8%)	2 (8.3%)	3 (8.6%)	5 (8.5%)
Grade 3	1 (2.8%)	1 (2.6%)	2 (2.7%)	0	2 (5.7%)	2 (3.4%)
Grade 5	1 (2.8%)	0	1 (1.4%)	0	0	0
Asthenic conditions	6 (16.7%)	8 (21.1%)	14 (18.9%)	1 (4.2%)	4 (11.4%)	5 (8.5%)
Grade 1	4 (11.1%)	4 (10.5%)	8 (10.8%)	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 2	2 (5.6%)	3 (7.9%)	5 (6.8%)	0	1 (2.9%)	1 (1.7%)
Grade 3	0	1 (2.6%)	1 (1.4%)	0	2 (5.7%)	2 (3.4%)
Fatigue	3 (8.3%)	2 (5.3%)	5 (6.8%)	0	2 (5.7%)	2 (3.4%)
Grade 1	2 (5.6%)	2 (5.3%)	4 (5.4%)	0	1 (2.9%)	1 (1.7%)
Grade 2	1 (2.8%)	0	1 (1.4%)	0	1 (2.9%)	1 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Asthenic conditions (cont)						
Asthenia	2 (4.0%)	4 (7.1%)	6 (5.7%)	1 (2.5%)	1 (2.0%)	2 (2.2%)
Grade 1	2 (4.0%)	2 (3.6%)	4 (3.8%)	0	0	0
Grade 2	0	2 (3.6%)	2 (1.9%)	1 (2.5%)	1 (2.0%)	2 (2.2%)
Grade 3	0	0	0	0	0	0
Malaise	1 (2.0%)	2 (3.6%)	3 (2.8%)	0	1 (2.0%)	1 (1.1%)
Grade 1	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	0	0
Grade 2	0	1 (1.8%)	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Grade 3	0	0	0	0	0	0
Febrile disorders	7 (14.0%)	7 (12.5%)	14 (13.2%)	2 (5.0%)	2 (4.1%)	4 (4.5%)
Grade 1	5 (10.0%)	7 (12.5%)	12 (11.3%)	1 (2.5%)	2 (4.1%)	3 (3.4%)
Grade 2	2 (4.0%)	0	2 (1.9%)	1 (2.5%)	0	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Asthenic conditions (cont)						
Asthenia	2 (5.6%)	5 (13.2%)	7 (9.5%)	1 (4.2%)	2 (5.7%)	3 (5.1%)
Grade 1	1 (2.8%)	2 (5.3%)	3 (4.1%)	1 (4.2%)	0	1 (1.7%)
Grade 2	1 (2.8%)	2 (5.3%)	3 (4.1%)	0	1 (2.9%)	1 (1.7%)
Grade 3	0	1 (2.6%)	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Malaise	1 (2.8%)	1 (2.6%)	2 (2.7%)	0	1 (2.9%)	1 (1.7%)
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 2	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 3	0	0	0	0	1 (2.9%)	1 (1.7%)
Febrile disorders	3 (8.3%)	3 (7.9%)	6 (8.1%)	2 (8.3%)	1 (2.9%)	3 (5.1%)
Grade 1	2 (5.6%)	2 (5.3%)	4 (5.4%)	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 2	0	1 (2.6%)	1 (1.4%)	1 (4.2%)	0	1 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Febrile disorders (cont)						
(cont)						
Grade 3	0	0	0	0	0	0
Pyrexia	7 (14.0%)	7 (12.5%)	14 (13.2%)	2 (5.0%)	2 (4.1%)	4 (4.5%)
Grade 1	5 (10.0%)	7 (12.5%)	12 (11.3%)	1 (2.5%)	2 (4.1%)	3 (3.4%)
Grade 2	2 (4.0%)	0	2 (1.9%)	1 (2.5%)	0	1 (1.1%)
Grade 3	0	0	0	0	0	0
Oedema NEC	6 (12.0%)	6 (10.7%)	12 (11.3%)	2 (5.0%)	1 (2.0%)	3 (3.4%)
Grade 1	3 (6.0%)	4 (7.1%)	7 (6.6%)	2 (5.0%)	1 (2.0%)	3 (3.4%)
Grade 2	3 (6.0%)	2 (3.6%)	5 (4.7%)	0	0	0
Oedema peripheral	5 (10.0%)	4 (7.1%)	9 (8.5%)	2 (5.0%)	0	2 (2.2%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Febrile disorders (cont)						
(cont)						
Grade 3	1 (2.8%)	0	1 (1.4%)	0	0	0
Pyrexia	3 (8.3%)	3 (7.9%)	6 (8.1%)	2 (8.3%)	1 (2.9%)	3 (5.1%)
Grade 1	2 (5.6%)	2 (5.3%)	4 (5.4%)	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 2	0	1 (2.6%)	1 (1.4%)	1 (4.2%)	0	1 (1.7%)
Grade 3	1 (2.8%)	0	1 (1.4%)	0	0	0
Oedema NEC	1 (2.8%)	4 (10.5%)	5 (6.8%)	2 (8.3%)	1 (2.9%)	3 (5.1%)
Grade 1	1 (2.8%)	4 (10.5%)	5 (6.8%)	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 2	0	0	0	1 (4.2%)	0	1 (1.7%)
Oedema peripheral	1 (2.8%)	4 (10.5%)	5 (6.8%)	2 (8.3%)	1 (2.9%)	3 (5.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Oedema NEC (cont)						
Oedema peripheral (cont)						
Grade 1	3 (6.0%)	3 (5.4%)	6 (5.7%)	2 (5.0%)	0	2 (2.2%)
Grade 2	2 (4.0%)	1 (1.8%)	3 (2.8%)	0	0	0
Generalised oedema	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	1 (2.0%)	0	1 (0.9%)	0	0	0
Oedema	1 (2.0%)	2 (3.6%)	3 (2.8%)	0	1 (2.0%)	1 (1.1%)
Grade 1	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	1 (2.0%)	1 (1.1%)
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0
Pain and discomfort NEC	4 (8.0%)	4 (7.1%)	8 (7.5%)	1 (2.5%)	0	1 (1.1%)
Grade 1	3 (6.0%)	4 (7.1%)	7 (6.6%)	1 (2.5%)	0	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Oedema NEC (cont)						
Oedema peripheral (cont)						
Grade 1	1 (2.8%)	4 (10.5%)	5 (6.8%)	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 2	0	0	0	1 (4.2%)	0	1 (1.7%)
Generalised oedema	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Oedema	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Pain and discomfort NEC	3 (8.3%)	1 (2.6%)	4 (5.4%)	0	1 (2.9%)	1 (1.7%)
Grade 1	2 (5.6%)	1 (2.6%)	3 (4.1%)	0	1 (2.9%)	1 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Pain and discomfort NEC (cont)						
(cont)						
Grade 2	1 (2.0%)	0	1 (0.9%)	0	0	0
Chest pain	3 (6.0%)	3 (5.4%)	6 (5.7%)	1 (2.5%)	0	1 (1.1%)
Grade 1	3 (6.0%)	3 (5.4%)	6 (5.7%)	1 (2.5%)	0	1 (1.1%)
Pain	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	1 (2.0%)	0	1 (0.9%)	0	0	0
Facial pain	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Pain and discomfort NEC (cont)						
(cont)						
Grade 2	1 (2.8%)	0	1 (1.4%)	0	0	0
Chest pain	1 (2.8%)	0	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Grade 1	1 (2.8%)	0	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Pain	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 2	0	0	0	0	0	0
Facial pain	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	1 (2.8%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Pain and discomfort NEC (cont)						
Chest discomfort	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
General signs and symptoms NEC	3 (6.0%)	4 (7.1%)	7 (6.6%)	3 (7.5%)	3 (6.1%)	6 (6.7%)
Grade 1	3 (6.0%)	4 (7.1%)	7 (6.6%)	2 (5.0%)	2 (4.1%)	4 (4.5%)
Grade 2	0	0	0	1 (2.5%)	1 (2.0%)	2 (2.2%)
Peripheral swelling	2 (4.0%)	0	2 (1.9%)	0	0	0
Grade 1	2 (4.0%)	0	2 (1.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Influenza like illness	1 (2.0%)	2 (3.6%)	3 (2.8%)	2 (5.0%)	3 (6.1%)	5 (5.6%)
Grade 1	1 (2.0%)	2 (3.6%)	3 (2.8%)	1 (2.5%)	2 (4.1%)	3 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Pain and discomfort NEC (cont)						
Chest discomfort	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (2.6%)	1 (1.4%)	0	0	0
General signs and symptoms NEC	2 (5.6%)	1 (2.6%)	3 (4.1%)	1 (4.2%)	0	1 (1.7%)
Grade 1	1 (2.8%)	1 (2.6%)	2 (2.7%)	1 (4.2%)	0	1 (1.7%)
Grade 2	1 (2.8%)	0	1 (1.4%)	0	0	0
Peripheral swelling	1 (2.8%)	0	1 (1.4%)	1 (4.2%)	0	1 (1.7%)
Grade 1	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 2	1 (2.8%)	0	1 (1.4%)	0	0	0
Influenza like illness	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
General signs and symptoms NEC (cont)						
Influenza like illness (cont)						
Grade 2	0	0	0	1 (2.5%)	1 (2.0%)	2 (2.2%)
Crepitations	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
General physical health deterioration	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Swelling	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
General signs and symptoms NEC (cont)						
Influenza like illness (cont)						
Grade 2	0	0	0	0	0	0
Crepitations	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
General physical health deterioration	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (2.6%)	1 (1.4%)	0	0	0
Swelling	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
General signs and symptoms NEC (cont)						
Xerosis	0	1 (1.8%)	1 (0.9%)	1 (2.5%)	0	1 (1.1%)
Grade 1	0	1 (1.8%)	1 (0.9%)	1 (2.5%)	0	1 (1.1%)
Mucosal findings abnormal	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 3	1 (2.0%)	0	1 (0.9%)	0	0	0
Mucosal inflammation	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	1 (2.0%)	0	1 (0.9%)	0	0	0
Mucosal haemorrhage	0	1 (1.8%)	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
General signs and symptoms NEC (cont)						
Xerosis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Mucosal findings abnormal	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Mucosal inflammation	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 3	0	0	0	0	0	0
Mucosal haemorrhage	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Mucosal findings abnormal (cont)						
Mucosal haemorrhage (cont)						
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0
Death and sudden death	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Sudden death	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Feelings and sensations NEC	1 (2.0%)	6 (10.7%)	7 (6.6%)	0	0	0
Grade 1	1 (2.0%)	5 (8.9%)	6 (5.7%)	0	0	0
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Mucosal findings abnormal (cont)						
Mucosal haemorrhage (cont)						
Grade 2	0	0	0	0	0	0
Death and sudden death	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 5	1 (2.8%)	0	1 (1.4%)	0	0	0
Sudden death	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 5	1 (2.8%)	0	1 (1.4%)	0	0	0
Feelings and sensations NEC	0	0	0	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 1	0	0	0	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Feelings and sensations NEC (cont)						
Chills	1 (2.0%)	3 (5.4%)	4 (3.8%)	0	0	0
Grade 1	1 (2.0%)	2 (3.6%)	3 (2.8%)	0	0	0
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0
Early satiety	0	2 (3.6%)	2 (1.9%)	0	0	0
Grade 1	0	2 (3.6%)	2 (1.9%)	0	0	0
Feeling cold	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0
Feeling hot	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Feelings and sensations NEC (cont)						
Chills	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Early satiety	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 1	0	0	0	1 (4.2%)	0	1 (1.7%)
Feeling cold	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Feeling hot	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Gait disturbances	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Gait disturbance	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Healing abnormal NEC	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Impaired healing	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Implant and catheter site reactions	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Gait disturbances	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Gait disturbance	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Healing abnormal NEC	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Impaired healing	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Implant and catheter site reactions	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 2	0	0	0	0	1 (2.9%)	1 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Implant and catheter site reactions (cont)						
Catheter site haemorrhage	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0
Catheter site pain	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Withdrawal and rebound effects	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Drug withdrawal syndrome	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Implant and catheter site reactions (cont)						
Catheter site haemorrhage	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Catheter site pain	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 2	0	0	0	0	1 (2.9%)	1 (1.7%)
Withdrawal and rebound effects	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 2	0	0	0	0	1 (2.9%)	1 (1.7%)
Drug withdrawal syndrome	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 2	0	0	0	0	1 (2.9%)	1 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations	25 (50.0%)	21 (37.5%)	46 (43.4%)	13 (32.5%)	19 (38.8%)	32 (36.0%)
Grade 1	10 (20.0%)	4 (7.1%)	14 (13.2%)	6 (15.0%)	4 (8.2%)	10 (11.2%)
Grade 2	6 (12.0%)	12 (21.4%)	18 (17.0%)	2 (5.0%)	12 (24.5%)	14 (15.7%)
Grade 3	8 (16.0%)	3 (5.4%)	11 (10.4%)	4 (10.0%)	3 (6.1%)	7 (7.9%)
Grade 4	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 5	1 (2.0%)	1 (1.8%)	2 (1.9%)	1 (2.5%)	0	1 (1.1%)
Urinary tract infections	4 (8.0%)	2 (3.6%)	6 (5.7%)	1 (2.5%)	1 (2.0%)	2 (2.2%)
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	2 (4.0%)	2 (3.6%)	4 (3.8%)	1 (2.5%)	1 (2.0%)	2 (2.2%)
Grade 3	1 (2.0%)	0	1 (0.9%)	0	0	0
Urinary tract infection	3 (6.0%)	2 (3.6%)	5 (4.7%)	1 (2.5%)	1 (2.0%)	2 (2.2%)
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	2 (4.0%)	2 (3.6%)	4 (3.8%)	1 (2.5%)	1 (2.0%)	2 (2.2%)
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations	12 (33.3%)	23 (60.5%)	35 (47.3%)	9 (37.5%)	14 (40.0%)	23 (39.0%)
Grade 1	6 (16.7%)	11 (28.9%)	17 (23.0%)	1 (4.2%)	4 (11.4%)	5 (8.5%)
Grade 2	4 (11.1%)	11 (28.9%)	15 (20.3%)	6 (25.0%)	8 (22.9%)	14 (23.7%)
Grade 3	1 (2.8%)	1 (2.6%)	2 (2.7%)	2 (8.3%)	2 (5.7%)	4 (6.8%)
Grade 4	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 5	0	0	0	0	0	0
Urinary tract infections	6 (16.7%)	2 (5.3%)	8 (10.8%)	4 (16.7%)	3 (8.6%)	7 (11.9%)
Grade 1	2 (5.6%)	0	2 (2.7%)	0	0	0
Grade 2	4 (11.1%)	2 (5.3%)	6 (8.1%)	3 (12.5%)	3 (8.6%)	6 (10.2%)
Grade 3	0	0	0	1 (4.2%)	0	1 (1.7%)
Urinary tract infection	3 (8.3%)	2 (5.3%)	5 (6.8%)	3 (12.5%)	2 (5.7%)	5 (8.5%)
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 2	2 (5.6%)	2 (5.3%)	4 (5.4%)	2 (8.3%)	2 (5.7%)	4 (6.8%)
Grade 3	0	0	0	1 (4.2%)	0	1 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Urinary tract infections (cont)						
Cystitis	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	1 (2.0%)	0	1 (0.9%)	0	0	0
Pyelocystitis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Lower respiratory tract and lung infections	6 (12.0%)	7 (12.5%)	13 (12.3%)	5 (12.5%)	6 (12.2%)	11 (12.4%)
Grade 1	1 (2.0%)	0	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Grade 2	1 (2.0%)	4 (7.1%)	5 (4.7%)	1 (2.5%)	3 (6.1%)	4 (4.5%)
Grade 3	4 (8.0%)	1 (1.8%)	5 (4.7%)	3 (7.5%)	2 (4.1%)	5 (5.6%)
Grade 4	0	1 (1.8%)	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Urinary tract infections (cont)						
Cystitis	3 (8.3%)	0	3 (4.1%)	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 2	2 (5.6%)	0	2 (2.7%)	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 3	0	0	0	0	0	0
Pyelocystitis	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 2	1 (2.8%)	0	1 (1.4%)	0	0	0
Lower respiratory tract and lung infections	2 (5.6%)	3 (7.9%)	5 (6.8%)	1 (4.2%)	3 (8.6%)	4 (6.8%)
Grade 1	1 (2.8%)	2 (5.3%)	3 (4.1%)	0	0	0
Grade 2	0	1 (2.6%)	1 (1.4%)	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 3	1 (2.8%)	0	1 (1.4%)	0	2 (5.7%)	2 (3.4%)
Grade 4	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Lower respiratory tract and lung infections (cont)						
(cont)						
Grade 5	0	1 (1.8%)	1 (0.9%)	1 (2.5%)	0	1 (1.1%)
Pneumonia	3 (6.0%)	4 (7.1%)	7 (6.6%)	4 (10.0%)	1 (2.0%)	5 (5.6%)
Grade 2	0	1 (1.8%)	1 (0.9%)	1 (2.5%)	0	1 (1.1%)
Grade 3	3 (6.0%)	1 (1.8%)	4 (3.8%)	2 (5.0%)	1 (2.0%)	3 (3.4%)
Grade 4	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 5	0	1 (1.8%)	1 (0.9%)	1 (2.5%)	0	1 (1.1%)
Lower respiratory tract infection	2 (4.0%)	0	2 (1.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	1 (2.0%)	0	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Lower respiratory tract and lung infections (cont)						
(cont)						
Grade 5	0	0	0	0	0	0
Pneumonia	1 (2.8%)	1 (2.6%)	2 (2.7%)	0	2 (5.7%)	2 (3.4%)
Grade 2	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 3	1 (2.8%)	0	1 (1.4%)	0	2 (5.7%)	2 (3.4%)
Grade 4	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Lower respiratory tract infection	1 (2.8%)	0	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 2	0	0	0	0	1 (2.9%)	1 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Lower respiratory tract and lung infections (cont)						
Lung infection	1 (2.0%)	0	1 (0.9%)	1 (2.5%)	0	1 (1.1%)
Grade 3	1 (2.0%)	0	1 (0.9%)	1 (2.5%)	0	1 (1.1%)
Bronchitis	0	3 (5.4%)	3 (2.8%)	0	5 (10.2%)	5 (5.6%)
Grade 1	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 2	0	3 (5.4%)	3 (2.8%)	0	3 (6.1%)	3 (3.4%)
Grade 3	0	0	0	0	1 (2.0%)	1 (1.1%)
Tracheobronchitis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Upper respiratory tract infections	6 (12.0%)	7 (12.5%)	13 (12.3%)	3 (7.5%)	6 (12.2%)	9 (10.1%)
Grade 1	5 (10.0%)	3 (5.4%)	8 (7.5%)	3 (7.5%)	2 (4.1%)	5 (5.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Lower respiratory tract and lung infections (cont)						
Lung infection	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Bronchitis	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 3	0	0	0	0	0	0
Tracheobronchitis	0	2 (5.3%)	2 (2.7%)	0	0	0
Grade 1	0	2 (5.3%)	2 (2.7%)	0	0	0
Upper respiratory tract infections	2 (5.6%)	8 (21.1%)	10 (13.5%)	2 (8.3%)	6 (17.1%)	8 (13.6%)
Grade 1	2 (5.6%)	4 (10.5%)	6 (8.1%)	0	3 (8.6%)	3 (5.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Upper respiratory tract infections (cont) (cont) (cont)						
Grade 2	1 (2.0%)	4 (7.1%)	5 (4.7%)	0	4 (8.2%)	4 (4.5%)
Upper respiratory tract infection	3 (6.0%)	3 (5.4%)	6 (5.7%)	1 (2.5%)	3 (6.1%)	4 (4.5%)
Grade 1	3 (6.0%)	0	3 (2.8%)	1 (2.5%)	0	1 (1.1%)
Grade 2	0	3 (5.4%)	3 (2.8%)	0	3 (6.1%)	3 (3.4%)
Nasopharyngitis	2 (4.0%)	2 (3.6%)	4 (3.8%)	2 (5.0%)	1 (2.0%)	3 (3.4%)
Grade 1	2 (4.0%)	2 (3.6%)	4 (3.8%)	2 (5.0%)	1 (2.0%)	3 (3.4%)
Grade 2	0	0	0	0	0	0
Laryngitis	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	1 (2.0%)	0	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Upper respiratory tract infections (cont) (cont)						
Grade 2	0	4 (10.5%)	4 (5.4%)	2 (8.3%)	3 (8.6%)	5 (8.5%)
Upper respiratory tract infection	2 (5.6%)	3 (7.9%)	5 (6.8%)	0	4 (11.4%)	4 (6.8%)
Grade 1	2 (5.6%)	0	2 (2.7%)	0	2 (5.7%)	2 (3.4%)
Grade 2	0	3 (7.9%)	3 (4.1%)	0	2 (5.7%)	2 (3.4%)
Nasopharyngitis	0	3 (7.9%)	3 (4.1%)	1 (4.2%)	2 (5.7%)	3 (5.1%)
Grade 1	0	2 (5.3%)	2 (2.7%)	0	1 (2.9%)	1 (1.7%)
Grade 2	0	1 (2.6%)	1 (1.4%)	1 (4.2%)	1 (2.9%)	2 (3.4%)
Laryngitis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Upper respiratory tract infections (cont)						
Rhinitis	0	2 (3.6%)	2 (1.9%)	0	0	0
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0
Sinusitis	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Tonsillitis	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 1	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 2	0	0	0	0	0	0
Tracheitis	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Upper respiratory tract infections (cont)						
Rhinitis	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 2	0	0	0	0	0	0
Sinusitis	0	0	0	0	2 (5.7%)	2 (3.4%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 2	0	0	0	0	1 (2.9%)	1 (1.7%)
Tonsillitis	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	1 (4.2%)	0	1 (1.7%)
Tracheitis	0	1 (2.6%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Upper respiratory tract infections (cont)						
Tracheitis (cont)						
Grade 1	0	0	0	0	0	0
Herpes viral infections	1 (2.0%)	5 (8.9%)	6 (5.7%)	1 (2.5%)	0	1 (1.1%)
Grade 1	0	1 (1.8%)	1 (0.9%)	1 (2.5%)	0	1 (1.1%)
Grade 2	1 (2.0%)	4 (7.1%)	5 (4.7%)	0	0	0
Grade 3	0	0	0	0	0	0
Herpes zoster	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Upper respiratory tract infections (cont)						
Tracheitis (cont)						
Grade 1	0	1 (2.6%)	1 (1.4%)	0	0	0
Herpes viral infections	3 (8.3%)	3 (7.9%)	6 (8.1%)	2 (8.3%)	3 (8.6%)	5 (8.5%)
Grade 1	1 (2.8%)	0	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Grade 2	2 (5.6%)	2 (5.3%)	4 (5.4%)	2 (8.3%)	2 (5.7%)	4 (6.8%)
Grade 3	0	1 (2.6%)	1 (1.4%)	0	0	0
Herpes zoster	3 (8.3%)	2 (5.3%)	5 (6.8%)	2 (8.3%)	0	2 (3.4%)
Grade 1	1 (2.8%)	0	1 (1.4%)	1 (4.2%)	0	1 (1.7%)
Grade 2	2 (5.6%)	1 (2.6%)	3 (4.1%)	1 (4.2%)	0	1 (1.7%)
Grade 3	0	1 (2.6%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
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Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Herpes viral infections (cont)						
Oral herpes	1 (2.0%)	4 (7.1%)	5 (4.7%)	1 (2.5%)	0	1 (1.1%)
Grade 1	0	1 (1.8%)	1 (0.9%)	1 (2.5%)	0	1 (1.1%)
Grade 2	1 (2.0%)	3 (5.4%)	4 (3.8%)	0	0	0
Genital herpes	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Herpes simplex	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Nasal herpes	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Herpes viral infections (cont)						
Oral herpes	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (2.6%)	1 (1.4%)	0	0	0
Genital herpes	0	0	0	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 2	0	0	0	1 (4.2%)	0	1 (1.7%)
Herpes simplex	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 2	0	0	0	0	1 (2.9%)	1 (1.7%)
Nasal herpes	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 2	0	0	0	1 (4.2%)	0	1 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Herpes viral infections (cont)						
Varicella zoster virus infection	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Dental and oral soft tissue infections	3 (6.0%)	0	3 (2.8%)	0	0	0
Grade 1	3 (6.0%)	0	3 (2.8%)	0	0	0
Gingivitis	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Lip infection	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Periodontitis	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Herpes viral infections (cont)						
Varicella zoster virus infection	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 2	0	0	0	0	1 (2.9%)	1 (1.7%)
Dental and oral soft tissue infections	0	1 (2.6%)	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Grade 1	0	1 (2.6%)	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Gingivitis	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (2.6%)	1 (1.4%)	0	0	0
Lip infection	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Periodontitis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Dental and oral soft tissue infections (cont)						
Tooth abscess	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Infections NEC	2 (4.0%)	6 (10.7%)	8 (7.5%)	0	0	0
Grade 1	1 (2.0%)	2 (3.6%)	3 (2.8%)	0	0	0
Grade 2	1 (2.0%)	4 (7.1%)	5 (4.7%)	0	0	0
Grade 3	0	0	0	0	0	0
Infection	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Localised infection	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Dental and oral soft tissue infections (cont)						
Tooth abscess	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Infections NEC	1 (2.8%)	4 (10.5%)	5 (6.8%)	0	1 (2.9%)	1 (1.7%)
Grade 1	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 2	0	3 (7.9%)	3 (4.1%)	0	1 (2.9%)	1 (1.7%)
Grade 3	1 (2.8%)	0	1 (1.4%)	0	0	0
Infection	1 (2.8%)	1 (2.6%)	2 (2.7%)	0	0	0
Grade 1	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 3	1 (2.8%)	0	1 (1.4%)	0	0	0
Localised infection	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Infections NEC (cont)						
Localised infection (cont)						
Grade 2	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	0	0
Respiratory tract infection	1 (2.0%)	3 (5.4%)	4 (3.8%)	0	0	0
Grade 1	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	0	0
Grade 2	0	2 (3.6%)	2 (1.9%)	0	0	0
Postoperative wound infection	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0
Wound infection	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Infections NEC (cont)						
Localised infection (cont)						
Grade 2	0	0	0	0	0	0
Respiratory tract infection	0	3 (7.9%)	3 (4.1%)	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	0	0
Grade 2	0	3 (7.9%)	3 (4.1%)	0	1 (2.9%)	1 (1.7%)
Postoperative wound infection	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Wound infection	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
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TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Sepsis, bacteraemia, viraemia and fungaemia NEC	3 (6.0%)	1 (1.8%)	4 (3.8%)	0	0	0
Grade 3	2 (4.0%)	1 (1.8%)	3 (2.8%)	0	0	0
Grade 5	1 (2.0%)	0	1 (0.9%)	0	0	0
Sepsis	3 (6.0%)	0	3 (2.8%)	0	0	0
Grade 3	2 (4.0%)	0	2 (1.9%)	0	0	0
Grade 5	1 (2.0%)	0	1 (0.9%)	0	0	0
Pulmonary sepsis	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 3	0	1 (1.8%)	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Sepsis, bacteraemia, viraemia and fungaemia NEC	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 3	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 5	0	0	0	0	0	0
Sepsis	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 3	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 5	0	0	0	0	0	0
Pulmonary sepsis	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Skin structures and soft tissue infections	3 (6.0%)	2 (3.6%)	5 (4.7%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	2 (4.0%)	2 (3.6%)	4 (3.8%)	0	0	0
Grade 3	1 (2.0%)	0	1 (0.9%)	0	0	0
Skin infection	3 (6.0%)	1 (1.8%)	4 (3.8%)	0	0	0
Grade 2	2 (4.0%)	1 (1.8%)	3 (2.8%)	0	0	0
Grade 3	1 (2.0%)	0	1 (0.9%)	0	0	0
Folliculitis	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0
Infected skin ulcer	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Skin structures and soft tissue infections	0	1 (2.6%)	1 (1.4%)	1 (4.2%)	0	1 (1.7%)
Grade 1	0	1 (2.6%)	1 (1.4%)	1 (4.2%)	0	1 (1.7%)
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Skin infection	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Folliculitis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Infected skin ulcer	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 1	0	0	0	1 (4.2%)	0	1 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Skin structures and soft tissue infections (cont)						
Paronychia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Abdominal and gastrointestinal infections	2 (4.0%)	2 (3.6%)	4 (3.8%)	0	1 (2.0%)	1 (1.1%)
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 3	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	0	0
Grade 4	0	1 (1.8%)	1 (0.9%)	0	0	0
Anal abscess	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 3	1 (2.0%)	0	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
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Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Skin structures and soft tissue infections (cont)						
Paronychia	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (2.6%)	1 (1.4%)	0	0	0
Abdominal and gastrointestinal infections	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 3	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Anal abscess	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Abdominal and gastrointestinal infections (cont)						
Gastroenteritis	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	1 (2.0%)	1 (1.1%)
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 3	0	1 (1.8%)	1 (0.9%)	0	0	0
Peritonitis	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 4	0	1 (1.8%)	1 (0.9%)	0	0	0
Bacterial infections NEC	2 (4.0%)	0	2 (1.9%)	1 (2.5%)	0	1 (1.1%)
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 3	1 (2.0%)	0	1 (0.9%)	1 (2.5%)	0	1 (1.1%)
Cellulitis	1 (2.0%)	0	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Abdominal and gastrointestinal infections (cont)						
Gastroenteritis	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 3	0	0	0	0	0	0
Peritonitis	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Bacterial infections NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Cellulitis	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Bacterial infections NEC (cont)						
Cellulitis (cont)						
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Pneumonia bacterial	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 3	1 (2.0%)	0	1 (0.9%)	0	0	0
Gangrene	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 3	0	0	0	1 (2.5%)	0	1 (1.1%)
Fungal infections NEC	2 (4.0%)	1 (1.8%)	3 (2.8%)	1 (2.5%)	0	1 (1.1%)
Grade 1	2 (4.0%)	0	2 (1.9%)	1 (2.5%)	0	1 (1.1%)
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0
Fungal infection	1 (2.0%)	0	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Bacterial infections NEC (cont)						
Cellulitis (cont)						
Grade 1	0	0	0	0	0	0
Pneumonia bacterial	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Gangrene	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Fungal infections NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Fungal infection	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Fungal infections NEC (cont)						
Fungal infection (cont)						
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Fungal skin infection	1 (2.0%)	0	1 (0.9%)	1 (2.5%)	0	1 (1.1%)
Grade 1	1 (2.0%)	0	1 (0.9%)	1 (2.5%)	0	1 (1.1%)
Fungal oesophagitis	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0
Borrelial infections	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Lyme disease	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Fungal infections NEC (cont)						
Fungal infection (cont)						
Grade 1	0	0	0	0	0	0
Fungal skin infection	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Fungal oesophagitis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Borrelial infections	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Lyme disease	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
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Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Candida infections	1 (2.0%)	0	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Oral candidiasis	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Gastrointestinal candidiasis	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Vulvovaginal candidiasis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Escherichia infections	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 1	0	0	0	1 (2.5%)	0	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Candida infections	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 2	0	0	0	0	0	0
Oral candidiasis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Gastrointestinal candidiasis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Vulvovaginal candidiasis	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (2.6%)	1 (1.4%)	0	0	0
Escherichia infections	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Escherichia infections (cont)						
(cont)						
Grade 4	0	0	0	0	0	0
Escherichia sepsis	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Escherichia urinary tract infection	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 1	0	0	0	1 (2.5%)	0	1 (1.1%)
Influenza viral infections	1 (2.0%)	2 (3.6%)	3 (2.8%)	0	1 (2.0%)	1 (1.1%)
Grade 1	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	0	0
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 3	0	1 (1.8%)	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Escherichia infections (cont)						
(cont)						
Grade 4	1 (2.8%)	0	1 (1.4%)	0	0	0
Escherichia sepsis	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 4	1 (2.8%)	0	1 (1.4%)	0	0	0
Escherichia urinary tract infection	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Influenza viral infections	0	2 (5.3%)	2 (2.7%)	0	0	0
Grade 1	0	2 (5.3%)	2 (2.7%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Influenza viral infections (cont)						
Influenza	1 (2.0%)	2 (3.6%)	3 (2.8%)	0	1 (2.0%)	1 (1.1%)
Grade 1	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	0	0
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 3	0	1 (1.8%)	1 (0.9%)	0	0	0
Male reproductive tract infections	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	1 (2.0%)	0	1 (0.9%)	0	0	0
Scrotal abscess	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	1 (2.0%)	0	1 (0.9%)	0	0	0
Tinea infections	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Influenza viral infections (cont)						
Influenza	0	2 (5.3%)	2 (2.7%)	0	0	0
Grade 1	0	2 (5.3%)	2 (2.7%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Male reproductive tract infections	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Scrotal abscess	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Tinea infections	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Tinea infections (cont)						
Tinea versicolour	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Bordetella infections	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 1	0	0	0	0	1 (2.0%)	1 (1.1%)
Pertussis	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 1	0	0	0	0	1 (2.0%)	1 (1.1%)
Clostridia infections	0	1 (1.8%)	1 (0.9%)	0	2 (4.1%)	2 (2.2%)
Grade 2	0	1 (1.8%)	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Grade 3	0	0	0	0	1 (2.0%)	1 (1.1%)
Clostridium difficile colitis	0	1 (1.8%)	1 (0.9%)	0	1 (2.0%)	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Tinea infections (cont)						
Tinea versicolour	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Bordetella infections	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Pertussis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Clostridia infections	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Clostridia infections (cont)						
Clostridium difficile colitis (cont)						
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 3	0	0	0	0	1 (2.0%)	1 (1.1%)
Clostridium difficile infection	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Ear infections	0	0	0	1 (2.5%)	1 (2.0%)	2 (2.2%)
Grade 1	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Ear infection	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 1	0	0	0	1 (2.5%)	0	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Clostridia infections (cont)						
Clostridium difficile colitis (cont)						
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Ear infections	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Ear infection	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Ear infections (cont)						
Labyrinthitis	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 1	0	0	0	1 (2.5%)	0	1 (1.1%)
Otitis externa	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Eye and eyelid infections	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0
Conjunctivitis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hordeolum	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Ear infections (cont)						
Labyrinthitis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Otitis externa	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Eye and eyelid infections	0	2 (5.3%)	2 (2.7%)	0	0	0
Grade 1	0	2 (5.3%)	2 (2.7%)	0	0	0
Conjunctivitis	0	2 (5.3%)	2 (2.7%)	0	0	0
Grade 1	0	2 (5.3%)	2 (2.7%)	0	0	0
Hordeolum	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Streptococcal infections	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Erysipelas	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Viral infections NEC	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Viral infection	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Viral uveitis	0	0	0	0	1 (2.0%)	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Streptococcal infections	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Erysipelas	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Viral infections NEC	0	0	0	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 1	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 2	0	0	0	0	1 (2.9%)	1 (1.7%)
Viral infection	0	0	0	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 1	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 2	0	0	0	0	1 (2.9%)	1 (1.7%)
Viral uveitis	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Viral infections NEC (cont)						
Viral uveitis (cont)						
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Nervous system disorders	23 (46.0%)	16 (28.6%)	39 (36.8%)	11 (27.5%)	12 (24.5%)	23 (25.8%)
Grade 1	19 (38.0%)	12 (21.4%)	31 (29.2%)	7 (17.5%)	7 (14.3%)	14 (15.7%)
Grade 2	3 (6.0%)	3 (5.4%)	6 (5.7%)	2 (5.0%)	3 (6.1%)	5 (5.6%)
Grade 3	1 (2.0%)	0	1 (0.9%)	1 (2.5%)	2 (4.1%)	3 (3.4%)
Grade 4	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 5	0	1 (1.8%)	1 (0.9%)	0	0	0
Neurological signs and symptoms NEC	10 (20.0%)	4 (7.1%)	14 (13.2%)	4 (10.0%)	5 (10.2%)	9 (10.1%)
Grade 1	9 (18.0%)	3 (5.4%)	12 (11.3%)	4 (10.0%)	4 (8.2%)	8 (9.0%)
Grade 2	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	1 (2.0%)	1 (1.1%)
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Viral infections NEC (cont)						
Viral uveitis (cont)						
Grade 2	0	0	0	0	0	0
Nervous system disorders	13 (36.1%)	14 (36.8%)	27 (36.5%)	2 (8.3%)	11 (31.4%)	13 (22.0%)
Grade 1	4 (11.1%)	9 (23.7%)	13 (17.6%)	2 (8.3%)	7 (20.0%)	9 (15.3%)
Grade 2	7 (19.4%)	4 (10.5%)	11 (14.9%)	0	1 (2.9%)	1 (1.7%)
Grade 3	2 (5.6%)	1 (2.6%)	3 (4.1%)	0	3 (8.6%)	3 (5.1%)
Grade 4	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Neurological signs and symptoms NEC	6 (16.7%)	6 (15.8%)	12 (16.2%)	1 (4.2%)	2 (5.7%)	3 (5.1%)
Grade 1	3 (8.3%)	5 (13.2%)	8 (10.8%)	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 2	2 (5.6%)	0	2 (2.7%)	0	0	0
Grade 3	1 (2.8%)	1 (2.6%)	2 (2.7%)	0	1 (2.9%)	1 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Neurological signs and symptoms NEC (cont)						
Dizziness	9 (18.0%)	4 (7.1%)	13 (12.3%)	4 (10.0%)	5 (10.2%)	9 (10.1%)
Grade 1	9 (18.0%)	3 (5.4%)	12 (11.3%)	4 (10.0%)	4 (8.2%)	8 (9.0%)
Grade 2	0	1 (1.8%)	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Grade 3	0	0	0	0	0	0
Presyncope	2 (4.0%)	0	2 (1.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 3	0	0	0	0	0	0
Headaches NEC	6 (12.0%)	9 (16.1%)	15 (14.2%)	1 (2.5%)	0	1 (1.1%)
Grade 1	6 (12.0%)	8 (14.3%)	14 (13.2%)	1 (2.5%)	0	1 (1.1%)
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Neurological signs and symptoms NEC (cont)						
Dizziness	6 (16.7%)	6 (15.8%)	12 (16.2%)	1 (4.2%)	2 (5.7%)	3 (5.1%)
Grade 1	4 (11.1%)	5 (13.2%)	9 (12.2%)	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 2	2 (5.6%)	0	2 (2.7%)	0	0	0
Grade 3	0	1 (2.6%)	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Presyncope	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	1 (2.8%)	0	1 (1.4%)	0	0	0
Headaches NEC	4 (11.1%)	6 (15.8%)	10 (13.5%)	0	2 (5.7%)	2 (3.4%)
Grade 1	1 (2.8%)	4 (10.5%)	5 (6.8%)	0	1 (2.9%)	1 (1.7%)
Grade 2	3 (8.3%)	2 (5.3%)	5 (6.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Headaches NEC (cont)						
(cont)						
Grade 3	0	0	0	0	0	0
Headache	6 (12.0%)	9 (16.1%)	15 (14.2%)	1 (2.5%)	0	1 (1.1%)
Grade 1	6 (12.0%)	8 (14.3%)	14 (13.2%)	1 (2.5%)	0	1 (1.1%)
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 3	0	0	0	0	0	0
Sinus headache	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Peripheral neuropathies NEC	6 (12.0%)	2 (3.6%)	8 (7.5%)	1 (2.5%)	7 (14.3%)	8 (9.0%)
Grade 1	5 (10.0%)	2 (3.6%)	7 (6.6%)	0	3 (6.1%)	3 (3.4%)
Grade 2	1 (2.0%)	0	1 (0.9%)	0	2 (4.1%)	2 (2.2%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Headaches NEC (cont)						
(cont)						
Grade 3	0	0	0	0	1 (2.9%)	1 (1.7%)
Headache	4 (11.1%)	6 (15.8%)	10 (13.5%)	0	1 (2.9%)	1 (1.7%)
Grade 1	1 (2.8%)	4 (10.5%)	5 (6.8%)	0	0	0
Grade 2	3 (8.3%)	2 (5.3%)	5 (6.8%)	0	0	0
Grade 3	0	0	0	0	1 (2.9%)	1 (1.7%)
Sinus headache	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Peripheral neuropathies NEC	4 (11.1%)	3 (7.9%)	7 (9.5%)	1 (4.2%)	2 (5.7%)	3 (5.1%)
Grade 1	2 (5.6%)	2 (5.3%)	4 (5.4%)	1 (4.2%)	2 (5.7%)	3 (5.1%)
Grade 2	2 (5.6%)	1 (2.6%)	3 (4.1%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Peripheral neuropathies NEC (cont)						
(cont)						
Grade 3	0	0	0	1 (2.5%)	2 (4.1%)	3 (3.4%)
Peripheral sensory neuropathy	6 (12.0%)	2 (3.6%)	8 (7.5%)	0	7 (14.3%)	7 (7.9%)
Grade 1	5 (10.0%)	2 (3.6%)	7 (6.6%)	0	3 (6.1%)	3 (3.4%)
Grade 2	1 (2.0%)	0	1 (0.9%)	0	2 (4.1%)	2 (2.2%)
Grade 3	0	0	0	0	2 (4.1%)	2 (2.2%)
Peripheral sensorimotor neuropathy	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 3	0	0	0	1 (2.5%)	0	1 (1.1%)
Paraesthesias and dysaesthesias	4 (8.0%)	2 (3.6%)	6 (5.7%)	4 (10.0%)	2 (4.1%)	6 (6.7%)
Grade 1	4 (8.0%)	2 (3.6%)	6 (5.7%)	3 (7.5%)	1 (2.0%)	4 (4.5%)
Grade 2	0	0	0	1 (2.5%)	1 (2.0%)	2 (2.2%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Peripheral neuropathies NEC (cont)						
(cont)						
Grade 3	0	0	0	0	0	0
Peripheral sensory neuropathy	4 (11.1%)	3 (7.9%)	7 (9.5%)	1 (4.2%)	2 (5.7%)	3 (5.1%)
Grade 1	2 (5.6%)	2 (5.3%)	4 (5.4%)	1 (4.2%)	2 (5.7%)	3 (5.1%)
Grade 2	2 (5.6%)	1 (2.6%)	3 (4.1%)	0	0	0
Grade 3	0	0	0	0	0	0
Peripheral sensorimotor neuropathy	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Paraesthesias and dysaesthesias	3 (8.3%)	1 (2.6%)	4 (5.4%)	0	2 (5.7%)	2 (3.4%)
Grade 1	3 (8.3%)	1 (2.6%)	4 (5.4%)	0	2 (5.7%)	2 (3.4%)
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Paraesthesias and dysaesthesias (cont)						
Paraesthesia	4 (8.0%)	2 (3.6%)	6 (5.7%)	2 (5.0%)	2 (4.1%)	4 (4.5%)
Grade 1	4 (8.0%)	2 (3.6%)	6 (5.7%)	2 (5.0%)	1 (2.0%)	3 (3.4%)
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Dysaesthesia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hypoaesthesia	0	0	0	3 (7.5%)	1 (2.0%)	4 (4.5%)
Grade 1	0	0	0	2 (5.0%)	1 (2.0%)	3 (3.4%)
Grade 2	0	0	0	1 (2.5%)	0	1 (1.1%)
Disturbances in consciousness NEC	2 (4.0%)	1 (1.8%)	3 (2.8%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Paraesthesias and dysaesthesias (cont)						
Paraesthesia	3 (8.3%)	1 (2.6%)	4 (5.4%)	0	1 (2.9%)	1 (1.7%)
Grade 1	3 (8.3%)	1 (2.6%)	4 (5.4%)	0	1 (2.9%)	1 (1.7%)
Grade 2	0	0	0	0	0	0
Dysaesthesia	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Hypoaesthesia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Disturbances in consciousness NEC	2 (5.6%)	0	2 (2.7%)	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 2	1 (2.8%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Disturbances in consciousness NEC (cont)						
(cont)						
Grade 3	1 (2.0%)	0	1 (0.9%)	0	0	0
Syncope	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 3	1 (2.0%)	0	1 (0.9%)	0	0	0
Lethargy	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0
Somnolence	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Coordination and balance disturbances	1 (2.0%)	0	1 (0.9%)	1 (2.5%)	2 (4.1%)	3 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Disturbances in consciousness NEC (cont)						
(cont)						
Grade 3	1 (2.8%)	0	1 (1.4%)	0	0	0
Syncope	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 3	1 (2.8%)	0	1 (1.4%)	0	0	0
Lethargy	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 2	1 (2.8%)	0	1 (1.4%)	0	0	0
Somnolence	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Coordination and balance disturbances	1 (2.8%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Coordination and balance disturbances (cont)						
(cont)						
Grade 1	1 (2.0%)	0	1 (0.9%)	0	2 (4.1%)	2 (2.2%)
Grade 2	0	0	0	1 (2.5%)	0	1 (1.1%)
Balance disorder	1 (2.0%)	0	1 (0.9%)	1 (2.5%)	1 (2.0%)	2 (2.2%)
Grade 1	1 (2.0%)	0	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Grade 2	0	0	0	1 (2.5%)	0	1 (1.1%)
Ataxia	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 1	0	0	0	0	1 (2.0%)	1 (1.1%)
Memory loss (excl dementia)	2 (4.0%)	1 (1.8%)	3 (2.8%)	0	1 (2.0%)	1 (1.1%)
Grade 1	2 (4.0%)	1 (1.8%)	3 (2.8%)	0	1 (2.0%)	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Coordination and balance disturbances (cont)						
(cont)						
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 2	0	0	0	0	0	0
Balance disorder	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 2	0	0	0	0	0	0
Ataxia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Memory loss (excl dementia)	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Memory loss (excl dementia) (cont)						
Amnesia	1 (2.0%)	0	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Grade 1	1 (2.0%)	0	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Memory impairment	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	0	0
Grade 1	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	0	0
Sensory abnormalities NEC	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Taste disorder	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Ageusia	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Memory loss (excl dementia) (cont)						
Amnesia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Memory impairment	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Sensory abnormalities NEC	1 (2.8%)	1 (2.6%)	2 (2.7%)	0	2 (5.7%)	2 (3.4%)
Grade 1	1 (2.8%)	0	1 (1.4%)	0	2 (5.7%)	2 (3.4%)
Grade 2	0	1 (2.6%)	1 (1.4%)	0	0	0
Taste disorder	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0
Ageusia	0	0	0	0	1 (2.9%)	1 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Sensory abnormalities NEC (cont)						
Ageusia (cont)						
Grade 1	0	0	0	0	0	0
Dysgeusia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Post herpetic neuralgia	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Central nervous system haemorrhages and cerebrovascular accidents	1 (2.0%)	0	1 (0.9%)	1 (2.5%)	0	1 (1.1%)
Grade 2	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 4	0	0	0	1 (2.5%)	0	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Sensory abnormalities NEC (cont)						
Ageusia (cont)						
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Dysgeusia	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Post herpetic neuralgia	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 2	0	1 (2.6%)	1 (1.4%)	0	0	0
Central nervous system haemorrhages and cerebrovascular accidents	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Central nervous system haemorrhages and cerebrovascular accidents (cont)						
Cerebral ischaemia	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	1 (2.0%)	0	1 (0.9%)	0	0	0
Cerebrovascular accident	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 4	0	0	0	1 (2.5%)	0	1 (1.1%)
Tremor (excl congenital)	1 (2.0%)	0	1 (0.9%)	1 (2.5%)	0	1 (1.1%)
Grade 1	1 (2.0%)	0	1 (0.9%)	1 (2.5%)	0	1 (1.1%)
Tremor	1 (2.0%)	0	1 (0.9%)	1 (2.5%)	0	1 (1.1%)
Grade 1	1 (2.0%)	0	1 (0.9%)	1 (2.5%)	0	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Central nervous system haemorrhages and cerebrovascular accidents (cont)						
Cerebral ischaemia	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Cerebrovascular accident	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Tremor (excl congenital)	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (2.6%)	1 (1.4%)	0	0	0
Tremor	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (2.6%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Central nervous system vascular disorders NEC	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 1	0	0	0	1 (2.5%)	0	1 (1.1%)
Cerebral microangiopathy	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 1	0	0	0	1 (2.5%)	0	1 (1.1%)
Coma states	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 5	0	1 (1.8%)	1 (0.9%)	0	0	0
Coma	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 5	0	1 (1.8%)	1 (0.9%)	0	0	0
Demyelinating disorders NEC	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 1	0	0	0	0	1 (2.0%)	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Central nervous system vascular disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Cerebral microangiopathy	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Coma states	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Coma	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Demyelinating disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Demyelinating disorders NEC (cont)						
Demyelination	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 1	0	0	0	0	1 (2.0%)	1 (1.1%)
Encephalopathies NEC	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 4	0	1 (1.8%)	1 (0.9%)	0	0	0
Encephalopathy	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 4	0	1 (1.8%)	1 (0.9%)	0	0	0
Lumbar spinal cord and nerve root disorders	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Sciatica	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Demyelinating disorders NEC (cont)						
Demyelination	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Encephalopathies NEC	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Encephalopathy	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Lumbar spinal cord and nerve root disorders	0	1 (2.6%)	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Grade 2	0	1 (2.6%)	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Sciatica	0	1 (2.6%)	1 (1.4%)	0	1 (2.9%)	1 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Lumbar spinal cord and nerve root disorders (cont)						
Sciatica (cont)						
Grade 2	0	0	0	0	0	0
Transient cerebrovascular events	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Transient ischaemic attack	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Lumbar spinal cord and nerve root disorders (cont)						
Sciatica (cont)						
Grade 2	0	1 (2.6%)	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Transient cerebrovascular events	0	1 (2.6%)	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Grade 1	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 3	0	0	0	0	1 (2.9%)	1 (1.7%)
Transient ischaemic attack	0	1 (2.6%)	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Grade 1	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 3	0	0	0	0	1 (2.9%)	1 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders	22 (44.0%)	36 (64.3%)	58 (54.7%)	8 (20.0%)	15 (30.6%)	23 (25.8%)
Grade 1	6 (12.0%)	4 (7.1%)	10 (9.4%)	3 (7.5%)	1 (2.0%)	4 (4.5%)
Grade 2	5 (10.0%)	10 (17.9%)	15 (14.2%)	0	6 (12.2%)	6 (6.7%)
Grade 3	9 (18.0%)	16 (28.6%)	25 (23.6%)	5 (12.5%)	6 (12.2%)	11 (12.4%)
Grade 4	2 (4.0%)	6 (10.7%)	8 (7.5%)	0	1 (2.0%)	1 (1.1%)
Grade 5	0	0	0	0	1 (2.0%)	1 (1.1%)
Thrombocytopenias	11 (22.0%)	21 (37.5%)	32 (30.2%)	6 (15.0%)	6 (12.2%)	12 (13.5%)
Grade 1	3 (6.0%)	8 (14.3%)	11 (10.4%)	3 (7.5%)	0	3 (3.4%)
Grade 2	2 (4.0%)	9 (16.1%)	11 (10.4%)	0	3 (6.1%)	3 (3.4%)
Grade 3	4 (8.0%)	2 (3.6%)	6 (5.7%)	3 (7.5%)	2 (4.1%)	5 (5.6%)
Grade 4	2 (4.0%)	2 (3.6%)	4 (3.8%)	0	1 (2.0%)	1 (1.1%)
Thrombocytopenia	11 (22.0%)	21 (37.5%)	32 (30.2%)	6 (15.0%)	6 (12.2%)	12 (13.5%)
Grade 1	3 (6.0%)	8 (14.3%)	11 (10.4%)	3 (7.5%)	0	3 (3.4%)
Grade 2	2 (4.0%)	9 (16.1%)	11 (10.4%)	0	3 (6.1%)	3 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders	13 (36.1%)	22 (57.9%)	35 (47.3%)	2 (8.3%)	8 (22.9%)	10 (16.9%)
Grade 1	1 (2.8%)	4 (10.5%)	5 (6.8%)	0	2 (5.7%)	2 (3.4%)
Grade 2	4 (11.1%)	7 (18.4%)	11 (14.9%)	0	1 (2.9%)	1 (1.7%)
Grade 3	7 (19.4%)	8 (21.1%)	15 (20.3%)	1 (4.2%)	4 (11.4%)	5 (8.5%)
Grade 4	1 (2.8%)	3 (7.9%)	4 (5.4%)	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 5	0	0	0	0	0	0
Thrombocytopenias	8 (22.2%)	11 (28.9%)	19 (25.7%)	1 (4.2%)	5 (14.3%)	6 (10.2%)
Grade 1	1 (2.8%)	5 (13.2%)	6 (8.1%)	0	1 (2.9%)	1 (1.7%)
Grade 2	4 (11.1%)	4 (10.5%)	8 (10.8%)	0	2 (5.7%)	2 (3.4%)
Grade 3	2 (5.6%)	2 (5.3%)	4 (5.4%)	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 4	1 (2.8%)	0	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Thrombocytopenia	8 (22.2%)	11 (28.9%)	19 (25.7%)	1 (4.2%)	5 (14.3%)	6 (10.2%)
Grade 1	1 (2.8%)	5 (13.2%)	6 (8.1%)	0	1 (2.9%)	1 (1.7%)
Grade 2	4 (11.1%)	4 (10.5%)	8 (10.8%)	0	2 (5.7%)	2 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Thrombocytopenias (cont)						
Thrombocytopenia (cont)						
Grade 3	4 (8.0%)	2 (3.6%)	6 (5.7%)	3 (7.5%)	2 (4.1%)	5 (5.6%)
Grade 4	2 (4.0%)	2 (3.6%)	4 (3.8%)	0	1 (2.0%)	1 (1.1%)
Anaemias NEC	7 (14.0%)	22 (39.3%)	29 (27.4%)	0	5 (10.2%)	5 (5.6%)
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 2	3 (6.0%)	4 (7.1%)	7 (6.6%)	0	3 (6.1%)	3 (3.4%)
Grade 3	4 (8.0%)	14 (25.0%)	18 (17.0%)	0	2 (4.1%)	2 (2.2%)
Grade 4	0	3 (5.4%)	3 (2.8%)	0	0	0
Anaemia	7 (14.0%)	22 (39.3%)	29 (27.4%)	0	5 (10.2%)	5 (5.6%)
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 2	3 (6.0%)	4 (7.1%)	7 (6.6%)	0	3 (6.1%)	3 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Thrombocytopenias (cont)						
Thrombocytopenia (cont)						
Grade 3	2 (5.6%)	2 (5.3%)	4 (5.4%)	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 4	1 (2.8%)	0	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Anaemias NEC	7 (19.4%)	14 (36.8%)	21 (28.4%)	2 (8.3%)	3 (8.6%)	5 (8.5%)
Grade 1	0	2 (5.3%)	2 (2.7%)	0	1 (2.9%)	1 (1.7%)
Grade 2	1 (2.8%)	3 (7.9%)	4 (5.4%)	0	0	0
Grade 3	6 (16.7%)	7 (18.4%)	13 (17.6%)	1 (4.2%)	2 (5.7%)	3 (5.1%)
Grade 4	0	2 (5.3%)	2 (2.7%)	1 (4.2%)	0	1 (1.7%)
Anaemia	7 (19.4%)	14 (36.8%)	21 (28.4%)	2 (8.3%)	3 (8.6%)	5 (8.5%)
Grade 1	0	2 (5.3%)	2 (2.7%)	0	1 (2.9%)	1 (1.7%)
Grade 2	1 (2.8%)	3 (7.9%)	4 (5.4%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Anaemias NEC (cont)						
Anaemia (cont)						
Grade 3	4 (8.0%)	14 (25.0%)	18 (17.0%)	0	2 (4.1%)	2 (2.2%)
Grade 4	0	3 (5.4%)	3 (2.8%)	0	0	0
Neutropenias	4 (8.0%)	6 (10.7%)	10 (9.4%)	1 (2.5%)	1 (2.0%)	2 (2.2%)
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	2 (4.0%)	4 (7.1%)	6 (5.7%)	1 (2.5%)	1 (2.0%)	2 (2.2%)
Grade 4	1 (2.0%)	2 (3.6%)	3 (2.8%)	0	0	0
Neutropenia	3 (6.0%)	6 (10.7%)	9 (8.5%)	1 (2.5%)	1 (2.0%)	2 (2.2%)
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Anaemias NEC (cont)						
Anaemia (cont)						
Grade 3	6 (16.7%)	7 (18.4%)	13 (17.6%)	1 (4.2%)	2 (5.7%)	3 (5.1%)
Grade 4	0	2 (5.3%)	2 (2.7%)	1 (4.2%)	0	1 (1.7%)
Neutropenias	1 (2.8%)	3 (7.9%)	4 (5.4%)	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 1	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 2	0	2 (5.3%)	2 (2.7%)	0	0	0
Grade 3	1 (2.8%)	0	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Grade 4	0	1 (2.6%)	1 (1.4%)	0	0	0
Neutropenia	1 (2.8%)	3 (7.9%)	4 (5.4%)	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 1	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 2	0	2 (5.3%)	2 (2.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Neutropenias (cont)						
Neutropenia (cont)						
Grade 3	1 (2.0%)	4 (7.1%)	5 (4.7%)	1 (2.5%)	1 (2.0%)	2 (2.2%)
Grade 4	1 (2.0%)	2 (3.6%)	3 (2.8%)	0	0	0
Febrile neutropenia	1 (2.0%)	0	1 (0.9%)	1 (2.5%)	0	1 (1.1%)
Grade 3	1 (2.0%)	0	1 (0.9%)	1 (2.5%)	0	1 (1.1%)
Leukopenias NEC	2 (4.0%)	0	2 (1.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 3	1 (2.0%)	0	1 (0.9%)	0	0	0
Leukopenia	2 (4.0%)	0	2 (1.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Neutropenias (cont)						
Neutropenia (cont)						
Grade 3	1 (2.8%)	0	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Grade 4	0	1 (2.6%)	1 (1.4%)	0	0	0
Febrile neutropenia	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Leukopenias NEC	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 3	0	0	0	0	0	0
Leukopenia	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (2.6%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Leukopenias NEC (cont)						
Leukopenia (cont)						
Grade 3	1 (2.0%)	0	1 (0.9%)	0	0	0
Bleeding tendencies	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Increased tendency to bruise	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Coagulation factor deficiencies	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Hypoprothrombinaemia	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Leukopenias NEC (cont)						
Leukopenia (cont)						
Grade 3	0	0	0	0	0	0
Bleeding tendencies	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Increased tendency to bruise	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Coagulation factor deficiencies	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 2	1 (2.8%)	0	1 (1.4%)	0	0	0
Hypoprothrombinaemia	1 (2.8%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Coagulation factor deficiencies (cont)						
Hypoprothrombinaemia (cont)						
Grade 2	0	0	0	0	0	0
Leukocytoses NEC	1 (2.0%)	0	1 (0.9%)	1 (2.5%)	2 (4.1%)	3 (3.4%)
Grade 1	1 (2.0%)	0	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 3	0	0	0	1 (2.5%)	0	1 (1.1%)
Leukocytosis	1 (2.0%)	0	1 (0.9%)	1 (2.5%)	2 (4.1%)	3 (3.4%)
Grade 1	1 (2.0%)	0	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 3	0	0	0	1 (2.5%)	0	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Coagulation factor deficiencies (cont)						
Hypoprothrombinaemia (cont)						
Grade 2	1 (2.8%)	0	1 (1.4%)	0	0	0
Leukocytoses NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Leukocytosis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Leukocytoses NEC (cont)						
Neutrophilia	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 1	0	0	0	0	1 (2.0%)	1 (1.1%)
Spleen disorders	1 (2.0%)	0	1 (0.9%)	1 (2.5%)	1 (2.0%)	2 (2.2%)
Grade 3	1 (2.0%)	0	1 (0.9%)	1 (2.5%)	0	1 (1.1%)
Grade 5	0	0	0	0	1 (2.0%)	1 (1.1%)
Splenomegaly	1 (2.0%)	0	1 (0.9%)	1 (2.5%)	0	1 (1.1%)
Grade 3	1 (2.0%)	0	1 (0.9%)	1 (2.5%)	0	1 (1.1%)
Splenic haematoma	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 5	0	0	0	0	1 (2.0%)	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Leukocytoses NEC (cont)						
Neutrophilia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Spleen disorders	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Splenomegaly	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Splenic haematoma	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Thrombocytoses	0	1 (1.8%)	1 (0.9%)	0	2 (4.1%)	2 (2.2%)
Grade 1	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 3	0	0	0	0	1 (2.0%)	1 (1.1%)
Thrombocytosis	0	1 (1.8%)	1 (0.9%)	0	2 (4.1%)	2 (2.2%)
Grade 1	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 3	0	0	0	0	1 (2.0%)	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Thrombocytoses	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Thrombocytosis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders	24 (48.0%)	21 (37.5%)	45 (42.5%)	10 (25.0%)	14 (28.6%)	24 (27.0%)
Grade 1	16 (32.0%)	13 (23.2%)	29 (27.4%)	7 (17.5%)	6 (12.2%)	13 (14.6%)
Grade 2	4 (8.0%)	6 (10.7%)	10 (9.4%)	3 (7.5%)	7 (14.3%)	10 (11.2%)
Grade 3	2 (4.0%)	1 (1.8%)	3 (2.8%)	0	1 (2.0%)	1 (1.1%)
Grade 4	2 (4.0%)	1 (1.8%)	3 (2.8%)	0	0	0
Breathing abnormalities	14 (28.0%)	8 (14.3%)	22 (20.8%)	0	3 (6.1%)	3 (3.4%)
Grade 1	12 (24.0%)	2 (3.6%)	14 (13.2%)	0	1 (2.0%)	1 (1.1%)
Grade 2	2 (4.0%)	5 (8.9%)	7 (6.6%)	0	1 (2.0%)	1 (1.1%)
Grade 3	0	1 (1.8%)	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Dyspnoea	10 (20.0%)	5 (8.9%)	15 (14.2%)	0	3 (6.1%)	3 (3.4%)
Grade 1	8 (16.0%)	0	8 (7.5%)	0	1 (2.0%)	1 (1.1%)
Grade 2	2 (4.0%)	4 (7.1%)	6 (5.7%)	0	1 (2.0%)	1 (1.1%)
Grade 3	0	1 (1.8%)	1 (0.9%)	0	1 (2.0%)	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders	8 (22.2%)	6 (15.8%)	14 (18.9%)	4 (16.7%)	5 (14.3%)	9 (15.3%)
Grade 1	7 (19.4%)	4 (10.5%)	11 (14.9%)	1 (4.2%)	4 (11.4%)	5 (8.5%)
Grade 2	1 (2.8%)	2 (5.3%)	3 (4.1%)	3 (12.5%)	0	3 (5.1%)
Grade 3	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 4	0	0	0	0	0	0
Breathing abnormalities	2 (5.6%)	3 (7.9%)	5 (6.8%)	0	1 (2.9%)	1 (1.7%)
Grade 1	2 (5.6%)	2 (5.3%)	4 (5.4%)	0	0	0
Grade 2	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 3	0	0	0	0	1 (2.9%)	1 (1.7%)
Dyspnoea	1 (2.8%)	3 (7.9%)	4 (5.4%)	0	1 (2.9%)	1 (1.7%)
Grade 1	1 (2.8%)	2 (5.3%)	3 (4.1%)	0	0	0
Grade 2	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 3	0	0	0	0	1 (2.9%)	1 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Breathing abnormalities (cont)						
Dyspnoea exertional	4 (8.0%)	4 (7.1%)	8 (7.5%)	0	0	0
Grade 1	4 (8.0%)	3 (5.4%)	7 (6.6%)	0	0	0
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0
Coughing and associated symptoms	9 (18.0%)	10 (17.9%)	19 (17.9%)	5 (12.5%)	7 (14.3%)	12 (13.5%)
Grade 1	7 (14.0%)	9 (16.1%)	16 (15.1%)	4 (10.0%)	4 (8.2%)	8 (9.0%)
Grade 2	2 (4.0%)	1 (1.8%)	3 (2.8%)	1 (2.5%)	3 (6.1%)	4 (4.5%)
Cough	8 (16.0%)	9 (16.1%)	17 (16.0%)	5 (12.5%)	7 (14.3%)	12 (13.5%)
Grade 1	7 (14.0%)	8 (14.3%)	15 (14.2%)	4 (10.0%)	4 (8.2%)	8 (9.0%)
Grade 2	1 (2.0%)	1 (1.8%)	2 (1.9%)	1 (2.5%)	3 (6.1%)	4 (4.5%)
Haemoptysis	1 (2.0%)	0	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Breathing abnormalities (cont)						
Dyspnoea exertional	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 2	0	0	0	0	0	0
Coughing and associated symptoms	4 (11.1%)	0	4 (5.4%)	3 (12.5%)	3 (8.6%)	6 (10.2%)
Grade 1	3 (8.3%)	0	3 (4.1%)	2 (8.3%)	3 (8.6%)	5 (8.5%)
Grade 2	1 (2.8%)	0	1 (1.4%)	1 (4.2%)	0	1 (1.7%)
Cough	4 (11.1%)	0	4 (5.4%)	2 (8.3%)	3 (8.6%)	5 (8.5%)
Grade 1	3 (8.3%)	0	3 (4.1%)	2 (8.3%)	3 (8.6%)	5 (8.5%)
Grade 2	1 (2.8%)	0	1 (1.4%)	0	0	0
Haemoptysis	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Coughing and associated symptoms (cont)						
Haemoptysis (cont)						
Grade 2	1 (2.0%)	0	1 (0.9%)	0	0	0
Productive cough	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	0	0
Grade 1	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Nasal disorders NEC	2 (4.0%)	3 (5.4%)	5 (4.7%)	3 (7.5%)	1 (2.0%)	4 (4.5%)
Grade 1	0	2 (3.6%)	2 (1.9%)	2 (5.0%)	0	2 (2.2%)
Grade 2	2 (4.0%)	1 (1.8%)	3 (2.8%)	1 (2.5%)	1 (2.0%)	2 (2.2%)
Epistaxis	2 (4.0%)	3 (5.4%)	5 (4.7%)	3 (7.5%)	1 (2.0%)	4 (4.5%)
Grade 1	0	2 (3.6%)	2 (1.9%)	2 (5.0%)	0	2 (2.2%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Coughing and associated symptoms (cont)						
Haemoptysis (cont)						
Grade 2	0	0	0	0	0	0
Productive cough	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	1 (4.2%)	0	1 (1.7%)
Nasal disorders NEC	2 (5.6%)	2 (5.3%)	4 (5.4%)	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 1	2 (5.6%)	1 (2.6%)	3 (4.1%)	0	1 (2.9%)	1 (1.7%)
Grade 2	0	1 (2.6%)	1 (1.4%)	1 (4.2%)	0	1 (1.7%)
Epistaxis	2 (5.6%)	2 (5.3%)	4 (5.4%)	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 1	2 (5.6%)	1 (2.6%)	3 (4.1%)	0	1 (2.9%)	1 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Nasal disorders NEC (cont)						
Epistaxis (cont)						
Grade 2	2 (4.0%)	1 (1.8%)	3 (2.8%)	1 (2.5%)	1 (2.0%)	2 (2.2%)
Upper respiratory tract signs and symptoms	3 (6.0%)	2 (3.6%)	5 (4.7%)	0	2 (4.1%)	2 (2.2%)
Grade 1	3 (6.0%)	2 (3.6%)	5 (4.7%)	0	1 (2.0%)	1 (1.1%)
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Dysphonia	1 (2.0%)	0	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Rhinorrhoea	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Nasal disorders NEC (cont)						
Epistaxis (cont)						
Grade 2	0	1 (2.6%)	1 (1.4%)	1 (4.2%)	0	1 (1.7%)
Upper respiratory tract signs and symptoms	1 (2.8%)	1 (2.6%)	2 (2.7%)	1 (4.2%)	0	1 (1.7%)
Grade 1	1 (2.8%)	1 (2.6%)	2 (2.7%)	1 (4.2%)	0	1 (1.7%)
Grade 2	0	0	0	0	0	0
Dysphonia	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 2	0	0	0	0	0	0
Rhinorrhoea	0	0	0	1 (4.2%)	0	1 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Upper respiratory tract signs and symptoms (cont)						
Rhinorrhoea (cont)						
Grade 1	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	0	0
Throat tightness	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Catarrh	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Oropharyngeal pain	0	1 (1.8%)	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Grade 1	0	1 (1.8%)	1 (0.9%)	0	1 (2.0%)	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Upper respiratory tract signs and symptoms (cont)						
Rhinorrhoea (cont)						
Grade 1	0	0	0	1 (4.2%)	0	1 (1.7%)
Throat tightness	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Catarrh	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (2.6%)	1 (1.4%)	0	0	0
Oropharyngeal pain	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Lower respiratory tract signs and symptoms	2 (4.0%)	1 (1.8%)	3 (2.8%)	1 (2.5%)	0	1 (1.1%)
Grade 1	1 (2.0%)	1 (1.8%)	2 (1.9%)	1 (2.5%)	0	1 (1.1%)
Grade 2	1 (2.0%)	0	1 (0.9%)	0	0	0
Rales	2 (4.0%)	0	2 (1.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	1 (2.0%)	0	1 (0.9%)	0	0	0
Hiccups	0	1 (1.8%)	1 (0.9%)	1 (2.5%)	0	1 (1.1%)
Grade 1	0	1 (1.8%)	1 (0.9%)	1 (2.5%)	0	1 (1.1%)
Bronchospasm and obstruction	1 (2.0%)	0	1 (0.9%)	2 (5.0%)	1 (2.0%)	3 (3.4%)
Grade 1	0	0	0	2 (5.0%)	0	2 (2.2%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Lower respiratory tract signs and symptoms	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Rales	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Hiccups	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Bronchospasm and obstruction	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

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Adverse events were mapped according to MedDRA Version 22.0
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SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Bronchospasm and obstruction (cont)						
(cont)						
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 3	1 (2.0%)	0	1 (0.9%)	0	0	0
Chronic obstructive pulmonary disease	1 (2.0%)	0	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 3	1 (2.0%)	0	1 (0.9%)	0	0	0
Bronchitis chronic	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 1	0	0	0	1 (2.5%)	0	1 (1.1%)
Wheezing	0	0	0	1 (2.5%)	0	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Bronchospasm and obstruction (cont) (cont)						
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Chronic obstructive pulmonary disease	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Bronchitis chronic	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Wheezing	0	0	0	0	0	0

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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Bronchospasm and obstruction (cont)						
Wheezing (cont)						
Grade 1	0	0	0	1 (2.5%)	0	1 (1.1%)
Conditions associated with abnormal gas exchange	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 4	1 (2.0%)	0	1 (0.9%)	0	0	0
Hypoxia	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 4	1 (2.0%)	0	1 (0.9%)	0	0	0
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)	1 (2.0%)	0	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Grade 2	1 (2.0%)	0	1 (0.9%)	0	1 (2.0%)	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
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Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Bronchospasm and obstruction (cont)						
Wheezing (cont)						
Grade 1	0	0	0	0	0	0
Conditions associated with abnormal gas exchange	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Hypoxia	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms) (cont)						
Reflux laryngitis	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	1 (2.0%)	0	1 (0.9%)	0	0	0
Laryngeal inflammation	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Lower respiratory tract inflammatory and immunologic conditions	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 3	1 (2.0%)	0	1 (0.9%)	0	0	0
Pneumonia aspiration	1 (2.0%)	0	1 (0.9%)	0	0	0

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Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms) (cont)						
Reflux laryngitis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Laryngeal inflammation	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Lower respiratory tract inflammatory and immunologic conditions	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Pneumonia aspiration	0	0	0	0	0	0

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	Male					
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Lower respiratory tract inflammatory and immunologic conditions (cont)						
Pneumonia aspiration (cont)						
Grade 3	1 (2.0%)	0	1 (0.9%)	0	0	0
Pharyngeal disorders (excl infections and neoplasms)	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 3	1 (2.0%)	0	1 (0.9%)	0	0	0
Pharyngeal ulceration	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 3	1 (2.0%)	0	1 (0.9%)	0	0	0
Respiratory failures (excl neonatal)	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Lower respiratory tract inflammatory and immunologic conditions (cont)						
Pneumonia aspiration (cont)						
Grade 3	0	0	0	0	0	0
Pharyngeal disorders (excl infections and neoplasms)	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Pharyngeal ulceration	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Respiratory failures (excl neonatal)	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 3	0	0	0	0	1 (2.9%)	1 (1.7%)

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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Respiratory failures (excl neonatal) (cont) (cont)						
Grade 4	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	0	0
Respiratory failure	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 3	0	0	0	0	0	0
Grade 4	1 (2.0%)	0	1 (0.9%)	0	0	0
Acute respiratory failure	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 4	0	1 (1.8%)	1 (0.9%)	0	0	0
Parenchymal lung disorders NEC	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 1	0	0	0	1 (2.5%)	0	1 (1.1%)

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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Respiratory failures (excl neonatal) (cont) (cont)						
Grade 4	0	0	0	0	0	0
Respiratory failure	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 3	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 4	0	0	0	0	0	0
Acute respiratory failure	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Parenchymal lung disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Parenchymal lung disorders NEC (cont)						
Emphysema	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 1	0	0	0	1 (2.5%)	0	1 (1.1%)
Pleural infections and inflammations	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 1	0	0	0	0	1 (2.0%)	1 (1.1%)
Pleurisy	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 1	0	0	0	0	1 (2.0%)	1 (1.1%)
Pneumothorax and pleural effusions NEC	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Pleural effusion	0	0	0	0	0	0

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Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Parenchymal lung disorders NEC (cont)						
Emphysema	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Pleural infections and inflammations	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Pleurisy	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Pneumothorax and pleural effusions NEC	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 3	0	0	0	0	1 (2.9%)	1 (1.7%)
Pleural effusion	0	0	0	0	1 (2.9%)	1 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Pneumothorax and pleural effusions NEC (cont)						
Pleural effusion (cont)						
Grade 3	0	0	0	0	0	0
Pulmonary oedemas	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Pulmonary oedema	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Pulmonary thrombotic and embolic conditions	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 2	0	0	0	1 (2.5%)	0	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Pneumothorax and pleural effusions NEC (cont)						
Pleural effusion (cont)						
Grade 3	0	0	0	0	1 (2.9%)	1 (1.7%)
Pulmonary oedemas	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 2	0	0	0	1 (4.2%)	0	1 (1.7%)
Pulmonary oedema	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 2	0	0	0	1 (4.2%)	0	1 (1.7%)
Pulmonary thrombotic and embolic conditions	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Pulmonary thrombotic and embolic conditions (cont)						
Pulmonary embolism	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 2	0	0	0	1 (2.5%)	0	1 (1.1%)
Respiratory tract disorders NEC	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Lung disorder	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Pulmonary thrombotic and embolic conditions (cont)						
Pulmonary embolism	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Respiratory tract disorders NEC	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Lung disorder	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders	19 (38.0%)	13 (23.2%)	32 (30.2%)	6 (15.0%)	18 (36.7%)	24 (27.0%)
Grade 1	10 (20.0%)	5 (8.9%)	15 (14.2%)	3 (7.5%)	9 (18.4%)	12 (13.5%)
Grade 2	4 (8.0%)	5 (8.9%)	9 (8.5%)	2 (5.0%)	7 (14.3%)	9 (10.1%)
Grade 3	4 (8.0%)	2 (3.6%)	6 (5.7%)	1 (2.5%)	0	1 (1.1%)
Grade 4	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	2 (4.1%)	2 (2.2%)
Potassium imbalance	5 (10.0%)	2 (3.6%)	7 (6.6%)	1 (2.5%)	3 (6.1%)	4 (4.5%)
Grade 1	1 (2.0%)	0	1 (0.9%)	0	2 (4.1%)	2 (2.2%)
Grade 2	2 (4.0%)	0	2 (1.9%)	0	1 (2.0%)	1 (1.1%)
Grade 3	2 (4.0%)	1 (1.8%)	3 (2.8%)	1 (2.5%)	0	1 (1.1%)
Grade 4	0	1 (1.8%)	1 (0.9%)	0	0	0
Hyperkalaemia	4 (8.0%)	1 (1.8%)	5 (4.7%)	1 (2.5%)	1 (2.0%)	2 (2.2%)
Grade 1	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 2	2 (4.0%)	0	2 (1.9%)	0	0	0
Grade 3	2 (4.0%)	1 (1.8%)	3 (2.8%)	1 (2.5%)	0	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders	8 (22.2%)	7 (18.4%)	15 (20.3%)	4 (16.7%)	5 (14.3%)	9 (15.3%)
Grade 1	1 (2.8%)	2 (5.3%)	3 (4.1%)	0	3 (8.6%)	3 (5.1%)
Grade 2	4 (11.1%)	4 (10.5%)	8 (10.8%)	3 (12.5%)	1 (2.9%)	4 (6.8%)
Grade 3	2 (5.6%)	1 (2.6%)	3 (4.1%)	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 4	1 (2.8%)	0	1 (1.4%)	0	0	0
Potassium imbalance	2 (5.6%)	2 (5.3%)	4 (5.4%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	2 (5.6%)	1 (2.6%)	3 (4.1%)	0	0	0
Grade 3	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 4	0	0	0	0	0	0
Hyperkalaemia	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	1 (2.6%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Potassium imbalance (cont)						
Hypokalaemia	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	2 (4.1%)	2 (2.2%)
Grade 1	1 (2.0%)	0	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 4	0	1 (1.8%)	1 (0.9%)	0	0	0
Disorders of purine metabolism	5 (10.0%)	2 (3.6%)	7 (6.6%)	0	4 (8.2%)	4 (4.5%)
Grade 1	3 (6.0%)	0	3 (2.8%)	0	2 (4.1%)	2 (2.2%)
Grade 2	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	0	0
Grade 3	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 4	1 (2.0%)	0	1 (0.9%)	0	2 (4.1%)	2 (2.2%)
Hyperuricaemia	4 (8.0%)	2 (3.6%)	6 (5.7%)	0	4 (8.2%)	4 (4.5%)
Grade 1	3 (6.0%)	0	3 (2.8%)	0	2 (4.1%)	2 (2.2%)
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Potassium imbalance (cont)						
Hypokalaemia	2 (5.6%)	1 (2.6%)	3 (4.1%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	2 (5.6%)	1 (2.6%)	3 (4.1%)	0	0	0
Grade 4	0	0	0	0	0	0
Disorders of purine metabolism	1 (2.8%)	1 (2.6%)	2 (2.7%)	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 1	0	1 (2.6%)	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 4	1 (2.8%)	0	1 (1.4%)	0	0	0
Hyperuricaemia	1 (2.8%)	1 (2.6%)	2 (2.7%)	0	1 (2.9%)	1 (1.7%)
Grade 1	0	1 (2.6%)	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Disorders of purine metabolism (cont)						
Hyperuricaemia (cont)						
Grade 3	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 4	1 (2.0%)	0	1 (0.9%)	0	2 (4.1%)	2 (2.2%)
Gout	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 3	0	0	0	0	0	0
Water soluble vitamin deficiencies	4 (8.0%)	5 (8.9%)	9 (8.5%)	3 (7.5%)	3 (6.1%)	6 (6.7%)
Grade 1	3 (6.0%)	3 (5.4%)	6 (5.7%)	1 (2.5%)	3 (6.1%)	4 (4.5%)
Grade 2	1 (2.0%)	2 (3.6%)	3 (2.8%)	2 (5.0%)	0	2 (2.2%)
Vitamin B1 deficiency	3 (6.0%)	5 (8.9%)	8 (7.5%)	3 (7.5%)	3 (6.1%)	6 (6.7%)
Grade 1	2 (4.0%)	3 (5.4%)	5 (4.7%)	1 (2.5%)	3 (6.1%)	4 (4.5%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Disorders of purine metabolism (cont)						
Hyperuricaemia (cont)						
Grade 3	0	0	0	0	0	0
Grade 4	1 (2.8%)	0	1 (1.4%)	0	0	0
Gout	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	1 (4.2%)	0	1 (1.7%)
Water soluble vitamin deficiencies	2 (5.6%)	2 (5.3%)	4 (5.4%)	1 (4.2%)	2 (5.7%)	3 (5.1%)
Grade 1	0	2 (5.3%)	2 (2.7%)	0	1 (2.9%)	1 (1.7%)
Grade 2	2 (5.6%)	0	2 (2.7%)	1 (4.2%)	1 (2.9%)	2 (3.4%)
Vitamin B1 deficiency	2 (5.6%)	1 (2.6%)	3 (4.1%)	1 (4.2%)	2 (5.7%)	3 (5.1%)
Grade 1	0	1 (2.6%)	1 (1.4%)	0	1 (2.9%)	1 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
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Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Water soluble vitamin deficiencies (cont)						
Vitamin B1 deficiency (cont)						
Grade 2	1 (2.0%)	2 (3.6%)	3 (2.8%)	2 (5.0%)	0	2 (2.2%)
Vitamin B complex deficiency	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Magnesium metabolism disorders	3 (6.0%)	0	3 (2.8%)	0	0	0
Grade 1	3 (6.0%)	0	3 (2.8%)	0	0	0
Grade 2	0	0	0	0	0	0
Hypomagnesaemia	3 (6.0%)	0	3 (2.8%)	0	0	0
Grade 1	3 (6.0%)	0	3 (2.8%)	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Water soluble vitamin deficiencies (cont)						
Vitamin B1 deficiency (cont)						
Grade 2	2 (5.6%)	0	2 (2.7%)	1 (4.2%)	1 (2.9%)	2 (3.4%)
Vitamin B complex deficiency	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (2.6%)	1 (1.4%)	0	0	0
Magnesium metabolism disorders	2 (5.6%)	0	2 (2.7%)	0	0	0
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 2	1 (2.8%)	0	1 (1.4%)	0	0	0
Hypomagnesaemia	2 (5.6%)	0	2 (2.7%)	0	0	0
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 2	1 (2.8%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Appetite disorders	4 (8.0%)	5 (8.9%)	9 (8.5%)	2 (5.0%)	4 (8.2%)	6 (6.7%)
Grade 1	3 (6.0%)	3 (5.4%)	6 (5.7%)	2 (5.0%)	2 (4.1%)	4 (4.5%)
Grade 2	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	2 (4.1%)	2 (2.2%)
Grade 3	0	1 (1.8%)	1 (0.9%)	0	0	0
Decreased appetite	4 (8.0%)	5 (8.9%)	9 (8.5%)	2 (5.0%)	4 (8.2%)	6 (6.7%)
Grade 1	3 (6.0%)	3 (5.4%)	6 (5.7%)	2 (5.0%)	2 (4.1%)	4 (4.5%)
Grade 2	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	2 (4.1%)	2 (2.2%)
Grade 3	0	1 (1.8%)	1 (0.9%)	0	0	0
Calcium metabolism disorders	1 (2.0%)	0	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Grade 2	1 (2.0%)	0	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Hypocalcaemia	1 (2.0%)	0	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Grade 2	1 (2.0%)	0	1 (0.9%)	0	1 (2.0%)	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Appetite disorders	0	1 (2.6%)	1 (1.4%)	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 2	0	1 (2.6%)	1 (1.4%)	1 (4.2%)	0	1 (1.7%)
Grade 3	0	0	0	0	0	0
Decreased appetite	0	1 (2.6%)	1 (1.4%)	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 2	0	1 (2.6%)	1 (1.4%)	1 (4.2%)	0	1 (1.7%)
Grade 3	0	0	0	0	0	0
Calcium metabolism disorders	2 (5.6%)	0	2 (2.7%)	0	0	0
Grade 2	2 (5.6%)	0	2 (2.7%)	0	0	0
Hypocalcaemia	2 (5.6%)	0	2 (2.7%)	0	0	0
Grade 2	2 (5.6%)	0	2 (2.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Fat soluble vitamin deficiencies and disorders	1 (2.0%)	0	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Vitamin D deficiency	1 (2.0%)	0	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Vitamin K deficiency	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Iron excess	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Fat soluble vitamin deficiencies and disorders	1 (2.8%)	1 (2.6%)	2 (2.7%)	0	0	0
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 2	0	1 (2.6%)	1 (1.4%)	0	0	0
Vitamin D deficiency	1 (2.8%)	1 (2.6%)	2 (2.7%)	0	0	0
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 2	0	1 (2.6%)	1 (1.4%)	0	0	0
Vitamin K deficiency	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Iron excess	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Iron excess (cont)						
(cont)						
Grade 3	0	0	0	0	0	0
Haemosiderosis	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Iron overload	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 3	0	0	0	0	0	0
Hyperglycaemic conditions NEC	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Iron excess (cont)						
(cont)						
Grade 3	1 (2.8%)	0	1 (1.4%)	0	0	0
Haemosiderosis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Iron overload	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	1 (2.8%)	0	1 (1.4%)	0	0	0
Hyperglycaemic conditions NEC	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (2.6%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Hyperglycaemic conditions NEC (cont)						
Hyperglycaemia	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Hypoglycaemic conditions NEC	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 3	1 (2.0%)	0	1 (0.9%)	0	0	0
Hypoglycaemia	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 3	1 (2.0%)	0	1 (0.9%)	0	0	0
Phosphorus metabolism disorders	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Hypophosphataemia	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Hyperglycaemic conditions NEC (cont)						
Hyperglycaemia	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (2.6%)	1 (1.4%)	0	0	0
Hypoglycaemic conditions NEC	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Hypoglycaemia	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Phosphorus metabolism disorders	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 3	1 (2.8%)	0	1 (1.4%)	0	0	0
Hypophosphataemia	1 (2.8%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Phosphorus metabolism disorders (cont)						
Hypophosphataemia (cont)						
Grade 3	0	0	0	0	0	0
Protein metabolism disorders NEC	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 1	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 2	0	0	0	0	0	0
Hypoalbuminaemia	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 1	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 2	0	0	0	0	0	0
Sodium imbalance	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Phosphorus metabolism disorders (cont)						
Hypophosphataemia (cont)						
Grade 3	1 (2.8%)	0	1 (1.4%)	0	0	0
Protein metabolism disorders NEC	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	1 (2.8%)	0	1 (1.4%)	0	0	0
Hypoalbuminaemia	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	1 (2.8%)	0	1 (1.4%)	0	0	0
Sodium imbalance	1 (2.8%)	0	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Grade 3	1 (2.8%)	0	1 (1.4%)	0	1 (2.9%)	1 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Sodium imbalance (cont)						
Hyponatraemia	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Total fluid volume decreased	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	2 (4.1%)	2 (2.2%)
Grade 2	0	1 (1.8%)	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Grade 3	1 (2.0%)	0	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Dehydration	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	2 (4.1%)	2 (2.2%)
Grade 2	0	1 (1.8%)	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Grade 3	1 (2.0%)	0	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Diabetes mellitus (incl subtypes)	0	0	0	0	3 (6.1%)	3 (3.4%)
Grade 1	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 2	0	0	0	0	2 (4.1%)	2 (2.2%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Sodium imbalance (cont)						
Hyponatraemia	1 (2.8%)	0	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Grade 3	1 (2.8%)	0	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Total fluid volume decreased	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Dehydration	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Diabetes mellitus (incl subtypes)	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Diabetes mellitus (incl subtypes) (cont)						
Diabetes mellitus	0	0	0	0	3 (6.1%)	3 (3.4%)
Grade 1	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 2	0	0	0	0	2 (4.1%)	2 (2.2%)
Electrolyte imbalance NEC	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	1 (1.8%)	1 (0.9%)	0	0	0
Electrolyte imbalance	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Tumour lysis syndrome	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 3	0	1 (1.8%)	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Diabetes mellitus (incl subtypes) (cont)						
Diabetes mellitus	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Electrolyte imbalance NEC	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 3	0	0	0	0	0	0
Electrolyte imbalance	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Tumour lysis syndrome	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
General nutritional disorders NEC	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Abnormal loss of weight	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Total fluid volume increased	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	1 (1.8%)	1 (0.9%)	0	0	0
Fluid retention	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Hypervolaemia	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 3	0	1 (1.8%)	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
General nutritional disorders NEC	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Abnormal loss of weight	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Total fluid volume increased	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 2	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 3	0	0	0	0	0	0
Fluid retention	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 2	0	0	0	1 (4.2%)	0	1 (1.7%)
Hypervolaemia	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders	16 (32.0%)	15 (26.8%)	31 (29.2%)	6 (15.0%)	12 (24.5%)	18 (20.2%)
Grade 1	9 (18.0%)	11 (19.6%)	20 (18.9%)	3 (7.5%)	3 (6.1%)	6 (6.7%)
Grade 2	6 (12.0%)	4 (7.1%)	10 (9.4%)	3 (7.5%)	9 (18.4%)	12 (13.5%)
Grade 3	1 (2.0%)	0	1 (0.9%)	0	0	0
Musculoskeletal and connective tissue pain and discomfort	11 (22.0%)	4 (7.1%)	15 (14.2%)	4 (10.0%)	9 (18.4%)	13 (14.6%)
Grade 1	7 (14.0%)	4 (7.1%)	11 (10.4%)	2 (5.0%)	3 (6.1%)	5 (5.6%)
Grade 2	3 (6.0%)	0	3 (2.8%)	2 (5.0%)	6 (12.2%)	8 (9.0%)
Grade 3	1 (2.0%)	0	1 (0.9%)	0	0	0
Pain in extremity	6 (12.0%)	3 (5.4%)	9 (8.5%)	3 (7.5%)	2 (4.1%)	5 (5.6%)
Grade 1	4 (8.0%)	3 (5.4%)	7 (6.6%)	1 (2.5%)	0	1 (1.1%)
Grade 2	2 (4.0%)	0	2 (1.9%)	2 (5.0%)	2 (4.1%)	4 (4.5%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders	6 (16.7%)	8 (21.1%)	14 (18.9%)	2 (8.3%)	6 (17.1%)	8 (13.6%)
Grade 1	4 (11.1%)	5 (13.2%)	9 (12.2%)	1 (4.2%)	5 (14.3%)	6 (10.2%)
Grade 2	2 (5.6%)	3 (7.9%)	5 (6.8%)	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 3	0	0	0	0	0	0
Musculoskeletal and connective tissue pain and discomfort	3 (8.3%)	3 (7.9%)	6 (8.1%)	1 (4.2%)	4 (11.4%)	5 (8.5%)
Grade 1	2 (5.6%)	2 (5.3%)	4 (5.4%)	1 (4.2%)	4 (11.4%)	5 (8.5%)
Grade 2	1 (2.8%)	1 (2.6%)	2 (2.7%)	0	0	0
Grade 3	0	0	0	0	0	0
Pain in extremity	3 (8.3%)	2 (5.3%)	5 (6.8%)	0	2 (5.7%)	2 (3.4%)
Grade 1	2 (5.6%)	1 (2.6%)	3 (4.1%)	0	2 (5.7%)	2 (3.4%)
Grade 2	1 (2.8%)	1 (2.6%)	2 (2.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Musculoskeletal and connective tissue pain and discomfort (cont)						
Back pain	5 (10.0%)	1 (1.8%)	6 (5.7%)	1 (2.5%)	5 (10.2%)	6 (6.7%)
Grade 1	3 (6.0%)	1 (1.8%)	4 (3.8%)	1 (2.5%)	2 (4.1%)	3 (3.4%)
Grade 2	1 (2.0%)	0	1 (0.9%)	0	3 (6.1%)	3 (3.4%)
Grade 3	1 (2.0%)	0	1 (0.9%)	0	0	0
Musculoskeletal pain	2 (4.0%)	0	2 (1.9%)	0	1 (2.0%)	1 (1.1%)
Grade 1	2 (4.0%)	0	2 (1.9%)	0	1 (2.0%)	1 (1.1%)
Flank pain	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Musculoskeletal chest pain	1 (2.0%)	0	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Musculoskeletal and connective tissue pain and discomfort (cont)						
Back pain	1 (2.8%)	1 (2.6%)	2 (2.7%)	1 (4.2%)	2 (5.7%)	3 (5.1%)
Grade 1	1 (2.8%)	0	1 (1.4%)	1 (4.2%)	2 (5.7%)	3 (5.1%)
Grade 2	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 3	0	0	0	0	0	0
Musculoskeletal pain	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (2.6%)	1 (1.4%)	0	0	0
Flank pain	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0
Musculoskeletal chest pain	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Musculoskeletal and connective tissue pain and discomfort (cont)						
Musculoskeletal chest pain (cont)						
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Neck pain	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Bone related signs and symptoms	1 (2.0%)	8 (14.3%)	9 (8.5%)	3 (7.5%)	2 (4.1%)	5 (5.6%)
Grade 1	0	4 (7.1%)	4 (3.8%)	2 (5.0%)	1 (2.0%)	3 (3.4%)
Grade 2	1 (2.0%)	4 (7.1%)	5 (4.7%)	1 (2.5%)	1 (2.0%)	2 (2.2%)
Bone pain	0	8 (14.3%)	8 (7.5%)	2 (5.0%)	2 (4.1%)	4 (4.5%)
Grade 1	0	4 (7.1%)	4 (3.8%)	1 (2.5%)	1 (2.0%)	2 (2.2%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Musculoskeletal and connective tissue pain and discomfort (cont)						
Musculoskeletal chest pain (cont)						
Grade 1	0	0	0	0	0	0
Neck pain	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Bone related signs and symptoms	3 (8.3%)	1 (2.6%)	4 (5.4%)	0	1 (2.9%)	1 (1.7%)
Grade 1	3 (8.3%)	0	3 (4.1%)	0	0	0
Grade 2	0	1 (2.6%)	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Bone pain	2 (5.6%)	1 (2.6%)	3 (4.1%)	0	1 (2.9%)	1 (1.7%)
Grade 1	2 (5.6%)	0	2 (2.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Bone related signs and symptoms (cont)						
Bone pain (cont)						
Grade 2	0	4 (7.1%)	4 (3.8%)	1 (2.5%)	1 (2.0%)	2 (2.2%)
Pain in jaw	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 1	0	0	0	1 (2.5%)	0	1 (1.1%)
Spinal pain	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	1 (2.0%)	0	1 (0.9%)	0	0	0
Joint related signs and symptoms	4 (8.0%)	1 (1.8%)	5 (4.7%)	1 (2.5%)	1 (2.0%)	2 (2.2%)
Grade 1	2 (4.0%)	1 (1.8%)	3 (2.8%)	0	0	0
Grade 2	2 (4.0%)	0	2 (1.9%)	1 (2.5%)	1 (2.0%)	2 (2.2%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Bone related signs and symptoms (cont)						
Bone pain (cont)						
Grade 2	0	1 (2.6%)	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Pain in jaw	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0
Spinal pain	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Joint related signs and symptoms	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Joint related signs and symptoms (cont)						
Arthralgia	4 (8.0%)	1 (1.8%)	5 (4.7%)	1 (2.5%)	0	1 (1.1%)
Grade 1	2 (4.0%)	1 (1.8%)	3 (2.8%)	0	0	0
Grade 2	2 (4.0%)	0	2 (1.9%)	1 (2.5%)	0	1 (1.1%)
Joint effusion	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Muscle related signs and symptoms NEC	2 (4.0%)	2 (3.6%)	4 (3.8%)	0	2 (4.1%)	2 (2.2%)
Grade 1	2 (4.0%)	2 (3.6%)	4 (3.8%)	0	1 (2.0%)	1 (1.1%)
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Muscle spasms	2 (4.0%)	2 (3.6%)	4 (3.8%)	0	2 (4.1%)	2 (2.2%)
Grade 1	2 (4.0%)	2 (3.6%)	4 (3.8%)	0	1 (2.0%)	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Joint related signs and symptoms (cont)						
Arthralgia	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 2	0	0	0	0	0	0
Joint effusion	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Muscle related signs and symptoms NEC	0	4 (10.5%)	4 (5.4%)	0	0	0
Grade 1	0	3 (7.9%)	3 (4.1%)	0	0	0
Grade 2	0	1 (2.6%)	1 (1.4%)	0	0	0
Muscle spasms	0	4 (10.5%)	4 (5.4%)	0	0	0
Grade 1	0	3 (7.9%)	3 (4.1%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Muscle related signs and symptoms NEC (cont)						
Muscle spasms (cont)						
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Soft tissue disorders NEC	2 (4.0%)	0	2 (1.9%)	0	0	0
Grade 1	2 (4.0%)	0	2 (1.9%)	0	0	0
Groin pain	2 (4.0%)	0	2 (1.9%)	0	0	0
Grade 1	2 (4.0%)	0	2 (1.9%)	0	0	0
Bursal disorders	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
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Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Muscle related signs and symptoms NEC (cont)						
Muscle spasms (cont)						
Grade 2	0	1 (2.6%)	1 (1.4%)	0	0	0
Soft tissue disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Groin pain	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Bursal disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
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Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Bursal disorders (cont)						
Bursal fluid accumulation	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Crystal arthropathic disorders	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	1 (2.0%)	0	1 (0.9%)	0	0	0
Gouty arthritis	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	1 (2.0%)	0	1 (0.9%)	0	0	0
Muscle pains	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	0	0
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 2	1 (2.0%)	0	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Bursal disorders (cont)						
Bursal fluid accumulation	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Crystal arthropathic disorders	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Gouty arthritis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Muscle pains	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

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SAF-Anemic Analysis Set

	Male					
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Muscle pains (cont)						
Myalgia	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	0	0
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 2	1 (2.0%)	0	1 (0.9%)	0	0	0
Tendon disorders	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Tendonitis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Arthropathies NEC	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0

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TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Muscle pains (cont)						
Myalgia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Tendon disorders	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 2	1 (2.8%)	0	1 (1.4%)	0	0	0
Tendonitis	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 2	1 (2.8%)	0	1 (1.4%)	0	0	0
Arthropathies NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

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	Male					
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Arthropathies NEC (cont)						
Arthritis	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0
Bone disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Bone lesion	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Osteosclerosis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Muscle weakness conditions	0	1 (1.8%)	1 (0.9%)	0	0	0

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Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Arthropathies NEC (cont)						
Arthritis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Bone disorders NEC	0	0	0	0	2 (5.7%)	2 (3.4%)
Grade 1	0	0	0	0	2 (5.7%)	2 (3.4%)
Bone lesion	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Osteosclerosis	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Muscle weakness conditions	0	2 (5.3%)	2 (2.7%)	1 (4.2%)	0	1 (1.7%)

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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Muscle weakness conditions (cont) (cont)						
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Muscular weakness	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Musculoskeletal and connective tissue infections and inflammations NEC	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 1	0	0	0	0	1 (2.0%)	1 (1.1%)
Fasciitis	0	0	0	0	1 (2.0%)	1 (1.1%)

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SAF-Anemic Analysis Set

(Continued)	Female					
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Muscle weakness conditions (cont) (cont)						
Grade 1	0	0	0	0	0	0
Grade 2	0	2 (5.3%)	2 (2.7%)	1 (4.2%)	0	1 (1.7%)
Muscular weakness	0	2 (5.3%)	2 (2.7%)	1 (4.2%)	0	1 (1.7%)
Grade 1	0	0	0	0	0	0
Grade 2	0	2 (5.3%)	2 (2.7%)	1 (4.2%)	0	1 (1.7%)
Musculoskeletal and connective tissue infections and inflammations NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Fasciitis	0	0	0	0	0	0

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SAF-Anemic Analysis Set

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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Musculoskeletal and connective tissue infections and inflammations NEC (cont)						
Fasciitis (cont)						
Grade 1	0	0	0	0	1 (2.0%)	1 (1.1%)
Investigations	14 (28.0%)	13 (23.2%)	27 (25.5%)	8 (20.0%)	10 (20.4%)	18 (20.2%)
Grade 1	7 (14.0%)	7 (12.5%)	14 (13.2%)	3 (7.5%)	5 (10.2%)	8 (9.0%)
Grade 2	4 (8.0%)	5 (8.9%)	9 (8.5%)	4 (10.0%)	5 (10.2%)	9 (10.1%)
Grade 3	2 (4.0%)	1 (1.8%)	3 (2.8%)	1 (2.5%)	0	1 (1.1%)
Grade 4	1 (2.0%)	0	1 (0.9%)	0	0	0
Liver function analyses	6 (12.0%)	6 (10.7%)	12 (11.3%)	3 (7.5%)	3 (6.1%)	6 (6.7%)
Grade 1	4 (8.0%)	4 (7.1%)	8 (7.5%)	2 (5.0%)	0	2 (2.2%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Musculoskeletal and connective tissue infections and inflammations NEC (cont)						
Fasciitis (cont)						
Grade 1	0	0	0	0	0	0
Investigations	7 (19.4%)	6 (15.8%)	13 (17.6%)	3 (12.5%)	5 (14.3%)	8 (13.6%)
Grade 1	2 (5.6%)	2 (5.3%)	4 (5.4%)	1 (4.2%)	4 (11.4%)	5 (8.5%)
Grade 2	3 (8.3%)	2 (5.3%)	5 (6.8%)	2 (8.3%)	1 (2.9%)	3 (5.1%)
Grade 3	2 (5.6%)	2 (5.3%)	4 (5.4%)	0	0	0
Grade 4	0	0	0	0	0	0
Liver function analyses	5 (13.9%)	5 (13.2%)	10 (13.5%)	0	2 (5.7%)	2 (3.4%)
Grade 1	1 (2.8%)	1 (2.6%)	2 (2.7%)	0	1 (2.9%)	1 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Liver function analyses (cont)						
(cont)						
Grade 2	0	1 (1.8%)	1 (0.9%)	0	3 (6.1%)	3 (3.4%)
Grade 3	2 (4.0%)	1 (1.8%)	3 (2.8%)	1 (2.5%)	0	1 (1.1%)
Alanine aminotransferase increased	3 (6.0%)	4 (7.1%)	7 (6.6%)	1 (2.5%)	2 (4.1%)	3 (3.4%)
Grade 1	2 (4.0%)	3 (5.4%)	5 (4.7%)	1 (2.5%)	1 (2.0%)	2 (2.2%)
Grade 2	0	1 (1.8%)	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Grade 3	1 (2.0%)	0	1 (0.9%)	0	0	0
Gamma-glutamyltransferase increased	3 (6.0%)	1 (1.8%)	4 (3.8%)	1 (2.5%)	1 (2.0%)	2 (2.2%)
Grade 1	1 (2.0%)	0	1 (0.9%)	1 (2.5%)	0	1 (1.1%)
Grade 2	1 (2.0%)	0	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Grade 3	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Liver function analyses (cont)						
(cont)						
Grade 2	2 (5.6%)	2 (5.3%)	4 (5.4%)	0	1 (2.9%)	1 (1.7%)
Grade 3	2 (5.6%)	2 (5.3%)	4 (5.4%)	0	0	0
Alanine aminotransferase increased	4 (11.1%)	2 (5.3%)	6 (8.1%)	0	1 (2.9%)	1 (1.7%)
Grade 1	1 (2.8%)	2 (5.3%)	3 (4.1%)	0	1 (2.9%)	1 (1.7%)
Grade 2	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 3	2 (5.6%)	0	2 (2.7%)	0	0	0
Gamma-glutamyltransferase increased	1 (2.8%)	3 (7.9%)	4 (5.4%)	0	1 (2.9%)	1 (1.7%)
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 2	0	1 (2.6%)	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Grade 3	0	2 (5.3%)	2 (2.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Liver function analyses (cont)						
Aspartate aminotransferase increased	2 (4.0%)	1 (1.8%)	3 (2.8%)	0	0	0
Grade 1	2 (4.0%)	1 (1.8%)	3 (2.8%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Blood bilirubin increased	0	2 (3.6%)	2 (1.9%)	0	1 (2.0%)	1 (1.1%)
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 2	0	1 (1.8%)	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Transaminases increased	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	0	0
Grade 1	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	0	0
Liver function test abnormal	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 3	0	0	0	1 (2.5%)	0	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Liver function analyses (cont)						
Aspartate aminotransferase increased	1 (2.8%)	2 (5.3%)	3 (4.1%)	0	1 (2.9%)	1 (1.7%)
Grade 1	0	1 (2.6%)	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Grade 2	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 3	1 (2.8%)	0	1 (1.4%)	0	0	0
Blood bilirubin increased	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	1 (2.8%)	0	1 (1.4%)	0	0	0
Transaminases increased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Liver function test abnormal	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Physical examination procedures and organ system status	5 (10.0%)	3 (5.4%)	8 (7.5%)	1 (2.5%)	2 (4.1%)	3 (3.4%)
Grade 1	5 (10.0%)	1 (1.8%)	6 (5.7%)	0	2 (4.1%)	2 (2.2%)
Grade 2	0	2 (3.6%)	2 (1.9%)	1 (2.5%)	0	1 (1.1%)
Weight decreased	3 (6.0%)	1 (1.8%)	4 (3.8%)	1 (2.5%)	1 (2.0%)	2 (2.2%)
Grade 1	3 (6.0%)	0	3 (2.8%)	0	1 (2.0%)	1 (1.1%)
Grade 2	0	1 (1.8%)	1 (0.9%)	1 (2.5%)	0	1 (1.1%)
Weight increased	2 (4.0%)	1 (1.8%)	3 (2.8%)	0	1 (2.0%)	1 (1.1%)
Grade 1	2 (4.0%)	0	2 (1.9%)	0	1 (2.0%)	1 (1.1%)
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0
Lymph node palpable	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Physical examination procedures and organ system status	1 (2.8%)	1 (2.6%)	2 (2.7%)	2 (8.3%)	0	2 (3.4%)
Grade 1	1 (2.8%)	1 (2.6%)	2 (2.7%)	0	0	0
Grade 2	0	0	0	2 (8.3%)	0	2 (3.4%)
Weight decreased	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	1 (4.2%)	0	1 (1.7%)
Weight increased	0	1 (2.6%)	1 (1.4%)	1 (4.2%)	0	1 (1.7%)
Grade 1	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 2	0	0	0	1 (4.2%)	0	1 (1.7%)
Lymph node palpable	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Physical examination procedures and organ system status (cont)						
Body temperature increased	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0
Renal function analyses	5 (10.0%)	1 (1.8%)	6 (5.7%)	3 (7.5%)	1 (2.0%)	4 (4.5%)
Grade 1	2 (4.0%)	1 (1.8%)	3 (2.8%)	1 (2.5%)	0	1 (1.1%)
Grade 2	3 (6.0%)	0	3 (2.8%)	2 (5.0%)	1 (2.0%)	3 (3.4%)
Blood creatinine increased	3 (6.0%)	1 (1.8%)	4 (3.8%)	2 (5.0%)	1 (2.0%)	3 (3.4%)
Grade 1	2 (4.0%)	1 (1.8%)	3 (2.8%)	1 (2.5%)	0	1 (1.1%)
Grade 2	1 (2.0%)	0	1 (0.9%)	1 (2.5%)	1 (2.0%)	2 (2.2%)
Creatinine renal clearance decreased	2 (4.0%)	0	2 (1.9%)	1 (2.5%)	0	1 (1.1%)
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Physical examination procedures and organ system status (cont)						
Body temperature increased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Renal function analyses	1 (2.8%)	0	1 (1.4%)	1 (4.2%)	3 (8.6%)	4 (6.8%)
Grade 1	1 (2.8%)	0	1 (1.4%)	1 (4.2%)	3 (8.6%)	4 (6.8%)
Grade 2	0	0	0	0	0	0
Blood creatinine increased	1 (2.8%)	0	1 (1.4%)	1 (4.2%)	2 (5.7%)	3 (5.1%)
Grade 1	1 (2.8%)	0	1 (1.4%)	1 (4.2%)	2 (5.7%)	3 (5.1%)
Grade 2	0	0	0	0	0	0
Creatinine renal clearance decreased	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Renal function analyses (cont)						
Creatinine renal clearance decreased (cont)						
Grade 2	2 (4.0%)	0	2 (1.9%)	1 (2.5%)	0	1 (1.1%)
ECG investigations	2 (4.0%)	2 (3.6%)	4 (3.8%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	0	2 (3.6%)	2 (1.9%)	0	0	0
Grade 4	1 (2.0%)	0	1 (0.9%)	0	0	0
Electrocardiogram QT prolonged	1 (2.0%)	2 (3.6%)	3 (2.8%)	0	0	0
Grade 2	0	2 (3.6%)	2 (1.9%)	0	0	0
Grade 4	1 (2.0%)	0	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Renal function analyses (cont)						
Creatinine renal clearance decreased (cont)						
Grade 2	0	0	0	0	0	0
ECG investigations	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Electrocardiogram QT prolonged	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
ECG investigations (cont)						
Electrocardiogram ST segment depression	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Protein analyses NEC	2 (4.0%)	0	2 (1.9%)	1 (2.5%)	0	1 (1.1%)
Grade 1	2 (4.0%)	0	2 (1.9%)	1 (2.5%)	0	1 (1.1%)
Protein total increased	2 (4.0%)	0	2 (1.9%)	1 (2.5%)	0	1 (1.1%)
Grade 1	2 (4.0%)	0	2 (1.9%)	1 (2.5%)	0	1 (1.1%)
Tissue enzyme analyses NEC	0	1 (1.8%)	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Grade 1	0	1 (1.8%)	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
ECG investigations (cont)						
Electrocardiogram ST segment depression	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Protein analyses NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Protein total increased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Tissue enzyme analyses NEC	2 (5.6%)	3 (7.9%)	5 (6.8%)	0	0	0
Grade 1	1 (2.8%)	2 (5.3%)	3 (4.1%)	0	0	0
Grade 2	1 (2.8%)	1 (2.6%)	2 (2.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Tissue enzyme analyses NEC (cont)						
Blood alkaline phosphatase increased	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Blood lactate dehydrogenase increased	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 1	0	0	0	0	1 (2.0%)	1 (1.1%)
Blood gas and acid base analyses	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Blood lactic acid increased	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
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Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Tissue enzyme analyses NEC (cont)						
Blood alkaline phosphatase increased	2 (5.6%)	3 (7.9%)	5 (6.8%)	0	0	0
Grade 1	1 (2.8%)	2 (5.3%)	3 (4.1%)	0	0	0
Grade 2	1 (2.8%)	1 (2.6%)	2 (2.7%)	0	0	0
Blood lactate dehydrogenase increased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Blood gas and acid base analyses	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Blood lactic acid increased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Mineral and electrolyte analyses	1 (2.0%)	0	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Grade 2	1 (2.0%)	0	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Blood bicarbonate decreased	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	1 (2.0%)	0	1 (0.9%)	0	0	0
Serum ferritin increased	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Autoimmunity analyses	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 2	0	0	0	1 (2.5%)	0	1 (1.1%)
Antiphospholipid antibodies positive	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 2	0	0	0	1 (2.5%)	0	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Mineral and electrolyte analyses	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Blood bicarbonate decreased	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Serum ferritin increased	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Autoimmunity analyses	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Antiphospholipid antibodies positive	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

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Adverse events were mapped according to MedDRA Version 22.0
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Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Cardiac auscultatory investigations	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Cardiac murmur	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Coagulation and bleeding analyses	0	0	0	0	2 (4.1%)	2 (2.2%)
Grade 1	0	0	0	0	2 (4.1%)	2 (2.2%)
Activated partial thromboplastin time prolonged	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
International normalised ratio increased	0	0	0	0	1 (2.0%)	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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SAF-Anemic Analysis Set

(Continued)	Female					
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Cardiac auscultatory investigations	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (2.6%)	1 (1.4%)	0	0	0
Cardiac murmur	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (2.6%)	1 (1.4%)	0	0	0
Coagulation and bleeding analyses	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Activated partial thromboplastin time prolonged	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
International normalised ratio increased	0	0	0	0	0	0

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Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
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SAF-Anemic Analysis Set

	Male					
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Coagulation and bleeding analyses (cont)						
International normalised ratio increased (cont)						
Grade 1	0	0	0	0	1 (2.0%)	1 (1.1%)
Prothrombin time prolonged	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 1	0	0	0	0	1 (2.0%)	1 (1.1%)
Digestive enzymes	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Lipase increased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

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(Continued)	Female					
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Coagulation and bleeding analyses (cont)						
International normalised ratio increased (cont)						
Grade 1	0	0	0	0	0	0
Prothrombin time prolonged	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Digestive enzymes	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (2.6%)	1 (1.4%)	0	0	0
Lipase increased	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (2.6%)	1 (1.4%)	0	0	0

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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Reproductive organ and breast imaging procedures	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Computerised tomogram pelvis abnormal	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Respiratory tract and thoracic imaging procedures	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Chest X-ray abnormal	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Reproductive organ and breast imaging procedures	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Computerised tomogram pelvis abnormal	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Respiratory tract and thoracic imaging procedures	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Chest X-ray abnormal	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)

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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Skeletal and cardiac muscle analyses	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Blood creatine phosphokinase increased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Vitamin analyses	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 2	0	0	0	1 (2.5%)	0	1 (1.1%)
Blood folate decreased	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 2	0	0	0	1 (2.5%)	0	1 (1.1%)

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Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
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Investigations (cont)						
Skeletal and cardiac muscle analyses	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (2.6%)	1 (1.4%)	0	0	0
Blood creatine phosphokinase increased	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (2.6%)	1 (1.4%)	0	0	0
Vitamin analyses	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Blood folate decreased	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders	15 (30.0%)	9 (16.1%)	24 (22.6%)	9 (22.5%)	9 (18.4%)	18 (20.2%)
Grade 1	11 (22.0%)	5 (8.9%)	16 (15.1%)	6 (15.0%)	7 (14.3%)	13 (14.6%)
Grade 2	4 (8.0%)	3 (5.4%)	7 (6.6%)	2 (5.0%)	1 (2.0%)	3 (3.4%)
Grade 3	0	1 (1.8%)	1 (0.9%)	1 (2.5%)	1 (2.0%)	2 (2.2%)
Rashes, eruptions and exanthems NEC	4 (8.0%)	1 (1.8%)	5 (4.7%)	2 (5.0%)	5 (10.2%)	7 (7.9%)
Grade 1	3 (6.0%)	0	3 (2.8%)	2 (5.0%)	5 (10.2%)	7 (7.9%)
Grade 2	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	0	0
Rash	3 (6.0%)	1 (1.8%)	4 (3.8%)	2 (5.0%)	3 (6.1%)	5 (5.6%)
Grade 1	2 (4.0%)	0	2 (1.9%)	2 (5.0%)	3 (6.1%)	5 (5.6%)
Grade 2	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	0	0
Rash maculo-papular	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 1	0	0	0	0	1 (2.0%)	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders	5 (13.9%)	6 (15.8%)	11 (14.9%)	4 (16.7%)	8 (22.9%)	12 (20.3%)
Grade 1	5 (13.9%)	5 (13.2%)	10 (13.5%)	3 (12.5%)	7 (20.0%)	10 (16.9%)
Grade 2	0	1 (2.6%)	1 (1.4%)	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 3	0	0	0	0	0	0
Rashes, eruptions and exanthems NEC	3 (8.3%)	1 (2.6%)	4 (5.4%)	1 (4.2%)	3 (8.6%)	4 (6.8%)
Grade 1	3 (8.3%)	1 (2.6%)	4 (5.4%)	1 (4.2%)	3 (8.6%)	4 (6.8%)
Grade 2	0	0	0	0	0	0
Rash	2 (5.6%)	1 (2.6%)	3 (4.1%)	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 1	2 (5.6%)	1 (2.6%)	3 (4.1%)	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 2	0	0	0	0	0	0
Rash maculo-papular	2 (5.6%)	0	2 (2.7%)	0	0	0
Grade 1	2 (5.6%)	0	2 (2.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Rashes, eruptions and exanthems NEC (cont)						
Rash macular	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Rash generalised	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Rash papular	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 1	0	0	0	0	1 (2.0%)	1 (1.1%)
Apocrine and eccrine gland disorders	4 (8.0%)	3 (5.4%)	7 (6.6%)	3 (7.5%)	2 (4.1%)	5 (5.6%)
Grade 1	4 (8.0%)	1 (1.8%)	5 (4.7%)	3 (7.5%)	1 (2.0%)	4 (4.5%)
Grade 2	0	2 (3.6%)	2 (1.9%)	0	1 (2.0%)	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Rashes, eruptions and exanthems NEC (cont)						
Rash macular	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Rash generalised	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Rash papular	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Apocrine and eccrine gland disorders	0	1 (2.6%)	1 (1.4%)	2 (8.3%)	3 (8.6%)	5 (8.5%)
Grade 1	0	1 (2.6%)	1 (1.4%)	2 (8.3%)	3 (8.6%)	5 (8.5%)
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Apocrine and eccrine gland disorders (cont)						
Night sweats	4 (8.0%)	1 (1.8%)	5 (4.7%)	3 (7.5%)	1 (2.0%)	4 (4.5%)
Grade 1	4 (8.0%)	0	4 (3.8%)	3 (7.5%)	0	3 (3.4%)
Grade 2	0	1 (1.8%)	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Hyperhidrosis	0	2 (3.6%)	2 (1.9%)	0	1 (2.0%)	1 (1.1%)
Grade 1	0	1 (1.8%)	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0
Purpura and related conditions	3 (6.0%)	0	3 (2.8%)	1 (2.5%)	0	1 (1.1%)
Grade 1	3 (6.0%)	0	3 (2.8%)	0	0	0
Grade 2	0	0	0	1 (2.5%)	0	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Apocrine and eccrine gland disorders (cont)						
Night sweats	0	0	0	2 (8.3%)	2 (5.7%)	4 (6.8%)
Grade 1	0	0	0	2 (8.3%)	2 (5.7%)	4 (6.8%)
Grade 2	0	0	0	0	0	0
Hyperhidrosis	0	1 (2.6%)	1 (1.4%)	0	2 (5.7%)	2 (3.4%)
Grade 1	0	1 (2.6%)	1 (1.4%)	0	2 (5.7%)	2 (3.4%)
Grade 2	0	0	0	0	0	0
Purpura and related conditions	1 (2.8%)	1 (2.6%)	2 (2.7%)	1 (4.2%)	0	1 (1.7%)
Grade 1	1 (2.8%)	1 (2.6%)	2 (2.7%)	1 (4.2%)	0	1 (1.7%)
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Purpura and related conditions (cont)						
Ecchymosis	1 (2.0%)	0	1 (0.9%)	1 (2.5%)	0	1 (1.1%)
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	0	0	0	1 (2.5%)	0	1 (1.1%)
Petechiae	2 (4.0%)	0	2 (1.9%)	0	0	0
Grade 1	2 (4.0%)	0	2 (1.9%)	0	0	0
Purpura	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dermatitis and eczema	2 (4.0%)	0	2 (1.9%)	1 (2.5%)	0	1 (1.1%)
Grade 1	2 (4.0%)	0	2 (1.9%)	0	0	0
Grade 3	0	0	0	1 (2.5%)	0	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Purpura and related conditions (cont)						
Ecchymosis	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 2	0	0	0	0	0	0
Petechiae	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (2.6%)	1 (1.4%)	0	0	0
Purpura	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 1	0	0	0	1 (4.2%)	0	1 (1.7%)
Dermatitis and eczema	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Dermatitis and eczema (cont)						
Dermatitis contact	2 (4.0%)	0	2 (1.9%)	0	0	0
Grade 1	2 (4.0%)	0	2 (1.9%)	0	0	0
Dermatitis allergic	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 3	0	0	0	1 (2.5%)	0	1 (1.1%)
Pruritus NEC	1 (2.0%)	4 (7.1%)	5 (4.7%)	1 (2.5%)	3 (6.1%)	4 (4.5%)
Grade 1	1 (2.0%)	3 (5.4%)	4 (3.8%)	0	3 (6.1%)	3 (3.4%)
Grade 2	0	1 (1.8%)	1 (0.9%)	1 (2.5%)	0	1 (1.1%)
Pruritus	1 (2.0%)	3 (5.4%)	4 (3.8%)	1 (2.5%)	3 (6.1%)	4 (4.5%)
Grade 1	1 (2.0%)	3 (5.4%)	4 (3.8%)	0	3 (6.1%)	3 (3.4%)
Grade 2	0	0	0	1 (2.5%)	0	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Dermatitis and eczema (cont)						
Dermatitis contact	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dermatitis allergic	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Pruritus NEC	1 (2.8%)	3 (7.9%)	4 (5.4%)	0	4 (11.4%)	4 (6.8%)
Grade 1	1 (2.8%)	2 (5.3%)	3 (4.1%)	0	3 (8.6%)	3 (5.1%)
Grade 2	0	1 (2.6%)	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Pruritus	0	3 (7.9%)	3 (4.1%)	0	4 (11.4%)	4 (6.8%)
Grade 1	0	2 (5.3%)	2 (2.7%)	0	3 (8.6%)	3 (5.1%)
Grade 2	0	1 (2.6%)	1 (1.4%)	0	1 (2.9%)	1 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Pruritus NEC (cont)						
Pruritus generalised	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Aquagenic pruritus	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Rash pruritic	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0
Alopecias	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Alopecia	1 (2.0%)	0	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Pruritus NEC (cont)						
Pruritus generalised	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0
Aquagenic pruritus	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (2.6%)	1 (1.4%)	0	0	0
Rash pruritic	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Alopecias	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Alopecia	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Alopecias (cont)						
Alopecia (cont)						
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Bullous conditions	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Blister	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Blood blister	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Dermal and epidermal conditions NEC	1 (2.0%)	3 (5.4%)	4 (3.8%)	2 (5.0%)	0	2 (2.2%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Alopecias (cont)						
Alopecia (cont)						
Grade 1	0	0	0	0	0	0
Bullous conditions	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Blister	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Blood blister	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dermal and epidermal conditions NEC	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Dermal and epidermal conditions NEC (cont)						
(cont)						
Grade 1	0	2 (3.6%)	2 (1.9%)	1 (2.5%)	0	1 (1.1%)
Grade 2	1 (2.0%)	1 (1.8%)	2 (1.9%)	1 (2.5%)	0	1 (1.1%)
Skin lesion	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	0	0
Grade 2	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	0	0
Dermatosis	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 2	0	0	0	1 (2.5%)	0	1 (1.1%)
Dry skin	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Dermal and epidermal conditions NEC (cont)						
(cont)						
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Skin lesion	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Dermatosis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Dry skin	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Dermal and epidermal conditions NEC (cont)						
Pain of skin	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0
Skin fragility	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 1	0	0	0	1 (2.5%)	0	1 (1.1%)
Erythemas	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Erythema	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Dermal and epidermal conditions NEC (cont)						
Pain of skin	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Skin fragility	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Erythemas	1 (2.8%)	0	1 (1.4%)	1 (4.2%)	0	1 (1.7%)
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 2	0	0	0	1 (4.2%)	0	1 (1.7%)
Erythema	1 (2.8%)	0	1 (1.4%)	1 (4.2%)	0	1 (1.7%)
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Erythemas (cont)						
Erythema (cont)						
Grade 2	0	0	0	0	0	0
Hyperkeratoses	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	1 (2.0%)	0	1 (0.9%)	0	0	0
Hyperkeratosis	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	1 (2.0%)	0	1 (0.9%)	0	0	0
Nail and nail bed conditions (excl infections and infestations)	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	1 (2.0%)	0	1 (0.9%)	0	0	0

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Adverse events were mapped according to MedDRA Version 22.0
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Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Erythemas (cont)						
Erythema (cont)						
Grade 2	0	0	0	1 (4.2%)	0	1 (1.7%)
Hyperkeratoses	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Hyperkeratosis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Nail and nail bed conditions (excl infections and infestations)	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
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Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Nail and nail bed conditions (excl infections and infestations) (cont)						
Ingrowing nail	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	1 (2.0%)	0	1 (0.9%)	0	0	0
Skin haemorrhages	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Skin haemorrhage	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Telangiectasia and related conditions	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Female					
(Continued)	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Nail and nail bed conditions (excl infections and infestations) (cont)						
Ingrowing nail	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Skin haemorrhages	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0
Skin haemorrhage	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0
Telangiectasia and related conditions	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Telangiectasia and related conditions (cont)						
Telangiectasia	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Dermatitis ascribed to specific agent	0	0	0	1 (2.5%)	1 (2.0%)	2 (2.2%)
Grade 3	0	0	0	1 (2.5%)	1 (2.0%)	2 (2.2%)
Drug eruption	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 3	0	0	0	0	1 (2.0%)	1 (1.1%)
Toxic skin eruption	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 3	0	0	0	1 (2.5%)	0	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Telangiectasia and related conditions (cont)						
Telangiectasia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dermatitis ascribed to specific agent	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Drug eruption	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Toxic skin eruption	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

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Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Exfoliative conditions	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Skin exfoliation	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Skin and subcutaneous tissue ulcerations	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 3	0	1 (1.8%)	1 (0.9%)	0	0	0
Skin ulcer	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 3	0	1 (1.8%)	1 (0.9%)	0	0	0
Skin preneoplastic conditions NEC	0	0	0	2 (5.0%)	0	2 (2.2%)

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Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Exfoliative conditions	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 1	0	0	0	1 (4.2%)	0	1 (1.7%)
Skin exfoliation	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 1	0	0	0	1 (4.2%)	0	1 (1.7%)
Skin and subcutaneous tissue ulcerations	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Skin ulcer	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Skin preneoplastic conditions NEC	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Skin preneoplastic conditions NEC (cont)						
(cont)						
Grade 1	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 2	0	0	0	1 (2.5%)	0	1 (1.1%)
Actinic keratosis	0	0	0	2 (5.0%)	0	2 (2.2%)
Grade 1	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 2	0	0	0	1 (2.5%)	0	1 (1.1%)
Vascular disorders	9 (18.0%)	6 (10.7%)	15 (14.2%)	5 (12.5%)	8 (16.3%)	13 (14.6%)
Grade 1	4 (8.0%)	3 (5.4%)	7 (6.6%)	2 (5.0%)	3 (6.1%)	5 (5.6%)
Grade 2	3 (6.0%)	0	3 (2.8%)	2 (5.0%)	3 (6.1%)	5 (5.6%)
Grade 3	2 (4.0%)	2 (3.6%)	4 (3.8%)	1 (2.5%)	2 (4.1%)	3 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Skin preneoplastic conditions NEC (cont)						
(cont)						
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Actinic keratosis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Vascular disorders	9 (25.0%)	4 (10.5%)	13 (17.6%)	3 (12.5%)	4 (11.4%)	7 (11.9%)
Grade 1	6 (16.7%)	0	6 (8.1%)	1 (4.2%)	2 (5.7%)	3 (5.1%)
Grade 2	2 (5.6%)	2 (5.3%)	4 (5.4%)	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 3	1 (2.8%)	2 (5.3%)	3 (4.1%)	1 (4.2%)	1 (2.9%)	2 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont) (cont) (cont) Grade 4	0	1 (1.8%)	1 (0.9%)	0	0	0
Vascular hypotensive disorders	6 (12.0%)	0	6 (5.7%)	0	1 (2.0%)	1 (1.1%)
Grade 1	2 (4.0%)	0	2 (1.9%)	0	0	0
Grade 2	3 (6.0%)	0	3 (2.8%)	0	1 (2.0%)	1 (1.1%)
Grade 3	1 (2.0%)	0	1 (0.9%)	0	0	0
Hypotension	6 (12.0%)	0	6 (5.7%)	0	1 (2.0%)	1 (1.1%)
Grade 1	2 (4.0%)	0	2 (1.9%)	0	0	0
Grade 2	3 (6.0%)	0	3 (2.8%)	0	1 (2.0%)	1 (1.1%)
Grade 3	1 (2.0%)	0	1 (0.9%)	0	0	0
Peripheral vascular disorders NEC	3 (6.0%)	0	3 (2.8%)	0	1 (2.0%)	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont) (cont) (cont)						
Grade 4	0	0	0	0	0	0
Vascular hypotensive disorders	6 (16.7%)	0	6 (8.1%)	1 (4.2%)	2 (5.7%)	3 (5.1%)
Grade 1	4 (11.1%)	0	4 (5.4%)	0	1 (2.9%)	1 (1.7%)
Grade 2	1 (2.8%)	0	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Grade 3	1 (2.8%)	0	1 (1.4%)	1 (4.2%)	0	1 (1.7%)
Hypotension	6 (16.7%)	0	6 (8.1%)	1 (4.2%)	2 (5.7%)	3 (5.1%)
Grade 1	4 (11.1%)	0	4 (5.4%)	0	1 (2.9%)	1 (1.7%)
Grade 2	1 (2.8%)	0	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Grade 3	1 (2.8%)	0	1 (1.4%)	1 (4.2%)	0	1 (1.7%)
Peripheral vascular disorders NEC	2 (5.6%)	0	2 (2.7%)	1 (4.2%)	1 (2.9%)	2 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Peripheral vascular disorders NEC (cont)						
(cont)						
Grade 1	3 (6.0%)	0	3 (2.8%)	0	1 (2.0%)	1 (1.1%)
Grade 2	0	0	0	0	0	0
Flushing	2 (4.0%)	0	2 (1.9%)	0	1 (2.0%)	1 (1.1%)
Grade 1	2 (4.0%)	0	2 (1.9%)	0	1 (2.0%)	1 (1.1%)
Grade 2	0	0	0	0	0	0
Hot flush	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Haemorrhages NEC	1 (2.0%)	2 (3.6%)	3 (2.8%)	2 (5.0%)	1 (2.0%)	3 (3.4%)
Grade 1	1 (2.0%)	2 (3.6%)	3 (2.8%)	2 (5.0%)	1 (2.0%)	3 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Peripheral vascular disorders NEC (cont) (cont)						
Grade 1	1 (2.8%)	0	1 (1.4%)	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 2	1 (2.8%)	0	1 (1.4%)	0	0	0
Flushing	2 (5.6%)	0	2 (2.7%)	0	0	0
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 2	1 (2.8%)	0	1 (1.4%)	0	0	0
Hot flush	0	0	0	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 1	0	0	0	1 (4.2%)	1 (2.9%)	2 (3.4%)
Haemorrhages NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Haemorrhages NEC (cont)						
Haematoma	1 (2.0%)	2 (3.6%)	3 (2.8%)	2 (5.0%)	1 (2.0%)	3 (3.4%)
Grade 1	1 (2.0%)	2 (3.6%)	3 (2.8%)	2 (5.0%)	1 (2.0%)	3 (3.4%)
Non-site specific vascular disorders NEC	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Poor venous access	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Peripheral vasoconstriction, necrosis and vascular insufficiency	0	1 (1.8%)	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Haemorrhages NEC (cont)						
Haematoma	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Non-site specific vascular disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Poor venous access	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Peripheral vasoconstriction, necrosis and vascular insufficiency	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
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Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Peripheral vasoconstriction, necrosis and vascular insufficiency (cont) (cont)						
Grade 4	0	1 (1.8%)	1 (0.9%)	0	0	0
Peripheral arterial occlusive disease	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Peripheral ischaemia	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 4	0	1 (1.8%)	1 (0.9%)	0	0	0
Vascular hypertensive disorders NEC	1 (2.0%)	3 (5.4%)	4 (3.8%)	2 (5.0%)	3 (6.1%)	5 (5.6%)
Grade 1	0	1 (1.8%)	1 (0.9%)	0	1 (2.0%)	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Peripheral vasoconstriction, necrosis and vascular insufficiency (cont) (cont)						
Grade 4	0	0	0	0	0	0
Peripheral arterial occlusive disease	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 2	0	0	0	0	0	0
Peripheral ischaemia	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Vascular hypertensive disorders NEC	0	4 (10.5%)	4 (5.4%)	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Vascular hypertensive disorders NEC (cont) (cont)						
Grade 2	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 3	1 (2.0%)	2 (3.6%)	3 (2.8%)	1 (2.5%)	2 (4.1%)	3 (3.4%)
Hypertension	1 (2.0%)	3 (5.4%)	4 (3.8%)	2 (5.0%)	3 (6.1%)	5 (5.6%)
Grade 1	0	1 (1.8%)	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Grade 2	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 3	1 (2.0%)	2 (3.6%)	3 (2.8%)	1 (2.5%)	2 (4.1%)	3 (3.4%)
Accelerated and malignant hypertension	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 3	0	1 (1.8%)	1 (0.9%)	0	0	0
Hypertensive crisis	0	1 (1.8%)	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Vascular hypertensive disorders NEC (cont) (cont) (cont)						
Grade 2	0	2 (5.3%)	2 (2.7%)	1 (4.2%)	0	1 (1.7%)
Grade 3	0	2 (5.3%)	2 (2.7%)	0	1 (2.9%)	1 (1.7%)
Hypertension	0	4 (10.5%)	4 (5.4%)	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 1	0	0	0	0	0	0
Grade 2	0	2 (5.3%)	2 (2.7%)	1 (4.2%)	0	1 (1.7%)
Grade 3	0	2 (5.3%)	2 (2.7%)	0	1 (2.9%)	1 (1.7%)
Accelerated and malignant hypertension	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Hypertensive crisis	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Accelerated and malignant hypertension (cont)						
Hypertensive crisis (cont)						
Grade 3	0	1 (1.8%)	1 (0.9%)	0	0	0
Aortic necrosis and vascular insufficiency	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Aortic stenosis	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Non-site specific necrosis and vascular insufficiency NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Accelerated and malignant hypertension (cont)						
Hypertensive crisis (cont)						
Grade 3	0	0	0	0	0	0
Aortic necrosis and vascular insufficiency	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Aortic stenosis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Non-site specific necrosis and vascular insufficiency NEC	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Non-site specific necrosis and vascular insufficiency NEC (cont)						
Arteriosclerosis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Peripheral embolism and thrombosis	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 2	0	0	0	1 (2.5%)	0	1 (1.1%)
Thrombophlebitis superficial	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 2	0	0	0	1 (2.5%)	0	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Non-site specific necrosis and vascular insufficiency NEC (cont)						
Arteriosclerosis	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Peripheral embolism and thrombosis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Thrombophlebitis superficial	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders	9 (18.0%)	4 (7.1%)	13 (12.3%)	2 (5.0%)	3 (6.1%)	5 (5.6%)
Grade 1	7 (14.0%)	0	7 (6.6%)	1 (2.5%)	0	1 (1.1%)
Grade 2	0	1 (1.8%)	1 (0.9%)	1 (2.5%)	2 (4.1%)	3 (3.4%)
Grade 3	2 (4.0%)	2 (3.6%)	4 (3.8%)	0	1 (2.0%)	1 (1.1%)
Grade 4	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 5	0	0	0	0	0	0
Renal failure and impairment	5 (10.0%)	1 (1.8%)	6 (5.7%)	2 (5.0%)	1 (2.0%)	3 (3.4%)
Grade 1	4 (8.0%)	0	4 (3.8%)	1 (2.5%)	0	1 (1.1%)
Grade 2	0	0	0	1 (2.5%)	1 (2.0%)	2 (2.2%)
Grade 3	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 4	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 5	0	0	0	0	0	0
Acute kidney injury	2 (4.0%)	1 (1.8%)	3 (2.8%)	1 (2.5%)	0	1 (1.1%)
Grade 1	2 (4.0%)	0	2 (1.9%)	1 (2.5%)	0	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders	4 (11.1%)	5 (13.2%)	9 (12.2%)	1 (4.2%)	5 (14.3%)	6 (10.2%)
Grade 1	1 (2.8%)	2 (5.3%)	3 (4.1%)	0	2 (5.7%)	2 (3.4%)
Grade 2	1 (2.8%)	3 (7.9%)	4 (5.4%)	0	1 (2.9%)	1 (1.7%)
Grade 3	0	0	0	1 (4.2%)	2 (5.7%)	3 (5.1%)
Grade 4	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 5	1 (2.8%)	0	1 (1.4%)	0	0	0
Renal failure and impairment	2 (5.6%)	1 (2.6%)	3 (4.1%)	1 (4.2%)	3 (8.6%)	4 (6.8%)
Grade 1	0	1 (2.6%)	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Grade 2	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 3	0	0	0	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 4	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 5	1 (2.8%)	0	1 (1.4%)	0	0	0
Acute kidney injury	0	0	0	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Renal failure and impairment (cont)						
Acute kidney injury (cont)						
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Grade 4	0	1 (1.8%)	1 (0.9%)	0	0	0
Renal failure	1 (2.0%)	0	1 (0.9%)	1 (2.5%)	1 (2.0%)	2 (2.2%)
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	0	0	0	1 (2.5%)	1 (2.0%)	2 (2.2%)
Grade 5	0	0	0	0	0	0
Renal impairment	2 (4.0%)	0	2 (1.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 3	1 (2.0%)	0	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Renal failure and impairment (cont)						
Acute kidney injury (cont)						
Grade 2	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 3	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 4	0	0	0	0	0	0
Renal failure	1 (2.8%)	1 (2.6%)	2 (2.7%)	0	1 (2.9%)	1 (1.7%)
Grade 1	0	1 (2.6%)	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Grade 2	0	0	0	0	0	0
Grade 5	1 (2.8%)	0	1 (1.4%)	0	0	0
Renal impairment	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Renal failure and impairment (cont)						
Chronic kidney disease	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Bladder and urethral symptoms	3 (6.0%)	1 (1.8%)	4 (3.8%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 3	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	0	0
Dysuria	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Pollakiuria	2 (4.0%)	0	2 (1.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Renal failure and impairment (cont)						
Chronic kidney disease	1 (2.8%)	0	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Grade 3	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 4	1 (2.8%)	0	1 (1.4%)	0	0	0
Bladder and urethral symptoms	2 (5.6%)	1 (2.6%)	3 (4.1%)	0	0	0
Grade 1	1 (2.8%)	1 (2.6%)	2 (2.7%)	0	0	0
Grade 2	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 3	0	0	0	0	0	0
Dysuria	1 (2.8%)	1 (2.6%)	2 (2.7%)	0	0	0
Grade 1	1 (2.8%)	1 (2.6%)	2 (2.7%)	0	0	0
Pollakiuria	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Bladder and urethral symptoms (cont)						
Pollakiuria (cont)						
Grade 3	1 (2.0%)	0	1 (0.9%)	0	0	0
Urinary incontinence	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	1 (1.8%)	1 (0.9%)	0	0	0
Urinary retention	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	1 (2.0%)	0	1 (0.9%)	0	0	0
Urinary tract signs and symptoms NEC	2 (4.0%)	1 (1.8%)	3 (2.8%)	0	0	0
Grade 1	2 (4.0%)	0	2 (1.9%)	0	0	0
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Bladder and urethral symptoms (cont)						
Pollakiuria (cont)						
Grade 3	0	0	0	0	0	0
Urinary incontinence	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 2	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 3	0	0	0	0	0	0
Urinary retention	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Urinary tract signs and symptoms NEC	0	2 (5.3%)	2 (2.7%)	0	2 (5.7%)	2 (3.4%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 2	0	2 (5.3%)	2 (2.7%)	0	0	0
Grade 3	0	0	0	0	1 (2.9%)	1 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Urinary tract signs and symptoms NEC (cont)						
Nocturia	2 (4.0%)	0	2 (1.9%)	0	0	0
Grade 1	2 (4.0%)	0	2 (1.9%)	0	0	0
Renal colic	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 3	0	0	0	0	0	0
Renal lithiasis	1 (2.0%)	2 (3.6%)	3 (2.8%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 3	0	1 (1.8%)	1 (0.9%)	0	0	0
Nephrolithiasis	1 (2.0%)	2 (3.6%)	3 (2.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Urinary tract signs and symptoms NEC (cont)						
Nocturia	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Renal colic	0	2 (5.3%)	2 (2.7%)	0	1 (2.9%)	1 (1.7%)
Grade 2	0	2 (5.3%)	2 (2.7%)	0	0	0
Grade 3	0	0	0	0	1 (2.9%)	1 (1.7%)
Renal lithiasis	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Nephrolithiasis	0	0	0	0	1 (2.9%)	1 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Renal lithiasis (cont)						
Nephrolithiasis (cont)						
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 3	0	1 (1.8%)	1 (0.9%)	0	0	0
Urinary abnormalities	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	2 (4.1%)	2 (2.2%)
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 3	0	1 (1.8%)	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Chromaturia	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Haematuria	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	2 (4.1%)	2 (2.2%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Renal lithiasis (cont)						
Nephrolithiasis (cont)						
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Urinary abnormalities	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Chromaturia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Haematuria	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Urinary abnormalities (cont)						
Haematuria (cont)						
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 3	0	1 (1.8%)	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Renal vascular and ischaemic conditions	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Renal artery stenosis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Urinary abnormalities (cont)						
Haematuria (cont)						
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Renal vascular and ischaemic conditions	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 2	0	1 (2.6%)	1 (1.4%)	0	0	0
Renal artery stenosis	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 2	0	1 (2.6%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders	9 (18.0%)	6 (10.7%)	15 (14.2%)	1 (2.5%)	4 (8.2%)	5 (5.6%)
Grade 1	2 (4.0%)	2 (3.6%)	4 (3.8%)	1 (2.5%)	0	1 (1.1%)
Grade 2	3 (6.0%)	2 (3.6%)	5 (4.7%)	0	2 (4.1%)	2 (2.2%)
Grade 3	4 (8.0%)	2 (3.6%)	6 (5.7%)	0	2 (4.1%)	2 (2.2%)
Grade 4	0	0	0	0	0	0
Supraventricular arrhythmias	5 (10.0%)	1 (1.8%)	6 (5.7%)	0	2 (4.1%)	2 (2.2%)
Grade 1	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	0	0
Grade 2	3 (6.0%)	0	3 (2.8%)	0	1 (2.0%)	1 (1.1%)
Grade 3	1 (2.0%)	0	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Atrial fibrillation	4 (8.0%)	0	4 (3.8%)	0	2 (4.1%)	2 (2.2%)
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	2 (4.0%)	0	2 (1.9%)	0	1 (2.0%)	1 (1.1%)
Grade 3	1 (2.0%)	0	1 (0.9%)	0	1 (2.0%)	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders	3 (8.3%)	2 (5.3%)	5 (6.8%)	2 (8.3%)	2 (5.7%)	4 (6.8%)
Grade 1	1 (2.8%)	0	1 (1.4%)	0	2 (5.7%)	2 (3.4%)
Grade 2	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 3	1 (2.8%)	2 (5.3%)	3 (4.1%)	1 (4.2%)	0	1 (1.7%)
Grade 4	1 (2.8%)	0	1 (1.4%)	0	0	0
Supraventricular arrhythmias	1 (2.8%)	1 (2.6%)	2 (2.7%)	2 (8.3%)	0	2 (3.4%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 3	1 (2.8%)	1 (2.6%)	2 (2.7%)	1 (4.2%)	0	1 (1.7%)
Atrial fibrillation	1 (2.8%)	1 (2.6%)	2 (2.7%)	1 (4.2%)	0	1 (1.7%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 3	1 (2.8%)	1 (2.6%)	2 (2.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Supraventricular arrhythmias (cont)						
Supraventricular tachycardia	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	1 (2.0%)	0	1 (0.9%)	0	0	0
Atrial flutter	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Sinus bradycardia	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 3	0	0	0	0	0	0
Heart failures NEC	2 (4.0%)	2 (3.6%)	4 (3.8%)	0	1 (2.0%)	1 (1.1%)
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (1.8%)	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Grade 3	2 (4.0%)	1 (1.8%)	3 (2.8%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
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Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Supraventricular arrhythmias (cont)						
Supraventricular tachycardia	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Atrial flutter	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Sinus bradycardia	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	1 (4.2%)	0	1 (1.7%)
Heart failures NEC	1 (2.8%)	2 (5.3%)	3 (4.1%)	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 2	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 3	1 (2.8%)	1 (2.6%)	2 (2.7%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Heart failures NEC (cont)						
Cardiac failure	1 (2.0%)	0	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 3	1 (2.0%)	0	1 (0.9%)	0	0	0
Cardiac failure congestive	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	0	0
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 3	1 (2.0%)	0	1 (0.9%)	0	0	0
Cardiac failure acute	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 3	0	1 (1.8%)	1 (0.9%)	0	0	0
Rate and rhythm disorders NEC	2 (4.0%)	0	2 (1.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Heart failures NEC (cont)						
Cardiac failure	1 (2.8%)	2 (5.3%)	3 (4.1%)	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 2	0	2 (5.3%)	2 (2.7%)	0	0	0
Grade 3	1 (2.8%)	0	1 (1.4%)	0	0	0
Cardiac failure congestive	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Cardiac failure acute	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 3	0	1 (2.6%)	1 (1.4%)	0	0	0
Rate and rhythm disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Rate and rhythm disorders NEC (cont)						
(cont)						
Grade 2	1 (2.0%)	0	1 (0.9%)	0	0	0
Extrasystoles	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Tachycardia	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	1 (2.0%)	0	1 (0.9%)	0	0	0
Cardiac conduction disorders	1 (2.0%)	0	1 (0.9%)	1 (2.5%)	0	1 (1.1%)
Grade 1	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 3	1 (2.0%)	0	1 (0.9%)	0	0	0
Atrioventricular block complete	1 (2.0%)	0	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Rate and rhythm disorders NEC (cont)						
(cont)						
Grade 2	0	0	0	0	0	0
Extrasystoles	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Tachycardia	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Cardiac conduction disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Atrioventricular block complete	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Cardiac conduction disorders (cont)						
Atrioventricular block complete (cont)						
Grade 3	1 (2.0%)	0	1 (0.9%)	0	0	0
Atrioventricular block first degree	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 1	0	0	0	1 (2.5%)	0	1 (1.1%)
Cardiac signs and symptoms NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Palpitations	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
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Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Cardiac conduction disorders (cont)						
Atrioventricular block complete (cont)						
Grade 3	0	0	0	0	0	0
Atrioventricular block first degree	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Cardiac signs and symptoms NEC	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0
Palpitations	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Ischaemic coronary artery disorders	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 4	0	0	0	0	0	0
Acute myocardial infarction	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Angina pectoris	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	1 (2.0%)	1 (1.1%)
Myocardial disorders NEC	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
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Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Ischaemic coronary artery disorders	1 (2.8%)	1 (2.6%)	2 (2.7%)	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 2	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 3	0	0	0	0	0	0
Grade 4	1 (2.8%)	0	1 (1.4%)	0	0	0
Acute myocardial infarction	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 4	1 (2.8%)	0	1 (1.4%)	0	0	0
Angina pectoris	1 (2.8%)	1 (2.6%)	2 (2.7%)	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 2	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 3	1 (2.8%)	0	1 (1.4%)	0	0	0
Myocardial disorders NEC	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Myocardial disorders NEC (cont)						
(cont)						
Grade 2	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	0	0
Cardiomegaly	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	1 (2.0%)	0	1 (0.9%)	0	0	0
Left ventricular dysfunction	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0
Pericardial disorders NEC	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 3	1 (2.0%)	0	1 (0.9%)	0	0	0
Pericardial effusion	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 3	1 (2.0%)	0	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Myocardial disorders NEC (cont)						
(cont)						
Grade 2	0	0	0	0	0	0
Cardiomegaly	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Left ventricular dysfunction	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Pericardial disorders NEC	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Pericardial effusion	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
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Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Cardiac hypertensive complications	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 3	0	1 (1.8%)	1 (0.9%)	0	0	0
Hypertensive heart disease	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 3	0	1 (1.8%)	1 (0.9%)	0	0	0
Cardiac valve disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Cardiac valve disease	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Left ventricular failures	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Cardiac hypertensive complications	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Hypertensive heart disease	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Cardiac valve disorders NEC	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Cardiac valve disease	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Left ventricular failures	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Left ventricular failures (cont)						
Left ventricular failure	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0
Mitral valvular disorders	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Mitral valve incompetence	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Injury, poisoning and procedural complications	8 (16.0%)	11 (19.6%)	19 (17.9%)	3 (7.5%)	5 (10.2%)	8 (9.0%)
Grade 1	6 (12.0%)	8 (14.3%)	14 (13.2%)	2 (5.0%)	1 (2.0%)	3 (3.4%)
Grade 2	2 (4.0%)	3 (5.4%)	5 (4.7%)	1 (2.5%)	3 (6.1%)	4 (4.5%)
Grade 3	0	0	0	0	1 (2.0%)	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
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Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Left ventricular failures (cont)						
Left ventricular failure	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Mitral valvular disorders	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 2	0	1 (2.6%)	1 (1.4%)	0	0	0
Mitral valve incompetence	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 2	0	1 (2.6%)	1 (1.4%)	0	0	0
Injury, poisoning and procedural complications	4 (11.1%)	4 (10.5%)	8 (10.8%)	3 (12.5%)	3 (8.6%)	6 (10.2%)
Grade 1	2 (5.6%)	1 (2.6%)	3 (4.1%)	2 (8.3%)	1 (2.9%)	3 (5.1%)
Grade 2	1 (2.8%)	2 (5.3%)	3 (4.1%)	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 3	1 (2.8%)	1 (2.6%)	2 (2.7%)	0	1 (2.9%)	1 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Skin injuries NEC	5 (10.0%)	4 (7.1%)	9 (8.5%)	2 (5.0%)	2 (4.1%)	4 (4.5%)
Grade 1	5 (10.0%)	4 (7.1%)	9 (8.5%)	2 (5.0%)	1 (2.0%)	3 (3.4%)
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Contusion	4 (8.0%)	1 (1.8%)	5 (4.7%)	2 (5.0%)	1 (2.0%)	3 (3.4%)
Grade 1	4 (8.0%)	1 (1.8%)	5 (4.7%)	2 (5.0%)	1 (2.0%)	3 (3.4%)
Grade 2	0	0	0	0	0	0
Skin abrasion	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	0	0
Grade 1	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	0	0
Skin laceration	0	2 (3.6%)	2 (1.9%)	0	1 (2.0%)	1 (1.1%)
Grade 1	0	2 (3.6%)	2 (1.9%)	0	0	0
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Skin injuries NEC	3 (8.3%)	3 (7.9%)	6 (8.1%)	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 1	2 (5.6%)	1 (2.6%)	3 (4.1%)	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 2	1 (2.8%)	2 (5.3%)	3 (4.1%)	0	0	0
Contusion	3 (8.3%)	3 (7.9%)	6 (8.1%)	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 1	2 (5.6%)	1 (2.6%)	3 (4.1%)	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 2	1 (2.8%)	2 (5.3%)	3 (4.1%)	0	0	0
Skin abrasion	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (2.6%)	1 (1.4%)	0	0	0
Skin laceration	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Non-site specific injuries NEC	4 (8.0%)	1 (1.8%)	5 (4.7%)	1 (2.5%)	4 (8.2%)	5 (5.6%)
Grade 1	4 (8.0%)	1 (1.8%)	5 (4.7%)	0	2 (4.1%)	2 (2.2%)
Grade 2	0	0	0	1 (2.5%)	2 (4.1%)	3 (3.4%)
Fall	4 (8.0%)	1 (1.8%)	5 (4.7%)	1 (2.5%)	4 (8.2%)	5 (5.6%)
Grade 1	4 (8.0%)	1 (1.8%)	5 (4.7%)	0	2 (4.1%)	2 (2.2%)
Grade 2	0	0	0	1 (2.5%)	2 (4.1%)	3 (3.4%)
Wound	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Non-site specific injuries NEC	0	3 (7.9%)	3 (4.1%)	1 (4.2%)	0	1 (1.7%)
Grade 1	0	3 (7.9%)	3 (4.1%)	1 (4.2%)	0	1 (1.7%)
Grade 2	0	0	0	0	0	0
Fall	0	3 (7.9%)	3 (4.1%)	1 (4.2%)	0	1 (1.7%)
Grade 1	0	3 (7.9%)	3 (4.1%)	1 (4.2%)	0	1 (1.7%)
Grade 2	0	0	0	0	0	0
Wound	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Non-site specific procedural complications	1 (2.0%)	2 (3.6%)	3 (2.8%)	0	1 (2.0%)	1 (1.1%)
Grade 1	0	0	0	0	0	0
Grade 2	1 (2.0%)	2 (3.6%)	3 (2.8%)	0	0	0
Grade 3	0	0	0	0	1 (2.0%)	1 (1.1%)
Post procedural complication	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	1 (2.0%)	0	1 (0.9%)	0	0	0
Post procedural contusion	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Procedural pain	0	1 (1.8%)	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Grade 2	0	1 (1.8%)	1 (0.9%)	0	1 (2.0%)	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Non-site specific procedural complications	2 (5.6%)	1 (2.6%)	3 (4.1%)	0	0	0
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	1 (2.8%)	1 (2.6%)	2 (2.7%)	0	0	0
Post procedural complication	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Post procedural contusion	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0
Procedural pain	1 (2.8%)	1 (2.6%)	2 (2.7%)	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
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TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Non-site specific procedural complications (cont)						
Procedural pain (cont)						
Grade 3	0	0	0	0	0	0
Post procedural haemorrhage	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 3	0	0	0	0	1 (2.0%)	1 (1.1%)
Seroma	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0
Site specific injuries NEC	3 (6.0%)	1 (1.8%)	4 (3.8%)	0	1 (2.0%)	1 (1.1%)
Grade 1	2 (4.0%)	0	2 (1.9%)	0	1 (2.0%)	1 (1.1%)
Grade 2	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Non-site specific procedural complications (cont)						
Procedural pain (cont)						
Grade 3	1 (2.8%)	1 (2.6%)	2 (2.7%)	0	0	0
Post procedural haemorrhage	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Seroma	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Site specific injuries NEC	0	0	0	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	1 (4.2%)	1 (2.9%)	2 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
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Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Site specific injuries NEC (cont)						
Limb injury	2 (4.0%)	0	2 (1.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	1 (2.0%)	0	1 (0.9%)	0	0	0
Limb crushing injury	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Head injury	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 1	0	0	0	0	1 (2.0%)	1 (1.1%)
Mouth injury	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Site specific injuries NEC (cont)						
Limb injury	0	0	0	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	1 (4.2%)	1 (2.9%)	2 (3.4%)
Limb crushing injury	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Head injury	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Mouth injury	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Chest and respiratory tract injuries NEC	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Traumatic haemothorax	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Eye injuries NEC	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0
Eye contusion	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
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Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Chest and respiratory tract injuries NEC	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 3	0	0	0	0	1 (2.9%)	1 (1.7%)
Traumatic haemothorax	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 3	0	0	0	0	1 (2.9%)	1 (1.7%)
Eye injuries NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Eye contusion	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Gastrointestinal and hepatobiliary procedural complications	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Procedural nausea	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Limb fractures and dislocations	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Patella fracture	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Muscle, tendon and ligament injuries	0	2 (3.6%)	2 (1.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Gastrointestinal and hepatobiliary procedural complications	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Procedural nausea	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Limb fractures and dislocations	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 2	0	0	0	0	1 (2.9%)	1 (1.7%)
Patella fracture	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 2	0	0	0	0	1 (2.9%)	1 (1.7%)
Muscle, tendon and ligament injuries	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Muscle, tendon and ligament injuries (cont)						
(cont)						
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0
Ligament rupture	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0
Ligament sprain	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0
Skull fractures, facial bone fractures and dislocations	0	0	0	0	1 (2.0%)	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Muscle, tendon and ligament injuries (cont)						
(cont)						
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Ligament rupture	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Ligament sprain	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Skull fractures, facial bone fractures and dislocations	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Skull fractures, facial bone fractures and dislocations (cont) (cont)						
Grade 1	0	0	0	0	1 (2.0%)	1 (1.1%)
Facial bones fracture	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 1	0	0	0	0	1 (2.0%)	1 (1.1%)
Transfusion related complications	0	2 (3.6%)	2 (1.9%)	0	0	0
Grade 1	0	2 (3.6%)	2 (1.9%)	0	0	0
Transfusion reaction	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Skull fractures, facial bone fractures and dislocations (cont) (cont)						
Grade 1	0	0	0	0	0	0
Facial bones fracture	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Transfusion related complications	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Transfusion reaction	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Transfusion related complications (cont)						
Transfusion related complication	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0
Eye disorders	8 (16.0%)	6 (10.7%)	14 (13.2%)	5 (12.5%)	1 (2.0%)	6 (6.7%)
Grade 1	7 (14.0%)	3 (5.4%)	10 (9.4%)	4 (10.0%)	1 (2.0%)	5 (5.6%)
Grade 2	1 (2.0%)	3 (5.4%)	4 (3.8%)	0	0	0
Grade 3	0	0	0	0	0	0
Grade 4	0	0	0	1 (2.5%)	0	1 (1.1%)
Cataract conditions	3 (6.0%)	1 (1.8%)	4 (3.8%)	1 (2.5%)	0	1 (1.1%)
Grade 1	2 (4.0%)	1 (1.8%)	3 (2.8%)	1 (2.5%)	0	1 (1.1%)
Grade 2	1 (2.0%)	0	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Transfusion related complications (cont)						
Transfusion related complication	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Eye disorders	2 (5.6%)	1 (2.6%)	3 (4.1%)	3 (12.5%)	3 (8.6%)	6 (10.2%)
Grade 1	2 (5.6%)	1 (2.6%)	3 (4.1%)	2 (8.3%)	3 (8.6%)	5 (8.5%)
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 4	0	0	0	0	0	0
Cataract conditions	0	0	0	3 (12.5%)	1 (2.9%)	4 (6.8%)
Grade 1	0	0	0	2 (8.3%)	1 (2.9%)	3 (5.1%)
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Cataract conditions (cont)						
(cont)						
Grade 3	0	0	0	0	0	0
Cataract	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Cataract cortical	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	1 (2.0%)	0	1 (0.9%)	0	0	0
Cataract nuclear	1 (2.0%)	1 (1.8%)	2 (1.9%)	1 (2.5%)	0	1 (1.1%)
Grade 1	1 (2.0%)	1 (1.8%)	2 (1.9%)	1 (2.5%)	0	1 (1.1%)
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Cataract conditions (cont)						
(cont)						
Grade 3	0	0	0	1 (4.2%)	0	1 (1.7%)
Cataract	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Cataract cortical	0	0	0	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 1	0	0	0	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 2	0	0	0	0	0	0
Cataract nuclear	0	0	0	2 (8.3%)	0	2 (3.4%)
Grade 1	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 3	0	0	0	1 (4.2%)	0	1 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Cataract conditions (cont)						
Cataract subcapsular	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0
Visual disorders NEC	2 (4.0%)	2 (3.6%)	4 (3.8%)	1 (2.5%)	0	1 (1.1%)
Grade 1	2 (4.0%)	0	2 (1.9%)	0	0	0
Grade 2	0	2 (3.6%)	2 (1.9%)	0	0	0
Grade 3	0	0	0	1 (2.5%)	0	1 (1.1%)
Vision blurred	2 (4.0%)	1 (1.8%)	3 (2.8%)	1 (2.5%)	0	1 (1.1%)
Grade 1	2 (4.0%)	0	2 (1.9%)	0	0	0
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 3	0	0	0	1 (2.5%)	0	1 (1.1%)
Diplopia	0	1 (1.8%)	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Cataract conditions (cont)						
Cataract subcapsular	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 1	0	0	0	1 (4.2%)	0	1 (1.7%)
Visual disorders NEC	1 (2.8%)	0	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Grade 1	1 (2.8%)	0	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Vision blurred	1 (2.8%)	0	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Grade 1	1 (2.8%)	0	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Diplopia	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Visual disorders NEC (cont)						
Diplopia (cont)						
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0
Lacrimation disorders	2 (4.0%)	2 (3.6%)	4 (3.8%)	0	1 (2.0%)	1 (1.1%)
Grade 1	2 (4.0%)	1 (1.8%)	3 (2.8%)	0	1 (2.0%)	1 (1.1%)
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0
Lacrimation increased	2 (4.0%)	0	2 (1.9%)	0	0	0
Grade 1	2 (4.0%)	0	2 (1.9%)	0	0	0
Dry eye	0	2 (3.6%)	2 (1.9%)	0	1 (2.0%)	1 (1.1%)
Grade 1	0	1 (1.8%)	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Visual disorders NEC (cont)						
Diplopia (cont)						
Grade 2	0	0	0	0	0	0
Lacrimation disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Lacrimation increased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dry eye	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Choroid and vitreous structural change, deposit and degeneration	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Hyalosis asteroid	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Corneal infections, oedemas and inflammations	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Keratitis	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Ocular disorders NEC	0	1 (1.8%)	1 (0.9%)	1 (2.5%)	0	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Choroid and vitreous structural change, deposit and degeneration	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hyalosis asteroid	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Corneal infections, oedemas and inflammations	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Keratitis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Ocular disorders NEC	1 (2.8%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Ocular disorders NEC (cont)						
(cont)						
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 3	0	0	0	1 (2.5%)	0	1 (1.1%)
Periorbital oedema	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Eye oedema	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0
Eye pain	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 3	0	0	0	1 (2.5%)	0	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Ocular disorders NEC (cont)						
(cont)						
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 3	0	0	0	0	0	0
Periorbital oedema	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0
Eye oedema	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Eye pain	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Retinal bleeding and vascular disorders (excl retinopathy)	1 (2.0%)	0	1 (0.9%)	1 (2.5%)	0	1 (1.1%)
Grade 1	1 (2.0%)	0	1 (0.9%)	1 (2.5%)	0	1 (1.1%)
Retinal haemorrhage	1 (2.0%)	0	1 (0.9%)	1 (2.5%)	0	1 (1.1%)
Grade 1	1 (2.0%)	0	1 (0.9%)	1 (2.5%)	0	1 (1.1%)
Retinal structural change, deposit and degeneration	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Macular degeneration	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Retinal bleeding and vascular disorders (excl retinopathy)	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Retinal haemorrhage	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Retinal structural change, deposit and degeneration	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Macular degeneration	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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SAF-Anemic Analysis Set

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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Visual impairment and blindness (excl colour blindness)	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0
Visual acuity reduced	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Visual impairment	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0
Conjunctival and corneal bleeding and vascular disorders	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 1	0	0	0	1 (2.5%)	0	1 (1.1%)
Conjunctival haemorrhage	0	0	0	1 (2.5%)	0	1 (1.1%)

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SAF-Anemic Analysis Set

(Continued)	Female					
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Visual impairment and blindness (excl colour blindness)	1 (2.8%)	1 (2.6%)	2 (2.7%)	0	0	0
Grade 1	1 (2.8%)	1 (2.6%)	2 (2.7%)	0	0	0
Visual acuity reduced	1 (2.8%)	1 (2.6%)	2 (2.7%)	0	0	0
Grade 1	1 (2.8%)	1 (2.6%)	2 (2.7%)	0	0	0
Visual impairment	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Conjunctival and corneal bleeding and vascular disorders	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Conjunctival haemorrhage	0	0	0	0	1 (2.9%)	1 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
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Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Conjunctival and corneal bleeding and vascular disorders (cont)						
Conjunctival haemorrhage (cont)						
Grade 1	0	0	0	1 (2.5%)	0	1 (1.1%)
Eyelid movement disorders	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 1	0	0	0	1 (2.5%)	0	1 (1.1%)
Eyelid ptosis	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 1	0	0	0	1 (2.5%)	0	1 (1.1%)
Lid, lash and lacrimal infections, irritations and inflammations	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
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SAF-Anemic Analysis Set

(Continued)	Female					
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Conjunctival and corneal bleeding and vascular disorders (cont)						
Conjunctival haemorrhage (cont)						
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Eyelid movement disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Eyelid ptosis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Lid, lash and lacrimal infections, irritations and inflammations	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
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Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
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	Male					
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Lid, lash and lacrimal infections, irritations and inflammations (cont)						
Eyelid oedema	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Ocular bleeding and vascular disorders NEC	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 4	0	0	0	1 (2.5%)	0	1 (1.1%)
Eye haemorrhage	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 4	0	0	0	1 (2.5%)	0	1 (1.1%)
Psychiatric disorders	5 (10.0%)	6 (10.7%)	11 (10.4%)	3 (7.5%)	6 (12.2%)	9 (10.1%)
Grade 1	3 (6.0%)	4 (7.1%)	7 (6.6%)	2 (5.0%)	2 (4.1%)	4 (4.5%)
Grade 2	2 (4.0%)	2 (3.6%)	4 (3.8%)	1 (2.5%)	4 (8.2%)	5 (5.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
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Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Lid, lash and lacrimal infections, irritations and inflammations (cont)						
Eyelid oedema	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Ocular bleeding and vascular disorders NEC	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Eye haemorrhage	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Psychiatric disorders	3 (8.3%)	0	3 (4.1%)	3 (12.5%)	2 (5.7%)	5 (8.5%)
Grade 1	1 (2.8%)	0	1 (1.4%)	2 (8.3%)	1 (2.9%)	3 (5.1%)
Grade 2	2 (5.6%)	0	2 (2.7%)	1 (4.2%)	1 (2.9%)	2 (3.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Anxiety symptoms	0	3 (5.4%)	3 (2.8%)	1 (2.5%)	0	1 (1.1%)
Grade 1	0	2 (3.6%)	2 (1.9%)	1 (2.5%)	0	1 (1.1%)
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0
Anxiety	0	3 (5.4%)	3 (2.8%)	1 (2.5%)	0	1 (1.1%)
Grade 1	0	2 (3.6%)	2 (1.9%)	1 (2.5%)	0	1 (1.1%)
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0
Depressive disorders	3 (6.0%)	0	3 (2.8%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	2 (4.0%)	0	2 (1.9%)	0	0	0
Depression	3 (6.0%)	0	3 (2.8%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	2 (4.0%)	0	2 (1.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Anxiety symptoms	3 (8.3%)	0	3 (4.1%)	0	0	0
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 2	2 (5.6%)	0	2 (2.7%)	0	0	0
Anxiety	3 (8.3%)	0	3 (4.1%)	0	0	0
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 2	2 (5.6%)	0	2 (2.7%)	0	0	0
Depressive disorders	0	0	0	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 1	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 2	0	0	0	0	1 (2.9%)	1 (1.7%)
Depression	0	0	0	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 1	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 2	0	0	0	0	1 (2.9%)	1 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Confusion and disorientation	1 (2.0%)	0	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Confusional state	1 (2.0%)	0	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Disturbances in initiating and maintaining sleep	1 (2.0%)	2 (3.6%)	3 (2.8%)	2 (5.0%)	3 (6.1%)	5 (5.6%)
Grade 1	1 (2.0%)	1 (1.8%)	2 (1.9%)	1 (2.5%)	1 (2.0%)	2 (2.2%)
Grade 2	0	1 (1.8%)	1 (0.9%)	1 (2.5%)	2 (4.1%)	3 (3.4%)
Insomnia	1 (2.0%)	2 (3.6%)	3 (2.8%)	2 (5.0%)	3 (6.1%)	5 (5.6%)
Grade 1	1 (2.0%)	1 (1.8%)	2 (1.9%)	1 (2.5%)	1 (2.0%)	2 (2.2%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Confusion and disorientation	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 1	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 2	0	0	0	0	0	0
Confusional state	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 1	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 2	0	0	0	0	0	0
Disturbances in initiating and maintaining sleep	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 2	0	0	0	0	0	0
Insomnia	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Disturbances in initiating and maintaining sleep (cont)						
Insomnia (cont)						
Grade 2	0	1 (1.8%)	1 (0.9%)	1 (2.5%)	2 (4.1%)	3 (3.4%)
Hallucinations (excl sleep-related)	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Hallucination	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Mental disorders NEC	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Mental status changes	1 (2.0%)	0	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Disturbances in initiating and maintaining sleep (cont)						
Insomnia (cont)						
Grade 2	0	0	0	0	0	0
Hallucinations (excl sleep-related)	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hallucination	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Mental disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Mental status changes	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase	DB Phase	DB Phase	OL Phase (Week 24 - 48) Continuing	OL Phase (Week 24 - 48) Switch	OL Phase (Week 24 - 48)
	MMB (N=50)	RUX (N=56)	Total (N=106)	(MMB->MMB) (N=40)	(RUX->MMB) (N=49)	Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Mental disorders NEC (cont)						
Mental status changes (cont)						
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Anxiety disorders NEC	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0
Anxiety disorder	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0
Parasomnias	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0
Nightmare	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Mental disorders NEC (cont)						
Mental status changes (cont)						
Grade 1	0	0	0	0	0	0
Anxiety disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Anxiety disorder	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Parasomnias	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Nightmare	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Sexual desire disorders	0	0	0	1 (2.5%)	1 (2.0%)	2 (2.2%)
Grade 1	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Libido decreased	0	0	0	1 (2.5%)	1 (2.0%)	2 (2.2%)
Grade 1	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 2	0	0	0	0	1 (2.0%)	1 (1.1%)
Sleep disorders NEC	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 1	0	0	0	0	1 (2.0%)	1 (1.1%)
Sleep disorder	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 1	0	0	0	0	1 (2.0%)	1 (1.1%)
Suicidal and self-injurious behaviour	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Sexual desire disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Libido decreased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Sleep disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Sleep disorder	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Suicidal and self-injurious behaviour	0	0	0	1 (4.2%)	0	1 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
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Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Suicidal and self-injurious behaviour (cont) (cont)						
Grade 2	0	0	0	0	0	0
Suicidal ideation	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Ear and labyrinth disorders	1 (2.0%)	4 (7.1%)	5 (4.7%)	2 (5.0%)	2 (4.1%)	4 (4.5%)
Grade 1	1 (2.0%)	4 (7.1%)	5 (4.7%)	0	2 (4.1%)	2 (2.2%)
Grade 2	0	0	0	2 (5.0%)	0	2 (2.2%)
Grade 3	0	0	0	0	0	0
Inner ear signs and symptoms	1 (2.0%)	3 (5.4%)	4 (3.8%)	0	1 (2.0%)	1 (1.1%)
Grade 1	1 (2.0%)	3 (5.4%)	4 (3.8%)	0	1 (2.0%)	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Suicidal and self-injurious behaviour (cont)						
(cont)						
Grade 2	0	0	0	1 (4.2%)	0	1 (1.7%)
Suicidal ideation	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 2	0	0	0	1 (4.2%)	0	1 (1.7%)
Ear and labyrinth disorders	4 (11.1%)	2 (5.3%)	6 (8.1%)	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 1	2 (5.6%)	1 (2.6%)	3 (4.1%)	1 (4.2%)	0	1 (1.7%)
Grade 2	2 (5.6%)	0	2 (2.7%)	0	1 (2.9%)	1 (1.7%)
Grade 3	0	1 (2.6%)	1 (1.4%)	0	0	0
Inner ear signs and symptoms	3 (8.3%)	1 (2.6%)	4 (5.4%)	1 (4.2%)	1 (2.9%)	2 (3.4%)
Grade 1	2 (5.6%)	0	2 (2.7%)	1 (4.2%)	0	1 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
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Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Ear and labyrinth disorders (cont)						
Inner ear signs and symptoms (cont)						
(cont)						
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Vertigo	1 (2.0%)	3 (5.4%)	4 (3.8%)	0	1 (2.0%)	1 (1.1%)
Grade 1	1 (2.0%)	3 (5.4%)	4 (3.8%)	0	1 (2.0%)	1 (1.1%)
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Motion sickness	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hearing losses	0	0	0	2 (5.0%)	1 (2.0%)	3 (3.4%)
Grade 1	0	0	0	0	1 (2.0%)	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Ear and labyrinth disorders (cont)						
Inner ear signs and symptoms (cont)						
(cont)						
Grade 2	1 (2.8%)	0	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Grade 3	0	1 (2.6%)	1 (1.4%)	0	0	0
Vertigo	3 (8.3%)	1 (2.6%)	4 (5.4%)	0	1 (2.9%)	1 (1.7%)
Grade 1	2 (5.6%)	0	2 (2.7%)	0	0	0
Grade 2	1 (2.8%)	0	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Grade 3	0	1 (2.6%)	1 (1.4%)	0	0	0
Motion sickness	0	0	0	1 (4.2%)	0	1 (1.7%)
Grade 1	0	0	0	1 (4.2%)	0	1 (1.7%)
Hearing losses	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Ear and labyrinth disorders (cont)						
Hearing losses (cont)						
(cont)						
Grade 2	0	0	0	2 (5.0%)	0	2 (2.2%)
Hypoacusis	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 1	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 2	0	0	0	0	0	0
Deafness	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 2	0	0	0	1 (2.5%)	0	1 (1.1%)
Sudden hearing loss	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 2	0	0	0	1 (2.5%)	0	1 (1.1%)
Ear disorders NEC	0	1 (1.8%)	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Ear and labyrinth disorders (cont)						
Hearing losses (cont)						
(cont)						
Grade 2	1 (2.8%)	0	1 (1.4%)	0	0	0
Hypoacusis	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	1 (2.8%)	0	1 (1.4%)	0	0	0
Deafness	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Sudden hearing loss	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Ear disorders NEC	0	1 (2.6%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Ear and labyrinth disorders (cont)						
Ear disorders NEC (cont)						
(cont)						
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0
Ear discomfort	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Ear pain	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Ear and labyrinth disorders (cont)						
Ear disorders NEC (cont)						
(cont)						
Grade 1	0	1 (2.6%)	1 (1.4%)	0	0	0
Ear discomfort	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (2.6%)	1 (1.4%)	0	0	0
Ear pain	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (4.0%)	6 (10.7%)	8 (7.5%)	2 (5.0%)	4 (8.2%)	6 (6.7%)
Grade 1	0	1 (1.8%)	1 (0.9%)	0	2 (4.1%)	2 (2.2%)
Grade 2	0	3 (5.4%)	3 (2.8%)	0	1 (2.0%)	1 (1.1%)
Grade 3	0	1 (1.8%)	1 (0.9%)	2 (5.0%)	1 (2.0%)	3 (3.4%)
Grade 4	2 (4.0%)	0	2 (1.9%)	0	0	0
Grade 5	0	1 (1.8%)	1 (0.9%)	0	0	0
Leukaemias acute myeloid	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 4	1 (2.0%)	0	1 (0.9%)	0	0	0
Acute myeloid leukaemia	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 4	1 (2.0%)	0	1 (0.9%)	0	0	0
Ovarian neoplasms malignant (excl germ cell)	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (2.8%)	0	1 (1.4%)	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 2	0	0	0	0	0	0
Grade 3	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 4	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Leukaemias acute myeloid	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Acute myeloid leukaemia	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Ovarian neoplasms malignant (excl germ cell)	1 (2.8%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Ovarian neoplasms malignant (excl germ cell) (cont) (cont)						
Grade 3	0	0	0	0	0	0
Ovarian clear cell carcinoma	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Splenic marginal zone lymphomas	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 4	1 (2.0%)	0	1 (0.9%)	0	0	0
Splenic marginal zone lymphoma	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 4	1 (2.0%)	0	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Ovarian neoplasms malignant (excl germ cell) (cont) (cont)						
Grade 3	1 (2.8%)	0	1 (1.4%)	0	0	0
Ovarian clear cell carcinoma	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 3	1 (2.8%)	0	1 (1.4%)	0	0	0
Splenic marginal zone lymphomas	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Splenic marginal zone lymphoma	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Uterine neoplasms malignant NEC	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Uterine cancer	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Bone neoplasms benign (excl cysts)	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Haemangioma of bone	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Colorectal neoplasms malignant	0	0	0	1 (2.5%)	0	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
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Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Uterine neoplasms malignant NEC	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 3	1 (2.8%)	0	1 (1.4%)	0	0	0
Uterine cancer	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 3	1 (2.8%)	0	1 (1.4%)	0	0	0
Bone neoplasms benign (excl cysts)	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Haemangioma of bone	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Colorectal neoplasms malignant	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Colorectal neoplasms malignant (cont) (cont)						
Grade 3	0	0	0	1 (2.5%)	0	1 (1.1%)
Rectal cancer	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 3	0	0	0	1 (2.5%)	0	1 (1.1%)
Mantle cell lymphomas	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 5	0	1 (1.8%)	1 (0.9%)	0	0	0
Mantle cell lymphoma recurrent	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 5	0	1 (1.8%)	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cists and polyps) (cont)						
Colorectal neoplasms malignant (cont) (cont)						
Grade 3	0	0	0	0	0	0
Rectal cancer	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Mantle cell lymphomas	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Mantle cell lymphoma recurrent	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Myeloproliferative disorders (excl leukaemias)	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 3	0	0	0	1 (2.5%)	0	1 (1.1%)
Leukoerythroblastosis	0	0	0	1 (2.5%)	0	1 (1.1%)
Grade 3	0	0	0	1 (2.5%)	0	1 (1.1%)
Nasal and paranasal sinus neoplasms benign	0	1 (1.8%)	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 3	0	0	0	0	1 (2.0%)	1 (1.1%)
Nasal neoplasm benign	0	1 (1.8%)	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Myeloproliferative disorders (excl leukaemias)	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Leukoerythroblastosis	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Nasal and paranasal sinus neoplasms benign	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Nasal neoplasm benign	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
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Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Nasal and paranasal sinus neoplasms benign (cont)						
Nasal neoplasm benign (cont)						
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0
Sinonasal papilloma	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 3	0	0	0	0	1 (2.0%)	1 (1.1%)
Neoplasms malignant site unspecified NEC	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 1	0	0	0	0	1 (2.0%)	1 (1.1%)
Metastatic squamous cell carcinoma	0	0	0	0	1 (2.0%)	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
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Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Nasal and paranasal sinus neoplasms benign (cont)						
Nasal neoplasm benign (cont)						
Grade 1	0	0	0	0	0	0
Sinonasal papilloma	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Neoplasms malignant site unspecified NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Metastatic squamous cell carcinoma	0	0	0	0	0	0

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SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
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Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Neoplasms malignant site unspecified NEC (cont)						
Metastatic squamous cell carcinoma (cont)						
Grade 1	0	0	0	0	1 (2.0%)	1 (1.1%)
Prostatic neoplasms malignant	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0
Prostate cancer recurrent	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0
Skin neoplasms benign	0	0	0	0	1 (2.0%)	1 (1.1%)

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SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Neoplasms malignant site unspecified NEC (cont)						
Metastatic squamous cell carcinoma (cont)						
Grade 1	0	0	0	0	0	0
Prostatic neoplasms malignant	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Prostate cancer recurrent	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Skin neoplasms benign	0	0	0	0	0	0

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Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Skin neoplasms benign (cont) (cont)						
Grade 1	0	0	0	0	1 (2.0%)	1 (1.1%)
Seborrhoeic keratosis	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 1	0	0	0	0	1 (2.0%)	1 (1.1%)
Skin neoplasms malignant and unspecified (excl melanoma)	0	3 (5.4%)	3 (2.8%)	0	1 (2.0%)	1 (1.1%)
Grade 2	0	2 (3.6%)	2 (1.9%)	0	1 (2.0%)	1 (1.1%)
Grade 3	0	1 (1.8%)	1 (0.9%)	0	0	0
Squamous cell carcinoma of skin	0	3 (5.4%)	3 (2.8%)	0	1 (2.0%)	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Skin neoplasms benign (cont) (cont)						
Grade 1	0	0	0	0	0	0
Seborrhoeic keratosis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Skin neoplasms malignant and unspecified (excl melanoma)	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Squamous cell carcinoma of skin	0	0	0	0	0	0

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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Skin neoplasms malignant and unspecified (excl melanoma) (cont)						
Squamous cell carcinoma of skin (cont)						
Grade 2	0	2 (3.6%)	2 (1.9%)	0	1 (2.0%)	1 (1.1%)
Grade 3	0	1 (1.8%)	1 (0.9%)	0	0	0
Uterine neoplasms benign	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Uterine leiomyoma	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

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Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
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(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Skin neoplasms malignant and unspecified (excl melanoma) (cont)						
Squamous cell carcinoma of skin (cont)						
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Uterine neoplasms benign	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)
Uterine leiomyoma	0	0	0	0	1 (2.9%)	1 (1.7%)
Grade 1	0	0	0	0	1 (2.9%)	1 (1.7%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Reproductive system and breast disorders	1 (2.0%)	1 (1.8%)	2 (1.9%)	0	1 (2.0%)	1 (1.1%)
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 3	0	1 (1.8%)	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Prostatic neoplasms and hypertrophy	1 (2.0%)	0	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 3	0	0	0	0	1 (2.0%)	1 (1.1%)
Benign prostatic hyperplasia	1 (2.0%)	0	1 (0.9%)	0	1 (2.0%)	1 (1.1%)
Grade 1	1 (2.0%)	0	1 (0.9%)	0	0	0
Grade 3	0	0	0	0	1 (2.0%)	1 (1.1%)
Vulvovaginal disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Vaginal haemorrhage	0	0	0	0	0	0

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Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Reproductive system and breast disorders	2 (5.6%)	0	2 (2.7%)	0	0	0
Grade 1	2 (5.6%)	0	2 (2.7%)	0	0	0
Grade 3	0	0	0	0	0	0
Prostatic neoplasms and hypertrophy	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Benign prostatic hyperplasia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Vulvovaginal disorders NEC	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0
Vaginal haemorrhage	1 (2.8%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Reproductive system and breast disorders (cont)						
Vulvovaginal disorders NEC (cont)						
Vaginal haemorrhage (cont)						
Grade 1	0	0	0	0	0	0
Vulvovaginal signs and symptoms	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Vulvovaginal pain	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Scrotal disorders NEC	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 3	0	1 (1.8%)	1 (0.9%)	0	0	0
Scrotal oedema	0	1 (1.8%)	1 (0.9%)	0	0	0

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Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Reproductive system and breast disorders (cont)						
Vulvovaginal disorders NEC (cont)						
Vaginal haemorrhage (cont)						
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0
Vulvovaginal signs and symptoms	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0
Vulvovaginal pain	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0
Scrotal disorders NEC	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Scrotal oedema	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Reproductive system and breast disorders (cont)						
Scrotal disorders NEC (cont)						
Scrotal oedema (cont)						
Grade 3	0	1 (1.8%)	1 (0.9%)	0	0	0
Surgical and medical procedures	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dental and gingival therapeutic procedures	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Tooth extraction	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Reproductive system and breast disorders (cont)						
Scrotal disorders NEC (cont)						
Scrotal oedema (cont)						
Grade 3	0	0	0	0	0	0
Surgical and medical procedures	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0
Dental and gingival therapeutic procedures	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0
Tooth extraction	1 (2.8%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.8%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Congenital, familial and genetic disorders	0	2 (3.6%)	2 (1.9%)	0	0	0
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0
Male reproductive tract disorders congenital	0	2 (3.6%)	2 (1.9%)	0	0	0
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0
Hydrocele	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0
Phimosis	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Congenital, familial and genetic disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Male reproductive tract disorders congenital	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Hydrocele	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Phimosis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Hepatobiliary disorders	0	2 (3.6%)	2 (1.9%)	1 (2.5%)	2 (4.1%)	3 (3.4%)
Grade 1	0	1 (1.8%)	1 (0.9%)	1 (2.5%)	1 (2.0%)	2 (2.2%)
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 3	0	0	0	0	1 (2.0%)	1 (1.1%)
Bile duct infections and inflammations	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 3	0	0	0	0	0	0
Biliary colic	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 1	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 3	0	0	0	0	0	0
Cholestasis and jaundice	0	0	0	1 (2.5%)	1 (2.0%)	2 (2.2%)
Grade 1	0	0	0	1 (2.5%)	1 (2.0%)	2 (2.2%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-db.pdf 29AUG2023: 9:41

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Hepatobiliary disorders	0	2 (5.3%)	2 (2.7%)	0	0	0
Grade 1	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	1 (2.6%)	1 (1.4%)	0	0	0
Bile duct infections and inflammations	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	1 (2.6%)	1 (1.4%)	0	0	0
Biliary colic	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	1 (2.6%)	1 (1.4%)	0	0	0
Cholestasis and jaundice	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Hepatobiliary disorders (cont)						
Cholestasis and jaundice (cont)						
Ocular icterus	0	0	0	1 (2.5%)	1 (2.0%)	2 (2.2%)
Grade 1	0	0	0	1 (2.5%)	1 (2.0%)	2 (2.2%)
Hepatic enzymes and function abnormalities	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hepatic function abnormal	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hepatic vascular disorders	0	0	0	0	1 (2.0%)	1 (1.1%)
Grade 3	0	0	0	0	1 (2.0%)	1 (1.1%)
Portal hypertension	0	0	0	0	1 (2.0%)	1 (1.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Hepatobiliary disorders (cont)						
Cholestasis and jaundice (cont)						
Ocular icterus	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hepatic enzymes and function abnormalities	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (2.6%)	1 (1.4%)	0	0	0
Hepatic function abnormal	0	1 (2.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (2.6%)	1 (1.4%)	0	0	0
Hepatic vascular disorders	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Portal hypertension	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

	Male					
	DB Phase MMB (N=50)	DB Phase RUX (N=56)	DB Phase Total (N=106)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 - 48) Total (N=89)
Number of Subjects with Any Treatment-Emergent AE	48 (96.0%)	54 (96.4%)	102 (96.2%)	35 (87.5%)	46 (93.9%)	81 (91.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Hepatobiliary disorders (cont)						
Hepatic vascular disorders (cont)						
Portal hypertension (cont)						
Grade 3	0	0	0	0	1 (2.0%)	1 (1.1%)
Hepatocellular damage and hepatitis NEC	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0
Hepatocellular injury	0	1 (1.8%)	1 (0.9%)	0	0	0
Grade 2	0	1 (1.8%)	1 (0.9%)	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0801: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Double-Blind Phase, and First 24 Weeks in Open-Label Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	DB Phase MMB (N=36)	DB Phase RUX (N=38)	DB Phase Total (N=74)	OL Phase (Week 24 - 48) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 - 48) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 - 48) Total (N=59)
Number of Subjects with Any Treatment-Emergent AE	33 (91.7%)	37 (97.4%)	70 (94.6%)	18 (75.0%)	28 (80.0%)	46 (78.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Hepatobiliary disorders (cont)						
Hepatic vascular disorders (cont)						
Portal hypertension (cont)						
Grade 3	0	0	0	0	0	0
Hepatocellular damage and hepatitis NEC	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Hepatocellular injury	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders	16 (40.0%)	28 (57.1%)	44 (49.4%)	60 (60.6%)
Grade 1	10 (25.0%)	8 (16.3%)	18 (20.2%)	28 (28.3%)
Grade 2	4 (10.0%)	13 (26.5%)	17 (19.1%)	20 (20.2%)
Grade 3	1 (2.5%)	6 (12.2%)	7 (7.9%)	10 (10.1%)
Grade 4	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 5	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Diarrhoea (excl infective)	8 (20.0%)	14 (28.6%)	22 (24.7%)	29 (29.3%)
Grade 1	7 (17.5%)	7 (14.3%)	14 (15.7%)	19 (19.2%)
Grade 2	1 (2.5%)	4 (8.2%)	5 (5.6%)	7 (7.1%)
Grade 3	0	3 (6.1%)	3 (3.4%)	3 (3.0%)
Diarrhoea	8 (20.0%)	14 (28.6%)	22 (24.7%)	29 (29.3%)
Grade 1	7 (17.5%)	7 (14.3%)	14 (15.7%)	19 (19.2%)
Grade 2	1 (2.5%)	4 (8.2%)	5 (5.6%)	7 (7.1%)
Grade 3	0	3 (6.1%)	3 (3.4%)	3 (3.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-ol.pdf 29AUG2023: 9:41

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders	14 (58.3%)	26 (74.3%)	40 (67.8%)	52 (73.2%)
Grade 1	9 (37.5%)	11 (31.4%)	20 (33.9%)	25 (35.2%)
Grade 2	5 (20.8%)	12 (34.3%)	17 (28.8%)	21 (29.6%)
Grade 3	0	3 (8.6%)	3 (5.1%)	5 (7.0%)
Grade 4	0	0	0	0
Grade 5	0	0	0	1 (1.4%)
Diarrhoea (excl infective)	6 (25.0%)	7 (20.0%)	13 (22.0%)	21 (29.6%)
Grade 1	5 (20.8%)	5 (14.3%)	10 (16.9%)	11 (15.5%)
Grade 2	1 (4.2%)	1 (2.9%)	2 (3.4%)	7 (9.9%)
Grade 3	0	1 (2.9%)	1 (1.7%)	3 (4.2%)
Diarrhoea	6 (25.0%)	7 (20.0%)	13 (22.0%)	21 (29.6%)
Grade 1	5 (20.8%)	5 (14.3%)	10 (16.9%)	11 (15.5%)
Grade 2	1 (4.2%)	1 (2.9%)	2 (3.4%)	7 (9.9%)
Grade 3	0	1 (2.9%)	1 (1.7%)	3 (4.2%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-ol.pdf 29AUG2023: 9:41

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Nausea and vomiting symptoms	3 (7.5%)	7 (14.3%)	10 (11.2%)	16 (16.2%)
Grade 1	3 (7.5%)	4 (8.2%)	7 (7.9%)	13 (13.1%)
Grade 2	0	3 (6.1%)	3 (3.4%)	3 (3.0%)
Grade 3	0	0	0	0
Nausea	3 (7.5%)	5 (10.2%)	8 (9.0%)	12 (12.1%)
Grade 1	3 (7.5%)	3 (6.1%)	6 (6.7%)	10 (10.1%)
Grade 2	0	2 (4.1%)	2 (2.2%)	2 (2.0%)
Grade 3	0	0	0	0
Vomiting	1 (2.5%)	4 (8.2%)	5 (5.6%)	7 (7.1%)
Grade 1	1 (2.5%)	2 (4.1%)	3 (3.4%)	5 (5.1%)
Grade 2	0	2 (4.1%)	2 (2.2%)	2 (2.0%)
Grade 3	0	0	0	0
Retching	0	1 (2.0%)	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-ol.pdf 29AUG2023: 9:41

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Nausea and vomiting symptoms	4 (16.7%)	11 (31.4%)	15 (25.4%)	28 (39.4%)
Grade 1	3 (12.5%)	8 (22.9%)	11 (18.6%)	17 (23.9%)
Grade 2	1 (4.2%)	2 (5.7%)	3 (5.1%)	8 (11.3%)
Grade 3	0	1 (2.9%)	1 (1.7%)	3 (4.2%)
Nausea	3 (12.5%)	8 (22.9%)	11 (18.6%)	24 (33.8%)
Grade 1	3 (12.5%)	7 (20.0%)	10 (16.9%)	19 (26.8%)
Grade 2	0	1 (2.9%)	1 (1.7%)	4 (5.6%)
Grade 3	0	0	0	1 (1.4%)
Vomiting	4 (16.7%)	4 (11.4%)	8 (13.6%)	12 (16.9%)
Grade 1	3 (12.5%)	1 (2.9%)	4 (6.8%)	4 (5.6%)
Grade 2	1 (4.2%)	2 (5.7%)	3 (5.1%)	6 (8.5%)
Grade 3	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Retching	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-ol.pdf 29AUG2023: 9:41

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Nausea and vomiting symptoms (cont)				
Retching (cont)				
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Gastrointestinal and abdominal pains (excl oral and throat)	5 (12.5%)	9 (18.4%)	14 (15.7%)	20 (20.2%)
Grade 1	4 (10.0%)	4 (8.2%)	8 (9.0%)	13 (13.1%)
Grade 2	0	4 (8.2%)	4 (4.5%)	4 (4.0%)
Grade 3	1 (2.5%)	1 (2.0%)	2 (2.2%)	3 (3.0%)
Abdominal pain	3 (7.5%)	7 (14.3%)	10 (11.2%)	15 (15.2%)
Grade 1	2 (5.0%)	4 (8.2%)	6 (6.7%)	10 (10.1%)
Grade 2	0	3 (6.1%)	3 (3.4%)	3 (3.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	2 (2.0%)
Abdominal pain upper	2 (5.0%)	2 (4.1%)	4 (4.5%)	7 (7.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Nausea and vomiting symptoms (cont)				
Retching (cont)				
Grade 1	0	0	0	0
Gastrointestinal and abdominal pains (excl oral and throat)	4 (16.7%)	6 (17.1%)	10 (16.9%)	15 (21.1%)
Grade 1	2 (8.3%)	2 (5.7%)	4 (6.8%)	6 (8.5%)
Grade 2	2 (8.3%)	3 (8.6%)	5 (8.5%)	7 (9.9%)
Grade 3	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Abdominal pain	1 (4.2%)	4 (11.4%)	5 (8.5%)	11 (15.5%)
Grade 1	1 (4.2%)	1 (2.9%)	2 (3.4%)	4 (5.6%)
Grade 2	0	2 (5.7%)	2 (3.4%)	5 (7.0%)
Grade 3	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Abdominal pain upper	3 (12.5%)	3 (8.6%)	6 (10.2%)	6 (8.5%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal and abdominal pains (excl oral and throat) (cont)				
Abdominal pain upper (cont)				
Grade 1	2 (5.0%)	0	2 (2.2%)	5 (5.1%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Abdominal rigidity	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Gastrointestinal atonic and hypomotility disorders NEC	3 (7.5%)	10 (20.4%)	13 (14.6%)	24 (24.2%)
Grade 1	1 (2.5%)	5 (10.2%)	6 (6.7%)	16 (16.2%)
Grade 2	2 (5.0%)	4 (8.2%)	6 (6.7%)	7 (7.1%)
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal and abdominal pains (excl oral and throat) (cont)				
Abdominal pain upper (cont)				
Grade 1	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Grade 2	2 (8.3%)	2 (5.7%)	4 (6.8%)	4 (5.6%)
Grade 3	0	0	0	0
Abdominal rigidity	0	0	0	0
Grade 1	0	0	0	0
Gastrointestinal atonic and hypomotility disorders NEC	2 (8.3%)	4 (11.4%)	6 (10.2%)	8 (11.3%)
Grade 1	2 (8.3%)	3 (8.6%)	5 (8.5%)	6 (8.5%)
Grade 2	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal atonic and hypomotility disorders NEC (cont)				
Constipation	2 (5.0%)	7 (14.3%)	9 (10.1%)	18 (18.2%)
Grade 1	1 (2.5%)	3 (6.1%)	4 (4.5%)	13 (13.1%)
Grade 2	1 (2.5%)	3 (6.1%)	4 (4.5%)	4 (4.0%)
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Gastrooesophageal reflux disease	2 (5.0%)	4 (8.2%)	6 (6.7%)	9 (9.1%)
Grade 1	0	3 (6.1%)	3 (3.4%)	5 (5.1%)
Grade 2	2 (5.0%)	1 (2.0%)	3 (3.4%)	4 (4.0%)
Flatulence, bloating and distension	0	2 (4.1%)	2 (2.2%)	5 (5.1%)
Grade 1	0	2 (4.1%)	2 (2.2%)	3 (3.0%)
Grade 2	0	0	0	2 (2.0%)
Abdominal distension	0	2 (4.1%)	2 (2.2%)	4 (4.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal atonic and hypomotility disorders NEC (cont)				
Constipation	2 (8.3%)	3 (8.6%)	5 (8.5%)	7 (9.9%)
Grade 1	2 (8.3%)	2 (5.7%)	4 (6.8%)	6 (8.5%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 3	0	0	0	0
Gastrooesophageal reflux disease	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	0	0	1 (1.4%)
Flatulence, bloating and distension	0	3 (8.6%)	3 (5.1%)	5 (7.0%)
Grade 1	0	2 (5.7%)	2 (3.4%)	4 (5.6%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Abdominal distension	0	2 (5.7%)	2 (3.4%)	3 (4.2%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Flatulence, bloating and distension (cont)				
Abdominal distension (cont)				
Grade 1	0	2 (4.1%)	2 (2.2%)	2 (2.0%)
Grade 2	0	0	0	2 (2.0%)
Flatulence	0	0	0	2 (2.0%)
Grade 1	0	0	0	2 (2.0%)
Grade 2	0	0	0	0
Gastrointestinal signs and symptoms NEC	0	1 (2.0%)	1 (1.1%)	4 (4.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	4 (4.0%)
Grade 2	0	0	0	0
Abdominal discomfort	0	1 (2.0%)	1 (1.1%)	3 (3.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	3 (3.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Flatulence, bloating and distension (cont)				
Abdominal distension (cont)				
Grade 1	0	2 (5.7%)	2 (3.4%)	3 (4.2%)
Grade 2	0	0	0	0
Flatulence	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Grade 1	0	0	0	1 (1.4%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Gastrointestinal signs and symptoms NEC	1 (4.2%)	3 (8.6%)	4 (6.8%)	5 (7.0%)
Grade 1	1 (4.2%)	2 (5.7%)	3 (5.1%)	4 (5.6%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Abdominal discomfort	1 (4.2%)	1 (2.9%)	2 (3.4%)	3 (4.2%)
Grade 1	1 (4.2%)	1 (2.9%)	2 (3.4%)	3 (4.2%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal signs and symptoms NEC (cont)				
Anal incontinence	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Dysphagia	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
Dyspeptic signs and symptoms	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Grade 1	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Grade 2	0	0	0	0
Dyspepsia	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Grade 1	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal signs and symptoms NEC (cont)				
Anal incontinence	0	2 (5.7%)	2 (3.4%)	2 (2.8%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Dysphagia	0	0	0	0
Grade 1	0	0	0	0
Dyspeptic signs and symptoms	1 (4.2%)	4 (11.4%)	5 (8.5%)	6 (8.5%)
Grade 1	1 (4.2%)	2 (5.7%)	3 (5.1%)	4 (5.6%)
Grade 2	0	2 (5.7%)	2 (3.4%)	2 (2.8%)
Dyspepsia	1 (4.2%)	4 (11.4%)	5 (8.5%)	6 (8.5%)
Grade 1	1 (4.2%)	2 (5.7%)	3 (5.1%)	4 (5.6%)
Grade 2	0	2 (5.7%)	2 (3.4%)	2 (2.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Dyspeptic signs and symptoms (cont)				
Epigastric discomfort	0	0	0	0
Grade 1	0	0	0	0
Intestinal haemorrhages	0	3 (6.1%)	3 (3.4%)	5 (5.1%)
Grade 1	0	2 (4.1%)	2 (2.2%)	2 (2.0%)
Grade 2	0	0	0	1 (1.0%)
Grade 3	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Rectal haemorrhage	0	3 (6.1%)	3 (3.4%)	5 (5.1%)
Grade 1	0	2 (4.1%)	2 (2.2%)	2 (2.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Grade 3	0	0	0	1 (1.0%)
Lower gastrointestinal haemorrhage	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Dyspeptic signs and symptoms (cont)				
Epigastric discomfort	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Intestinal haemorrhages	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	0	0	0
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 3	0	0	0	0
Rectal haemorrhage	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Lower gastrointestinal haemorrhage	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Intestinal haemorrhages (cont)				
Small intestinal haemorrhage	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Oral dryness and saliva altered	1 (2.5%)	2 (4.1%)	3 (3.4%)	5 (5.1%)
Grade 1	1 (2.5%)	0	1 (1.1%)	3 (3.0%)
Grade 2	0	2 (4.1%)	2 (2.2%)	2 (2.0%)
Dry mouth	1 (2.5%)	2 (4.1%)	3 (3.4%)	5 (5.1%)
Grade 1	1 (2.5%)	0	1 (1.1%)	3 (3.0%)
Grade 2	0	2 (4.1%)	2 (2.2%)	2 (2.0%)
Peritoneal and retroperitoneal disorders	1 (2.5%)	2 (4.1%)	3 (3.4%)	3 (3.0%)
Grade 2	1 (2.5%)	2 (4.1%)	3 (3.4%)	3 (3.0%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Intestinal haemorrhages (cont)				
Small intestinal haemorrhage	0	0	0	0
Grade 3	0	0	0	0
Oral dryness and saliva altered	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	0	0	0	0
Dry mouth	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	0	0	0	0
Peritoneal and retroperitoneal disorders	2 (8.3%)	0	2 (3.4%)	3 (4.2%)
Grade 2	2 (8.3%)	0	2 (3.4%)	2 (2.8%)
Grade 3	0	0	0	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Peritoneal and retroperitoneal disorders (cont)				
Ascites	1 (2.5%)	2 (4.1%)	3 (3.4%)	3 (3.0%)
Grade 2	1 (2.5%)	2 (4.1%)	3 (3.4%)	3 (3.0%)
Grade 3	0	0	0	0
Haemorrhoids and gastrointestinal varices (excl oesophageal)	0	2 (4.1%)	2 (2.2%)	4 (4.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Haemorrhoids	0	2 (4.1%)	2 (2.2%)	4 (4.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Haemorrhoidal haemorrhage	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Peritoneal and retroperitoneal disorders (cont)				
Ascites	2 (8.3%)	0	2 (3.4%)	3 (4.2%)
Grade 2	2 (8.3%)	0	2 (3.4%)	2 (2.8%)
Grade 3	0	0	0	1 (1.4%)
Haemorrhoids and gastrointestinal varices (excl oesophageal)	0	0	0	1 (1.4%)
Grade 1	0	0	0	1 (1.4%)
Grade 2	0	0	0	0
Haemorrhoids	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Haemorrhoidal haemorrhage	0	0	0	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Haemorrhoids and gastrointestinal varices (excl oesophageal) (cont)				
Haemorrhoidal haemorrhage (cont)				
Grade 1	0	0	0	0
Oesophageal varices	1 (2.5%)	2 (4.1%)	3 (3.4%)	3 (3.0%)
Grade 1	0	0	0	0
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Varices oesophageal	1 (2.5%)	2 (4.1%)	3 (3.4%)	3 (3.0%)
Grade 1	0	0	0	0
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Oral soft tissue haemorrhages	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Haemorrhoids and gastrointestinal varices (excl oesophageal) (cont)				
Haemorrhoidal haemorrhage (cont)				
Grade 1	0	0	0	1 (1.4%)
Oesophageal varices	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Varices oesophageal	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Oral soft tissue haemorrhages	0	2 (5.7%)	2 (3.4%)	2 (2.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Oral soft tissue haemorrhages (cont)				
(cont)				
Grade 1	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Grade 2	0	0	0	0
Mouth haemorrhage	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	0	0	0
Oral mucosa haematoma	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Stomatitis and ulceration	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Oral soft tissue haemorrhages (cont)				
(cont)				
Grade 1	0	0	0	0
Grade 2	0	2 (5.7%)	2 (3.4%)	2 (2.8%)
Mouth haemorrhage	0	2 (5.7%)	2 (3.4%)	2 (2.8%)
Grade 1	0	0	0	0
Grade 2	0	2 (5.7%)	2 (3.4%)	2 (2.8%)
Oral mucosa haematoma	0	0	0	0
Grade 1	0	0	0	0
Stomatitis and ulceration	3 (12.5%)	0	3 (5.1%)	3 (4.2%)
Grade 1	2 (8.3%)	0	2 (3.4%)	2 (2.8%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Stomatitis and ulceration (cont)				
Stomatitis	0	0	0	0
Grade 1	0	0	0	0
Aphthous ulcer	0	0	0	0
Grade 2	0	0	0	0
Mouth ulceration	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
Dental pain and sensation disorders	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Toothache	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	2 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Stomatitis and ulceration (cont)				
Stomatitis	2 (8.3%)	0	2 (3.4%)	2 (2.8%)
Grade 1	2 (8.3%)	0	2 (3.4%)	2 (2.8%)
Aphthous ulcer	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Mouth ulceration	0	0	0	0
Grade 1	0	0	0	0
Dental pain and sensation disorders	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Toothache	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastritis (excl infective)	0	0	0	0
Grade 1	0	0	0	0
Gastritis	0	0	0	0
Grade 1	0	0	0	0
Chronic gastritis	0	0	0	0
Grade 1	0	0	0	0
Non-site specific gastrointestinal haemorrhages	2 (5.0%)	1 (2.0%)	3 (3.4%)	3 (3.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 4	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Gastrointestinal haemorrhage	0	1 (2.0%)	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastritis (excl infective)	1 (4.2%)	2 (5.7%)	3 (5.1%)	3 (4.2%)
Grade 1	1 (4.2%)	2 (5.7%)	3 (5.1%)	3 (4.2%)
Gastritis	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Grade 1	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Chronic gastritis	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Non-site specific gastrointestinal haemorrhages	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Gastrointestinal haemorrhage	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-ol.pdf 29AUG2023: 9:41

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Non-site specific gastrointestinal haemorrhages (cont)				
Gastrointestinal haemorrhage (cont)				
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Haematemesis	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 4	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Melaena	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Oral soft tissue disorders NEC	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
Grade 2	0	0	0	0
Cheilitis	0	0	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Non-site specific gastrointestinal haemorrhages (cont)				
Gastrointestinal haemorrhage (cont)				
Grade 3	0	0	0	0
Haematemesis	0	0	0	0
Grade 4	0	0	0	0
Melaena	0	0	0	0
Grade 1	0	0	0	0
Oral soft tissue disorders NEC	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Cheilitis	0	1 (2.9%)	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Oral soft tissue disorders NEC (cont)				
Cheilitis (cont)				
Grade 1	0	0	0	1 (1.0%)
Grade 2	0	0	0	0
Angina bullosa haemorrhagica	0	0	0	0
Grade 1	0	0	0	0
Oral soft tissue pain and paraesthesia	0	1 (2.0%)	1 (1.1%)	3 (3.0%)
Grade 1	0	0	0	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	0	0	0	1 (1.0%)
Lip pain	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)

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Adverse events were mapped according to MedDRA Version 22.0
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SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Oral soft tissue disorders NEC (cont)				
Cheilitis (cont)				
Grade 1	0	0	0	0
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Angina bullosa haemorrhagica	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Oral soft tissue pain and paraesthesia	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Lip pain	0	0	0	0
Grade 1	0	0	0	0

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Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Oral soft tissue pain and paraesthesia (cont)				
Odynophagia	0	0	0	1 (1.0%)
Grade 3	0	0	0	1 (1.0%)
Oral pain	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Anal and rectal pains	0	0	0	2 (2.0%)
Grade 2	0	0	0	2 (2.0%)
Proctalgia	0	0	0	2 (2.0%)
Grade 2	0	0	0	2 (2.0%)
Dental disorders NEC	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Oral soft tissue pain and paraesthesia (cont)				
Odynophagia	0	0	0	0
Grade 3	0	0	0	0
Oral pain	0	0	0	0
Grade 2	0	0	0	0
Anal and rectal pains	0	0	0	0
Grade 2	0	0	0	0
Proctalgia	0	0	0	0
Grade 2	0	0	0	0
Dental disorders NEC	0	2 (5.7%)	2 (3.4%)	2 (2.8%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Dental disorders NEC (cont)				
(cont)				
Grade 2	0	0	0	0
Periodontal disease	0	0	0	0
Grade 1	0	0	0	0
Tooth impacted	0	0	0	0
Grade 2	0	0	0	0
Gastric and oesophageal haemorrhages	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Grade 3	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Gastric haemorrhage	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Dental disorders NEC (cont)				
(cont)				
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Periodontal disease	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Tooth impacted	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Gastric and oesophageal haemorrhages	0	0	0	0
Grade 3	0	0	0	0
Gastric haemorrhage	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastric and oesophageal haemorrhages (cont)				
Oesophageal varices haemorrhage	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Gastric ulcers and perforation	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Gastric ulcer	0	0	0	0
Grade 2	0	0	0	0
Gastritis erosive	0	0	0	0
Grade 1	0	0	0	0
Gastrointestinal vascular occlusion and infarction	0	1 (2.0%)	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastric and oesophageal haemorrhages (cont)				
Oesophageal varices haemorrhage	0	0	0	0
Grade 3	0	0	0	0
Gastric ulcers and perforation	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	0	0	1 (1.4%)
Gastric ulcer	0	0	0	1 (1.4%)
Grade 2	0	0	0	1 (1.4%)
Gastritis erosive	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Gastrointestinal vascular occlusion and infarction	0	0	0	1 (1.4%)

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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal vascular occlusion and infarction (cont) (cont)				
Grade 5	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Intestinal infarction	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 5	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Mesenteric vein thrombosis	0	0	0	0
Grade 5	0	0	0	0
Oral soft tissue infections	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Angular cheilitis	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)

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(Continued)	Female			
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal vascular occlusion and infarction (cont) (cont)				
Grade 5	0	0	0	1 (1.4%)
Intestinal infarction	0	0	0	0
Grade 5	0	0	0	0
Mesenteric vein thrombosis	0	0	0	1 (1.4%)
Grade 5	0	0	0	1 (1.4%)
Oral soft tissue infections	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Angular cheilitis	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)

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	Male			
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Colitis (excl infective)	0	0	0	0
Grade 2	0	0	0	0
Colitis	0	0	0	0
Grade 2	0	0	0	0
Cystic pancreatic disorders	0	0	0	0
Grade 1	0	0	0	0
Pancreatic cyst	0	0	0	0
Grade 1	0	0	0	0
Dental and periodontal infections and inflammations	0	0	0	0
Grade 1	0	0	0	0

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Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Colitis (excl infective)	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Colitis	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Cystic pancreatic disorders	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Pancreatic cyst	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Dental and periodontal infections and inflammations	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Dental and periodontal infections and inflammations (cont)				
Dental caries	0	0	0	0
Grade 1	0	0	0	0
Diaphragmatic hernias	0	0	0	0
Grade 1	0	0	0	0
Hiatus hernia	0	0	0	0
Grade 1	0	0	0	0
Diverticula	0	0	0	0
Grade 2	0	0	0	0
Diverticulum	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Dental and periodontal infections and inflammations (cont)				
Dental caries	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Diaphragmatic hernias	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Hiatus hernia	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Diverticula	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Diverticulum	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Faecal abnormalities NEC	0	0	0	0
Grade 1	0	0	0	0
Abnormal faeces	0	0	0	0
Grade 1	0	0	0	0
Gastrointestinal spastic and hypermotility disorders	0	0	0	0
Grade 1	0	0	0	0
Defaecation urgency	0	0	0	0
Grade 1	0	0	0	0
Gingival disorders, signs and symptoms NEC	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Faecal abnormalities NEC	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Abnormal faeces	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Gastrointestinal spastic and hypermotility disorders	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Defaecation urgency	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Gingival disorders, signs and symptoms NEC	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gingival disorders, signs and symptoms NEC (cont)				
Gingival ulceration	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Gingival haemorrhages	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Gingival bleeding	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Inguinal hernias	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Inguinal hernia	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gingival disorders, signs and symptoms NEC (cont)				
Gingival ulceration	0	0	0	0
Grade 2	0	0	0	0
Gingival haemorrhages	0	0	0	0
Grade 2	0	0	0	0
Gingival bleeding	0	0	0	0
Grade 2	0	0	0	0
Inguinal hernias	0	0	0	0
Grade 2	0	0	0	0
Inguinal hernia	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Pancreatic disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Pancreatic steatosis	0	0	0	0
Grade 1	0	0	0	0
Infections and infestations	21 (52.5%)	29 (59.2%)	50 (56.2%)	65 (65.7%)
Grade 1	4 (10.0%)	5 (10.2%)	9 (10.1%)	15 (15.2%)
Grade 2	6 (15.0%)	14 (28.6%)	20 (22.5%)	21 (21.2%)
Grade 3	8 (20.0%)	7 (14.3%)	15 (16.9%)	22 (22.2%)
Grade 4	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 5	3 (7.5%)	2 (4.1%)	5 (5.6%)	6 (6.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Pancreatic disorders NEC	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Pancreatic steatosis	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Infections and infestations	16 (66.7%)	23 (65.7%)	39 (66.1%)	42 (59.2%)
Grade 1	0	4 (11.4%)	4 (6.8%)	4 (5.6%)
Grade 2	10 (41.7%)	10 (28.6%)	20 (33.9%)	21 (29.6%)
Grade 3	3 (12.5%)	9 (25.7%)	12 (20.3%)	13 (18.3%)
Grade 4	3 (12.5%)	0	3 (5.1%)	4 (5.6%)
Grade 5	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Lower respiratory tract and lung infections	10 (25.0%)	12 (24.5%)	22 (24.7%)	28 (28.3%)
Grade 1	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Grade 2	1 (2.5%)	5 (10.2%)	6 (6.7%)	7 (7.1%)
Grade 3	7 (17.5%)	4 (8.2%)	11 (12.4%)	15 (15.2%)
Grade 4	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 5	2 (5.0%)	1 (2.0%)	3 (3.4%)	3 (3.0%)
Pneumonia	8 (20.0%)	8 (16.3%)	16 (18.0%)	19 (19.2%)
Grade 2	1 (2.5%)	3 (6.1%)	4 (4.5%)	4 (4.0%)
Grade 3	6 (15.0%)	3 (6.1%)	9 (10.1%)	12 (12.1%)
Grade 4	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 5	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Bronchitis	1 (2.5%)	5 (10.2%)	6 (6.7%)	6 (6.1%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	3 (6.1%)	4 (4.5%)	4 (4.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Lower respiratory tract and lung infections	6 (25.0%)	5 (14.3%)	11 (18.6%)	12 (16.9%)
Grade 1	0	0	0	0
Grade 2	2 (8.3%)	2 (5.7%)	4 (6.8%)	4 (5.6%)
Grade 3	3 (12.5%)	3 (8.6%)	6 (10.2%)	7 (9.9%)
Grade 4	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 5	0	0	0	0
Pneumonia	4 (16.7%)	4 (11.4%)	8 (13.6%)	9 (12.7%)
Grade 2	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Grade 3	2 (8.3%)	3 (8.6%)	5 (8.5%)	6 (8.5%)
Grade 4	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 5	0	0	0	0
Bronchitis	2 (8.3%)	0	2 (3.4%)	2 (2.8%)
Grade 1	0	0	0	0
Grade 2	2 (8.3%)	0	2 (3.4%)	2 (2.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Lower respiratory tract and lung infections (cont)				
Bronchitis (cont)				
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Lower respiratory tract infection	0	0	0	2 (2.0%)
Grade 1	0	0	0	1 (1.0%)
Grade 2	0	0	0	1 (1.0%)
Lung infection	2 (5.0%)	0	2 (2.2%)	3 (3.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	2 (2.0%)
Grade 5	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Upper respiratory tract infections	6 (15.0%)	8 (16.3%)	14 (15.7%)	18 (18.2%)
Grade 1	3 (7.5%)	2 (4.1%)	5 (5.6%)	9 (9.1%)
Grade 2	3 (7.5%)	6 (12.2%)	9 (10.1%)	9 (9.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Lower respiratory tract and lung infections (cont)				
Bronchitis (cont)				
Grade 3	0	0	0	0
Lower respiratory tract infection	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Grade 1	0	0	0	1 (1.4%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Lung infection	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 3	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 5	0	0	0	0
Upper respiratory tract infections	6 (25.0%)	9 (25.7%)	15 (25.4%)	16 (22.5%)
Grade 1	1 (4.2%)	2 (5.7%)	3 (5.1%)	4 (5.6%)
Grade 2	4 (16.7%)	7 (20.0%)	11 (18.6%)	11 (15.5%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Upper respiratory tract infections (cont)				
(cont)				
Grade 3	0	0	0	0
Upper respiratory tract infection	4 (10.0%)	4 (8.2%)	8 (9.0%)	11 (11.1%)
Grade 1	1 (2.5%)	0	1 (1.1%)	4 (4.0%)
Grade 2	3 (7.5%)	4 (8.2%)	7 (7.9%)	7 (7.1%)
Nasopharyngitis	2 (5.0%)	2 (4.1%)	4 (4.5%)	5 (5.1%)
Grade 1	2 (5.0%)	1 (2.0%)	3 (3.4%)	4 (4.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Sinusitis	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	0	0	0
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Upper respiratory tract infections (cont) (cont)				
Grade 3	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Upper respiratory tract infection	2 (8.3%)	5 (14.3%)	7 (11.9%)	8 (11.3%)
Grade 1	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Grade 2	2 (8.3%)	4 (11.4%)	6 (10.2%)	6 (8.5%)
Nasopharyngitis	2 (8.3%)	3 (8.6%)	5 (8.5%)	5 (7.0%)
Grade 1	1 (4.2%)	2 (5.7%)	3 (5.1%)	3 (4.2%)
Grade 2	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Sinusitis	2 (8.3%)	3 (8.6%)	5 (8.5%)	5 (7.0%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	1 (4.2%)	2 (5.7%)	3 (5.1%)	3 (4.2%)
Grade 3	1 (4.2%)	0	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Upper respiratory tract infections (cont)				
Laryngitis	0	0	0	1 (1.0%)
Grade 2	0	0	0	1 (1.0%)
Tonsillitis	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	0	0	0
Pharyngitis	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Urinary tract infections	3 (7.5%)	3 (6.1%)	6 (6.7%)	8 (8.1%)
Grade 1	0	0	0	1 (1.0%)
Grade 2	2 (5.0%)	3 (6.1%)	5 (5.6%)	5 (5.1%)
Grade 3	1 (2.5%)	0	1 (1.1%)	2 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Upper respiratory tract infections (cont)				
Laryngitis	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Tonsillitis	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	0	0	0	0
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Pharyngitis	0	0	0	0
Grade 1	0	0	0	0
Urinary tract infections	8 (33.3%)	7 (20.0%)	15 (25.4%)	17 (23.9%)
Grade 1	0	0	0	0
Grade 2	6 (25.0%)	5 (14.3%)	11 (18.6%)	13 (18.3%)
Grade 3	2 (8.3%)	2 (5.7%)	4 (6.8%)	4 (5.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Urinary tract infections (cont)				
Urinary tract infection	2 (5.0%)	3 (6.1%)	5 (5.6%)	7 (7.1%)
Grade 1	0	0	0	1 (1.0%)
Grade 2	1 (2.5%)	3 (6.1%)	4 (4.5%)	5 (5.1%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Cystitis	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	0
Grade 3	0	0	0	1 (1.0%)
Pyelocystitis	0	0	0	0
Grade 2	0	0	0	0
Pyelonephritis	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Urinary tract infections (cont)				
Urinary tract infection	7 (29.2%)	5 (14.3%)	12 (20.3%)	13 (18.3%)
Grade 1	0	0	0	0
Grade 2	5 (20.8%)	4 (11.4%)	9 (15.3%)	10 (14.1%)
Grade 3	2 (8.3%)	1 (2.9%)	3 (5.1%)	3 (4.2%)
Cystitis	2 (8.3%)	1 (2.9%)	3 (5.1%)	5 (7.0%)
Grade 2	2 (8.3%)	1 (2.9%)	3 (5.1%)	5 (7.0%)
Grade 3	0	0	0	0
Pyelocystitis	0	0	0	1 (1.4%)
Grade 2	0	0	0	1 (1.4%)
Pyelonephritis	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 3	0	1 (2.9%)	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Herpes viral infections	3 (7.5%)	2 (4.1%)	5 (5.6%)	6 (6.1%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	2 (5.0%)	2 (4.1%)	4 (4.5%)	5 (5.1%)
Herpes zoster	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Grade 1	0	0	0	0
Grade 2	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Oral herpes	2 (5.0%)	1 (2.0%)	3 (3.4%)	4 (4.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	1 (2.0%)	2 (2.2%)	3 (3.0%)
Genital herpes	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Herpes viral infections	2 (8.3%)	3 (8.6%)	5 (8.5%)	7 (9.9%)
Grade 1	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Grade 2	2 (8.3%)	2 (5.7%)	4 (6.8%)	5 (7.0%)
Herpes zoster	2 (8.3%)	0	2 (3.4%)	4 (5.6%)
Grade 1	1 (4.2%)	0	1 (1.7%)	2 (2.8%)
Grade 2	1 (4.2%)	0	1 (1.7%)	2 (2.8%)
Oral herpes	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	0	0	0
Genital herpes	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Herpes viral infections (cont)				
Herpes simplex	0	0	0	0
Grade 2	0	0	0	0
Nasal herpes	0	0	0	0
Grade 2	0	0	0	0
Varicella zoster virus infection	0	0	0	0
Grade 2	0	0	0	0
Infections NEC	1 (2.5%)	2 (4.1%)	3 (3.4%)	5 (5.1%)
Grade 1	0	0	0	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	2 (2.0%)
Grade 3	0	2 (4.1%)	2 (2.2%)	2 (2.0%)
Respiratory tract infection	1 (2.5%)	0	1 (1.1%)	2 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Herpes viral infections (cont)				
Herpes simplex	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Grade 2	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Nasal herpes	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Varicella zoster virus infection	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Infections NEC	1 (4.2%)	1 (2.9%)	2 (3.4%)	3 (4.2%)
Grade 1	0	0	0	0
Grade 2	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Grade 3	0	0	0	1 (1.4%)
Respiratory tract infection	0	1 (2.9%)	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Infections NEC (cont)				
Respiratory tract infection (cont)				
Grade 1	0	0	0	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Localised infection	0	0	0	1 (1.0%)
Grade 2	0	0	0	1 (1.0%)
Device related infection	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Infection	0	0	0	0
Grade 3	0	0	0	0
Wound infection	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Infections NEC (cont)				
Respiratory tract infection (cont)				
Grade 1	0	0	0	0
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Localised infection	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Device related infection	0	0	0	0
Grade 3	0	0	0	0
Infection	0	0	0	1 (1.4%)
Grade 3	0	0	0	1 (1.4%)
Wound infection	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Abdominal and gastrointestinal infections	0	2 (4.1%)	2 (2.2%)	4 (4.0%)
Grade 1	0	0	0	1 (1.0%)
Grade 2	0	2 (4.1%)	2 (2.2%)	2 (2.0%)
Grade 3	0	0	0	1 (1.0%)
Gastroenteritis	0	2 (4.1%)	2 (2.2%)	3 (3.0%)
Grade 1	0	0	0	1 (1.0%)
Grade 2	0	2 (4.1%)	2 (2.2%)	2 (2.0%)
Anal abscess	0	0	0	1 (1.0%)
Grade 3	0	0	0	1 (1.0%)
Diverticulitis	0	0	0	0
Grade 3	0	0	0	0
Enterocolitis infectious	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-ol.pdf 29AUG2023: 9:41

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Abdominal and gastrointestinal infections	2 (8.3%)	1 (2.9%)	3 (5.1%)	3 (4.2%)
Grade 1	0	0	0	0
Grade 2	2 (8.3%)	0	2 (3.4%)	2 (2.8%)
Grade 3	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Gastroenteritis	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	0	0	0	0
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Anal abscess	0	0	0	0
Grade 3	0	0	0	0
Diverticulitis	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 3	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Enterocolitis infectious	1 (4.2%)	0	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-ol.pdf 29AUG2023: 9:41

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Abdominal and gastrointestinal infections (cont)				
Enterocolitis infectious (cont)				
Grade 2	0	0	0	0
Sepsis, bacteraemia, viraemia and fungaemia NEC	1 (2.5%)	2 (4.1%)	3 (3.4%)	5 (5.1%)
Grade 3	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Grade 4	0	0	0	0
Grade 5	1 (2.5%)	1 (2.0%)	2 (2.2%)	3 (3.0%)
Sepsis	1 (2.5%)	1 (2.0%)	2 (2.2%)	4 (4.0%)
Grade 3	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Grade 4	0	0	0	0
Grade 5	1 (2.5%)	0	1 (1.1%)	2 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Abdominal and gastrointestinal infections (cont)				
Enterocolitis infectious (cont)				
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Sepsis, bacteraemia, viraemia and fungaemia NEC	2 (8.3%)	0	2 (3.4%)	2 (2.8%)
Grade 3	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 4	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 5	0	0	0	0
Sepsis	2 (8.3%)	0	2 (3.4%)	2 (2.8%)
Grade 3	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 4	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 5	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Sepsis, bacteraemia, viraemia and fungaemia NEC (cont)				
Bacteraemia	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Septic shock	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 5	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Influenza viral infections	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Grade 1	0	0	0	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	0	0	0	0
Influenza	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Grade 1	0	0	0	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Sepsis, bacteraemia, viraemia and fungaemia NEC (cont)				
Bacteraemia	0	0	0	0
Grade 3	0	0	0	0
Septic shock	0	0	0	0
Grade 5	0	0	0	0
Influenza viral infections	1 (4.2%)	3 (8.6%)	4 (6.8%)	4 (5.6%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Grade 3	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Influenza	1 (4.2%)	3 (8.6%)	4 (6.8%)	4 (5.6%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Influenza viral infections (cont)				
Influenza (cont)				
Grade 3	0	0	0	0
Skin structures and soft tissue infections	1 (2.5%)	0	1 (1.1%)	4 (4.0%)
Grade 1	0	0	0	0
Grade 2	1 (2.5%)	0	1 (1.1%)	3 (3.0%)
Grade 3	0	0	0	1 (1.0%)
Skin infection	0	0	0	3 (3.0%)
Grade 2	0	0	0	2 (2.0%)
Grade 3	0	0	0	1 (1.0%)
Folliculitis	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Influenza viral infections (cont)				
Influenza (cont)				
Grade 3	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Skin structures and soft tissue infections	2 (8.3%)	0	2 (3.4%)	2 (2.8%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 3	0	0	0	0
Skin infection	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Folliculitis	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Skin structures and soft tissue infections (cont)				
Infected dermal cyst	0	0	0	0
Grade 2	0	0	0	0
Infected skin ulcer	0	0	0	0
Grade 1	0	0	0	0
Subcutaneous abscess	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Viral infections NEC	0	3 (6.1%)	3 (3.4%)	3 (3.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Skin structures and soft tissue infections (cont)				
Infected dermal cyst	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Infected skin ulcer	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Subcutaneous abscess	0	0	0	0
Grade 2	0	0	0	0
Viral infections NEC	2 (8.3%)	1 (2.9%)	3 (5.1%)	3 (4.2%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Viral infections NEC (cont)				
Viral infection	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Gastroenteritis viral	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Pneumonia viral	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Vestibular neuronitis	0	0	0	0
Grade 2	0	0	0	0
Viral uveitis	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Viral infections NEC (cont)				
Viral infection	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Gastroenteritis viral	0	0	0	0
Grade 1	0	0	0	0
Pneumonia viral	0	0	0	0
Grade 3	0	0	0	0
Vestibular neuronitis	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Viral uveitis	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Dental and oral soft tissue infections	1 (2.5%)	0	1 (1.1%)	4 (4.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	4 (4.0%)
Periodontitis	1 (2.5%)	0	1 (1.1%)	2 (2.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	2 (2.0%)
Gingivitis	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
Lip infection	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
Tooth abscess	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Dental and oral soft tissue infections	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Periodontitis	0	0	0	0
Grade 1	0	0	0	0
Gingivitis	0	0	0	0
Grade 1	0	0	0	0
Lip infection	0	0	0	0
Grade 1	0	0	0	0
Tooth abscess	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Bacterial infections NEC	1 (2.5%)	0	1 (1.1%)	3 (3.0%)
Grade 1	0	0	0	1 (1.0%)
Grade 2	0	0	0	0
Grade 3	1 (2.5%)	0	1 (1.1%)	2 (2.0%)
Cellulitis	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
Grade 2	0	0	0	0
Gangrene	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Pneumonia bacterial	0	0	0	1 (1.0%)
Grade 3	0	0	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Bacterial infections NEC	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	0	0	0
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 3	0	0	0	0
Cellulitis	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	0	0	0
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Gangrene	0	0	0	0
Grade 3	0	0	0	0
Pneumonia bacterial	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Clostridia infections	0	2 (4.1%)	2 (2.2%)	2 (2.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 4	0	0	0	0
Clostridium difficile colitis	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Clostridium difficile infection	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Tetanus	0	0	0	0
Grade 4	0	0	0	0
Ear infections	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Clostridia infections	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Grade 4	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Clostridium difficile colitis	0	0	0	0
Grade 3	0	0	0	0
Clostridium difficile infection	0	0	0	0
Grade 2	0	0	0	0
Tetanus	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 4	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Ear infections	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Ear infections (cont)				
(cont)				
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Ear infection	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Labyrinthitis	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Otitis externa	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Otitis media	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Ear infections (cont)				
(cont)				
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Ear infection	0	0	0	0
Grade 1	0	0	0	0
Labyrinthitis	0	0	0	0
Grade 1	0	0	0	0
Otitis externa	0	0	0	0
Grade 2	0	0	0	0
Otitis media	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Escherichia infections	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Escherichia urinary tract infection	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	0	0	0	0
Escherichia infection	0	0	0	0
Grade 2	0	0	0	0
Escherichia sepsis	0	0	0	0
Grade 4	0	0	0	0
Fungal infections NEC	1 (2.5%)	0	1 (1.1%)	3 (3.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Escherichia infections	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Grade 1	0	0	0	0
Grade 3	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 4	0	0	0	1 (1.4%)
Escherichia urinary tract infection	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	0	0	0
Grade 3	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Escherichia infection	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Escherichia sepsis	0	0	0	1 (1.4%)
Grade 4	0	0	0	1 (1.4%)
Fungal infections NEC	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Fungal infections NEC (cont)				
(cont)				
Grade 1	1 (2.5%)	0	1 (1.1%)	3 (3.0%)
Fungal skin infection	1 (2.5%)	0	1 (1.1%)	2 (2.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	2 (2.0%)
Fungal infection	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
Borrelial infections	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
Grade 3	0	0	0	0
Borrelia infection	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Fungal infections NEC (cont)				
(cont)				
Grade 1	0	0	0	0
Fungal skin infection	0	0	0	0
Grade 1	0	0	0	0
Fungal infection	0	0	0	0
Grade 1	0	0	0	0
Borrelial infections	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	0	0	0
Grade 3	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Borrelia infection	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Borrelial infections (cont)				
Lyme disease	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
Neuroborreliosis	0	0	0	0
Grade 3	0	0	0	0
Candida infections	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Grade 1	0	0	0	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Gastrointestinal candidiasis	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Oral candidiasis	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Borrelial infections (cont)				
Lyme disease	0	0	0	0
Grade 1	0	0	0	0
Neuroborreliosis	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 3	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Candida infections	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Gastrointestinal candidiasis	0	0	0	0
Grade 2	0	0	0	0
Oral candidiasis	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Staphylococcal infections	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Furuncle	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Bordetella infections	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Pertussis	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Eye and eyelid infections	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Eye infection	1 (2.5%)	0	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-ol.pdf 29AUG2023: 9:41

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Staphylococcal infections	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Furuncle	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Bordetella infections	0	0	0	0
Grade 1	0	0	0	0
Pertussis	0	0	0	0
Grade 1	0	0	0	0
Eye and eyelid infections	0	0	0	0
Grade 2	0	0	0	0
Eye infection	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Eye and eyelid infections (cont)				
Eye infection (cont)				
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Male reproductive tract infections	0	0	0	1 (1.0%)
Grade 2	0	0	0	1 (1.0%)
Scrotal abscess	0	0	0	1 (1.0%)
Grade 2	0	0	0	1 (1.0%)
Streptococcal infections	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Erysipelas	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-ol.pdf 29AUG2023: 9:41

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Eye and eyelid infections (cont)				
Eye infection (cont)				
Grade 2	0	0	0	0
Male reproductive tract infections	0	0	0	0
Grade 2	0	0	0	0
Scrotal abscess	0	0	0	0
Grade 2	0	0	0	0
Streptococcal infections	0	0	0	0
Grade 2	0	0	0	0
Erysipelas	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Tinea infections	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
Tinea versicolour	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
Tuberculous infections	0	0	0	0
Grade 2	0	0	0	0
Tuberculosis	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-ol.pdf 29AUG2023: 9:41

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Tinea infections	0	0	0	0
Grade 1	0	0	0	0
Tinea versicolour	0	0	0	0
Grade 1	0	0	0	0
Tuberculous infections	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Tuberculosis	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions	16 (40.0%)	17 (34.7%)	33 (37.1%)	49 (49.5%)
Grade 1	6 (15.0%)	7 (14.3%)	13 (14.6%)	25 (25.3%)
Grade 2	8 (20.0%)	9 (18.4%)	17 (19.1%)	20 (20.2%)
Grade 3	2 (5.0%)	1 (2.0%)	3 (3.4%)	4 (4.0%)
Grade 5	0	0	0	0
Asthenic conditions	9 (22.5%)	10 (20.4%)	19 (21.3%)	30 (30.3%)
Grade 1	3 (7.5%)	4 (8.2%)	7 (7.9%)	17 (17.2%)
Grade 2	5 (12.5%)	5 (10.2%)	10 (11.2%)	11 (11.1%)
Grade 3	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Fatigue	5 (12.5%)	8 (16.3%)	13 (14.6%)	22 (22.2%)
Grade 1	1 (2.5%)	4 (8.2%)	5 (5.6%)	13 (13.1%)
Grade 2	3 (7.5%)	3 (6.1%)	6 (6.7%)	7 (7.1%)
Grade 3	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions	13 (54.2%)	14 (40.0%)	27 (45.8%)	37 (52.1%)
Grade 1	9 (37.5%)	3 (8.6%)	12 (20.3%)	17 (23.9%)
Grade 2	3 (12.5%)	8 (22.9%)	11 (18.6%)	14 (19.7%)
Grade 3	0	3 (8.6%)	3 (5.1%)	4 (5.6%)
Grade 5	1 (4.2%)	0	1 (1.7%)	2 (2.8%)
Asthenic conditions	3 (12.5%)	8 (22.9%)	11 (18.6%)	17 (23.9%)
Grade 1	2 (8.3%)	1 (2.9%)	3 (5.1%)	7 (9.9%)
Grade 2	1 (4.2%)	5 (14.3%)	6 (10.2%)	8 (11.3%)
Grade 3	0	2 (5.7%)	2 (3.4%)	2 (2.8%)
Fatigue	1 (4.2%)	4 (11.4%)	5 (8.5%)	8 (11.3%)
Grade 1	1 (4.2%)	1 (2.9%)	2 (3.4%)	4 (5.6%)
Grade 2	0	3 (8.6%)	3 (5.1%)	4 (5.6%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Asthenic conditions (cont)				
Asthenia	3 (7.5%)	1 (2.0%)	4 (4.5%)	6 (6.1%)
Grade 1	2 (5.0%)	0	2 (2.2%)	4 (4.0%)
Grade 2	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Grade 3	0	0	0	0
Malaise	1 (2.5%)	1 (2.0%)	2 (2.2%)	3 (3.0%)
Grade 1	0	0	0	1 (1.0%)
Grade 2	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Grade 3	0	0	0	0
Febrile disorders	7 (17.5%)	4 (8.2%)	11 (12.4%)	17 (17.2%)
Grade 1	2 (5.0%)	3 (6.1%)	5 (5.6%)	10 (10.1%)
Grade 2	4 (10.0%)	1 (2.0%)	5 (5.6%)	6 (6.1%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Asthenic conditions (cont)				
Asthenia	2 (8.3%)	4 (11.4%)	6 (10.2%)	8 (11.3%)
Grade 1	1 (4.2%)	0	1 (1.7%)	2 (2.8%)
Grade 2	1 (4.2%)	3 (8.6%)	4 (6.8%)	5 (7.0%)
Grade 3	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Malaise	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Grade 1	0	0	0	1 (1.4%)
Grade 2	0	0	0	0
Grade 3	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Febrile disorders	4 (16.7%)	2 (5.7%)	6 (10.2%)	8 (11.3%)
Grade 1	2 (8.3%)	2 (5.7%)	4 (6.8%)	5 (7.0%)
Grade 2	2 (8.3%)	0	2 (3.4%)	2 (2.8%)
Grade 3	0	0	0	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Febrile disorders (cont)				
Pyrexia	7 (17.5%)	4 (8.2%)	11 (12.4%)	17 (17.2%)
Grade 1	2 (5.0%)	3 (6.1%)	5 (5.6%)	10 (10.1%)
Grade 2	4 (10.0%)	1 (2.0%)	5 (5.6%)	6 (6.1%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Oedema NEC	3 (7.5%)	2 (4.1%)	5 (5.6%)	10 (10.1%)
Grade 1	3 (7.5%)	1 (2.0%)	4 (4.5%)	6 (6.1%)
Grade 2	0	1 (2.0%)	1 (1.1%)	4 (4.0%)
Oedema peripheral	3 (7.5%)	1 (2.0%)	4 (4.5%)	8 (8.1%)
Grade 1	3 (7.5%)	0	3 (3.4%)	5 (5.1%)
Grade 2	0	1 (2.0%)	1 (1.1%)	3 (3.0%)
Oedema	0	1 (2.0%)	1 (1.1%)	2 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Febrile disorders (cont)				
Pyrexia	4 (16.7%)	2 (5.7%)	6 (10.2%)	8 (11.3%)
Grade 1	2 (8.3%)	2 (5.7%)	4 (6.8%)	5 (7.0%)
Grade 2	2 (8.3%)	0	2 (3.4%)	2 (2.8%)
Grade 3	0	0	0	1 (1.4%)
Oedema NEC	5 (20.8%)	2 (5.7%)	7 (11.9%)	8 (11.3%)
Grade 1	3 (12.5%)	2 (5.7%)	5 (8.5%)	6 (8.5%)
Grade 2	2 (8.3%)	0	2 (3.4%)	2 (2.8%)
Oedema peripheral	5 (20.8%)	2 (5.7%)	7 (11.9%)	8 (11.3%)
Grade 1	3 (12.5%)	2 (5.7%)	5 (8.5%)	6 (8.5%)
Grade 2	2 (8.3%)	0	2 (3.4%)	2 (2.8%)
Oedema	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Oedema NEC (cont)				
Oedema (cont)				
Grade 1	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Generalised oedema	0	0	0	1 (1.0%)
Grade 2	0	0	0	1 (1.0%)
General signs and symptoms NEC	3 (7.5%)	5 (10.2%)	8 (9.0%)	11 (11.1%)
Grade 1	2 (5.0%)	3 (6.1%)	5 (5.6%)	8 (8.1%)
Grade 2	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 5	0	0	0	0
Influenza like illness	2 (5.0%)	3 (6.1%)	5 (5.6%)	6 (6.1%)
Grade 1	1 (2.5%)	2 (4.1%)	3 (3.4%)	4 (4.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Oedema NEC (cont)				
Oedema (cont)				
Grade 1	0	0	0	0
Generalised oedema	0	0	0	0
Grade 2	0	0	0	0
General signs and symptoms NEC	3 (12.5%)	0	3 (5.1%)	4 (5.6%)
Grade 1	2 (8.3%)	0	2 (3.4%)	2 (2.8%)
Grade 2	0	0	0	1 (1.4%)
Grade 3	0	0	0	0
Grade 5	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Influenza like illness	0	0	0	1 (1.4%)
Grade 1	0	0	0	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
General signs and symptoms NEC (cont)				
Influenza like illness (cont)				
Grade 2	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Peripheral swelling	0	1 (2.0%)	1 (1.1%)	3 (3.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	3 (3.0%)
Grade 2	0	0	0	0
Crepitations	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
General physical health deterioration	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Multiple organ dysfunction syndrome	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
General signs and symptoms NEC (cont)				
Influenza like illness (cont)				
Grade 2	0	0	0	0
Peripheral swelling	2 (8.3%)	0	2 (3.4%)	3 (4.2%)
Grade 1	2 (8.3%)	0	2 (3.4%)	2 (2.8%)
Grade 2	0	0	0	1 (1.4%)
Crepitations	0	0	0	0
Grade 1	0	0	0	0
General physical health deterioration	0	0	0	0
Grade 3	0	0	0	0
Multiple organ dysfunction syndrome	1 (4.2%)	0	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
General signs and symptoms NEC (cont)				
Multiple organ dysfunction syndrome (cont)				
Grade 5	0	0	0	0
Swelling	0	0	0	0
Grade 1	0	0	0	0
Xerosis	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Pain and discomfort NEC	1 (2.5%)	0	1 (1.1%)	5 (5.1%)
Grade 1	1 (2.5%)	0	1 (1.1%)	4 (4.0%)
Grade 2	0	0	0	1 (1.0%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
General signs and symptoms NEC (cont)				
Multiple organ dysfunction syndrome (cont)				
Grade 5	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Swelling	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Xerosis	0	0	0	0
Grade 1	0	0	0	0
Pain and discomfort NEC	0	4 (11.4%)	4 (6.8%)	7 (9.9%)
Grade 1	0	2 (5.7%)	2 (3.4%)	4 (5.6%)
Grade 2	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Grade 3	0	1 (2.9%)	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Pain and discomfort NEC (cont)				
Chest pain	1 (2.5%)	0	1 (1.1%)	4 (4.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	4 (4.0%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Pain	0	0	0	1 (1.0%)
Grade 1	0	0	0	0
Grade 2	0	0	0	1 (1.0%)
Facial pain	0	0	0	0
Grade 2	0	0	0	0
Non-cardiac chest pain	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Pain and discomfort NEC (cont)				
Chest pain	0	3 (8.6%)	3 (5.1%)	4 (5.6%)
Grade 1	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 3	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Pain	0	0	0	1 (1.4%)
Grade 1	0	0	0	1 (1.4%)
Grade 2	0	0	0	0
Facial pain	0	0	0	1 (1.4%)
Grade 2	0	0	0	1 (1.4%)
Non-cardiac chest pain	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Feelings and sensations NEC	1 (2.5%)	1 (2.0%)	2 (2.2%)	3 (3.0%)
Grade 1	1 (2.5%)	1 (2.0%)	2 (2.2%)	3 (3.0%)
Chills	1 (2.5%)	1 (2.0%)	2 (2.2%)	3 (3.0%)
Grade 1	1 (2.5%)	1 (2.0%)	2 (2.2%)	3 (3.0%)
Early satiety	0	0	0	0
Grade 1	0	0	0	0
Feeling hot	0	0	0	0
Grade 1	0	0	0	0
Healing abnormal NEC	0	2 (4.1%)	2 (2.2%)	2 (2.0%)
Grade 2	0	2 (4.1%)	2 (2.2%)	2 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Feelings and sensations NEC	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Grade 1	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Chills	0	0	0	0
Grade 1	0	0	0	0
Early satiety	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Feeling hot	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Healing abnormal NEC	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
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	Male			
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Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Healing abnormal NEC (cont)				
Impaired healing	0	2 (4.1%)	2 (2.2%)	2 (2.0%)
Grade 2	0	2 (4.1%)	2 (2.2%)	2 (2.0%)
Mucosal findings abnormal	0	0	0	1 (1.0%)
Grade 1	0	0	0	0
Grade 3	0	0	0	1 (1.0%)
Mucosal inflammation	0	0	0	1 (1.0%)
Grade 1	0	0	0	0
Grade 3	0	0	0	1 (1.0%)
Death and sudden death	0	0	0	0
Grade 5	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Healing abnormal NEC (cont)				
Impaired healing	0	0	0	0
Grade 2	0	0	0	0
Mucosal findings abnormal	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 3	0	0	0	0
Mucosal inflammation	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 3	0	0	0	0
Death and sudden death	0	0	0	1 (1.4%)
Grade 5	0	0	0	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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	Male			
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Death and sudden death (cont)				
Sudden death	0	0	0	0
Grade 5	0	0	0	0
Gait disturbances	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
Gait disturbance	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
Implant and catheter site reactions	0	0	0	0
Grade 2	0	0	0	0
Catheter site pain	0	0	0	0
Grade 2	0	0	0	0

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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Death and sudden death (cont)				
Sudden death	0	0	0	1 (1.4%)
Grade 5	0	0	0	1 (1.4%)
Gait disturbances	0	0	0	0
Grade 1	0	0	0	0
Gait disturbance	0	0	0	0
Grade 1	0	0	0	0
Implant and catheter site reactions	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Catheter site pain	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)

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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Withdrawal and rebound effects	0	0	0	0
Grade 2	0	0	0	0
Drug withdrawal syndrome	0	0	0	0
Grade 2	0	0	0	0
Blood and lymphatic system disorders	15 (37.5%)	21 (42.9%)	36 (40.4%)	49 (49.5%)
Grade 1	1 (2.5%)	2 (4.1%)	3 (3.4%)	5 (5.1%)
Grade 2	2 (5.0%)	8 (16.3%)	10 (11.2%)	14 (14.1%)
Grade 3	11 (27.5%)	9 (18.4%)	20 (22.5%)	25 (25.3%)
Grade 4	1 (2.5%)	1 (2.0%)	2 (2.2%)	4 (4.0%)
Grade 5	0	1 (2.0%)	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Withdrawal and rebound effects	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Drug withdrawal syndrome	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Blood and lymphatic system disorders	9 (37.5%)	17 (48.6%)	26 (44.1%)	36 (50.7%)
Grade 1	1 (4.2%)	2 (5.7%)	3 (5.1%)	4 (5.6%)
Grade 2	1 (4.2%)	6 (17.1%)	7 (11.9%)	11 (15.5%)
Grade 3	4 (16.7%)	7 (20.0%)	11 (18.6%)	15 (21.1%)
Grade 4	3 (12.5%)	2 (5.7%)	5 (8.5%)	6 (8.5%)
Grade 5	0	0	0	0

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Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Thrombocytopenias	8 (20.0%)	8 (16.3%)	16 (18.0%)	23 (23.2%)
Grade 1	2 (5.0%)	1 (2.0%)	3 (3.4%)	3 (3.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	3 (3.0%)
Grade 3	5 (12.5%)	5 (10.2%)	10 (11.2%)	13 (13.1%)
Grade 4	1 (2.5%)	1 (2.0%)	2 (2.2%)	4 (4.0%)
Thrombocytopenia	8 (20.0%)	8 (16.3%)	16 (18.0%)	23 (23.2%)
Grade 1	2 (5.0%)	1 (2.0%)	3 (3.4%)	3 (3.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	3 (3.0%)
Grade 3	5 (12.5%)	5 (10.2%)	10 (11.2%)	13 (13.1%)
Grade 4	1 (2.5%)	1 (2.0%)	2 (2.2%)	4 (4.0%)
Anaemias NEC	8 (20.0%)	7 (14.3%)	15 (16.9%)	20 (20.2%)
Grade 2	2 (5.0%)	4 (8.2%)	6 (6.7%)	8 (8.1%)
Grade 3	5 (12.5%)	3 (6.1%)	8 (9.0%)	11 (11.1%)
Grade 4	1 (2.5%)	0	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Thrombocytopenias	4 (16.7%)	8 (22.9%)	12 (20.3%)	20 (28.2%)
Grade 1	2 (8.3%)	2 (5.7%)	4 (6.8%)	5 (7.0%)
Grade 2	0	1 (2.9%)	1 (1.7%)	5 (7.0%)
Grade 3	2 (8.3%)	4 (11.4%)	6 (10.2%)	8 (11.3%)
Grade 4	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Thrombocytopenia	4 (16.7%)	8 (22.9%)	12 (20.3%)	20 (28.2%)
Grade 1	2 (8.3%)	2 (5.7%)	4 (6.8%)	5 (7.0%)
Grade 2	0	1 (2.9%)	1 (1.7%)	5 (7.0%)
Grade 3	2 (8.3%)	4 (11.4%)	6 (10.2%)	8 (11.3%)
Grade 4	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Anaemias NEC	8 (33.3%)	8 (22.9%)	16 (27.1%)	21 (29.6%)
Grade 2	1 (4.2%)	5 (14.3%)	6 (10.2%)	7 (9.9%)
Grade 3	5 (20.8%)	3 (8.6%)	8 (13.6%)	12 (16.9%)
Grade 4	2 (8.3%)	0	2 (3.4%)	2 (2.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-ol.pdf 29AUG2023: 9:41

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Anaemias NEC (cont)				
Anaemia	8 (20.0%)	7 (14.3%)	15 (16.9%)	20 (20.2%)
Grade 2	2 (5.0%)	4 (8.2%)	6 (6.7%)	8 (8.1%)
Grade 3	5 (12.5%)	3 (6.1%)	8 (9.0%)	11 (11.1%)
Grade 4	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Leukocytoses NEC	2 (5.0%)	6 (12.2%)	8 (9.0%)	9 (9.1%)
Grade 1	1 (2.5%)	2 (4.1%)	3 (3.4%)	4 (4.0%)
Grade 2	0	4 (8.2%)	4 (4.5%)	4 (4.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Leukocytosis	2 (5.0%)	6 (12.2%)	8 (9.0%)	9 (9.1%)
Grade 1	1 (2.5%)	2 (4.1%)	3 (3.4%)	4 (4.0%)
Grade 2	0	4 (8.2%)	4 (4.5%)	4 (4.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Anaemias NEC (cont)				
Anaemia	8 (33.3%)	8 (22.9%)	16 (27.1%)	21 (29.6%)
Grade 2	1 (4.2%)	5 (14.3%)	6 (10.2%)	7 (9.9%)
Grade 3	5 (20.8%)	3 (8.6%)	8 (13.6%)	12 (16.9%)
Grade 4	2 (8.3%)	0	2 (3.4%)	2 (2.8%)
Leukocytoses NEC	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Grade 1	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Leukocytosis	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Grade 1	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Leukocytoses NEC (cont)				
Neutrophilia	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Neutropenias	1 (2.5%)	1 (2.0%)	2 (2.2%)	5 (5.1%)
Grade 1	0	0	0	1 (1.0%)
Grade 3	1 (2.5%)	1 (2.0%)	2 (2.2%)	3 (3.0%)
Grade 4	0	0	0	1 (1.0%)
Neutropenia	1 (2.5%)	1 (2.0%)	2 (2.2%)	4 (4.0%)
Grade 1	0	0	0	1 (1.0%)
Grade 3	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Grade 4	0	0	0	1 (1.0%)
Febrile neutropenia	1 (2.5%)	0	1 (1.1%)	2 (2.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	2 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Leukocytoses NEC (cont)				
Neutrophilia	0	0	0	0
Grade 1	0	0	0	0
Neutropenias	1 (4.2%)	2 (5.7%)	3 (5.1%)	4 (5.6%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 3	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Grade 4	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Neutropenia	1 (4.2%)	2 (5.7%)	3 (5.1%)	4 (5.6%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 3	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Grade 4	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Febrile neutropenia	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Leukopenias NEC	1 (2.5%)	1 (2.0%)	2 (2.2%)	4 (4.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Grade 2	0	0	0	0
Grade 3	0	0	0	1 (1.0%)
Grade 4	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Leukopenia	1 (2.5%)	1 (2.0%)	2 (2.2%)	4 (4.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	2 (2.0%)
Lymphopenia	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	0	0	0	0
Grade 4	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Spleen disorders	2 (5.0%)	1 (2.0%)	3 (3.4%)	4 (4.0%)
Grade 3	2 (5.0%)	0	2 (2.2%)	3 (3.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Leukopenias NEC	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	0	0	0
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Leukopenia	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Lymphopenia	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 4	0	0	0	0
Spleen disorders	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Spleen disorders (cont)				
(cont)				
Grade 5	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Splenomegaly	1 (2.5%)	0	1 (1.1%)	2 (2.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	2 (2.0%)
Splenic haematoma	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 5	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Splenic infarction	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Thrombocytoses	0	2 (4.1%)	2 (2.2%)	2 (2.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Spleen disorders (cont)				
(cont)				
Grade 5	0	0	0	0
Splenomegaly	0	0	0	0
Grade 3	0	0	0	0
Splenic haematoma	0	0	0	0
Grade 5	0	0	0	0
Splenic infarction	0	0	0	0
Grade 3	0	0	0	0
Thrombocytoses	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	0	0	0
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Thrombocytoses (cont)				
(cont)				
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Thrombocytosis	0	2 (4.1%)	2 (2.2%)	2 (2.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	0	0	0
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Bleeding tendencies	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
Increased tendency to bruise	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
Anaemias haemolytic NEC	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Thrombocytoses (cont)				
(cont)				
Grade 3	0	0	0	0
Thrombocytosis	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	0	0	0
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 3	0	0	0	0
Bleeding tendencies	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Increased tendency to bruise	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Anaemias haemolytic NEC	1 (4.2%)	0	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Anaemias haemolytic NEC (cont)				
(cont)				
Grade 4	0	0	0	0
Haemolytic anaemia	0	0	0	0
Grade 4	0	0	0	0
Coagulation factor deficiencies	0	0	0	0
Grade 2	0	0	0	0
Hypoprothrombinaemia	0	0	0	0
Grade 2	0	0	0	0
Haemolyses NEC	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Anaemias haemolytic NEC (cont)				
(cont)				
Grade 4	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Haemolytic anaemia	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 4	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Coagulation factor deficiencies	0	0	0	1 (1.4%)
Grade 2	0	0	0	1 (1.4%)
Hypoprothrombinaemia	0	0	0	1 (1.4%)
Grade 2	0	0	0	1 (1.4%)
Haemolyses NEC	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Haemolyses NEC (cont)				
Haemolysis	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Respiratory, thoracic and mediastinal disorders	15 (37.5%)	21 (42.9%)	36 (40.4%)	52 (52.5%)
Grade 1	8 (20.0%)	9 (18.4%)	17 (19.1%)	26 (26.3%)
Grade 2	5 (12.5%)	9 (18.4%)	14 (15.7%)	18 (18.2%)
Grade 3	1 (2.5%)	2 (4.1%)	3 (3.4%)	4 (4.0%)
Grade 4	0	0	0	2 (2.0%)
Grade 5	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Coughing and associated symptoms	8 (20.0%)	9 (18.4%)	17 (19.1%)	25 (25.3%)
Grade 1	6 (15.0%)	6 (12.2%)	12 (13.5%)	18 (18.2%)
Grade 2	2 (5.0%)	3 (6.1%)	5 (5.6%)	7 (7.1%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Haemolyses NEC (cont)				
Haemolysis	0	0	0	0
Grade 3	0	0	0	0
Respiratory, thoracic and mediastinal disorders	11 (45.8%)	15 (42.9%)	26 (44.1%)	29 (40.8%)
Grade 1	4 (16.7%)	6 (17.1%)	10 (16.9%)	12 (16.9%)
Grade 2	5 (20.8%)	4 (11.4%)	9 (15.3%)	10 (14.1%)
Grade 3	0	5 (14.3%)	5 (8.5%)	5 (7.0%)
Grade 4	2 (8.3%)	0	2 (3.4%)	2 (2.8%)
Grade 5	0	0	0	0
Coughing and associated symptoms	5 (20.8%)	7 (20.0%)	12 (20.3%)	16 (22.5%)
Grade 1	2 (8.3%)	4 (11.4%)	6 (10.2%)	9 (12.7%)
Grade 2	3 (12.5%)	1 (2.9%)	4 (6.8%)	5 (7.0%)
Grade 3	0	2 (5.7%)	2 (3.4%)	2 (2.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Coughing and associated symptoms (cont)				
Cough	8 (20.0%)	9 (18.4%)	17 (19.1%)	24 (24.2%)
Grade 1	6 (15.0%)	6 (12.2%)	12 (13.5%)	18 (18.2%)
Grade 2	2 (5.0%)	3 (6.1%)	5 (5.6%)	6 (6.1%)
Grade 3	0	0	0	0
Productive cough	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
Grade 2	0	0	0	0
Haemoptysis	0	0	0	1 (1.0%)
Grade 2	0	0	0	1 (1.0%)
Breathing abnormalities	4 (10.0%)	7 (14.3%)	11 (12.4%)	25 (25.3%)
Grade 1	3 (7.5%)	3 (6.1%)	6 (6.7%)	18 (18.2%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Coughing and associated symptoms (cont)				
Cough	4 (16.7%)	7 (20.0%)	11 (18.6%)	15 (21.1%)
Grade 1	2 (8.3%)	4 (11.4%)	6 (10.2%)	9 (12.7%)
Grade 2	2 (8.3%)	1 (2.9%)	3 (5.1%)	4 (5.6%)
Grade 3	0	2 (5.7%)	2 (3.4%)	2 (2.8%)
Productive cough	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	0	0	0	0
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Haemoptysis	0	0	0	0
Grade 2	0	0	0	0
Breathing abnormalities	3 (12.5%)	4 (11.4%)	7 (11.9%)	9 (12.7%)
Grade 1	2 (8.3%)	1 (2.9%)	3 (5.1%)	5 (7.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-ol.pdf 29AUG2023: 9:41

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Breathing abnormalities (cont) (cont)				
Grade 2	1 (2.5%)	2 (4.1%)	3 (3.4%)	5 (5.1%)
Grade 3	0	2 (4.1%)	2 (2.2%)	2 (2.0%)
Dyspnoea	3 (7.5%)	6 (12.2%)	9 (10.1%)	19 (19.2%)
Grade 1	2 (5.0%)	2 (4.1%)	4 (4.5%)	12 (12.1%)
Grade 2	1 (2.5%)	2 (4.1%)	3 (3.4%)	5 (5.1%)
Grade 3	0	2 (4.1%)	2 (2.2%)	2 (2.0%)
Dyspnoea exertional	1 (2.5%)	0	1 (1.1%)	5 (5.1%)
Grade 1	1 (2.5%)	0	1 (1.1%)	5 (5.1%)
Hypoventilation	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Breathing abnormalities (cont) (cont)				
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 3	0	3 (8.6%)	3 (5.1%)	3 (4.2%)
Dyspnoea	3 (12.5%)	3 (8.6%)	6 (10.2%)	7 (9.9%)
Grade 1	2 (8.3%)	0	2 (3.4%)	3 (4.2%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 3	0	3 (8.6%)	3 (5.1%)	3 (4.2%)
Dyspnoea exertional	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Grade 1	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Hypoventilation	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Breathing abnormalities (cont)				
Tachypnoea	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Nasal disorders NEC	3 (7.5%)	2 (4.1%)	5 (5.6%)	7 (7.1%)
Grade 1	2 (5.0%)	1 (2.0%)	3 (3.4%)	3 (3.0%)
Grade 2	1 (2.5%)	1 (2.0%)	2 (2.2%)	4 (4.0%)
Epistaxis	3 (7.5%)	2 (4.1%)	5 (5.6%)	7 (7.1%)
Grade 1	2 (5.0%)	1 (2.0%)	3 (3.4%)	3 (3.0%)
Grade 2	1 (2.5%)	1 (2.0%)	2 (2.2%)	4 (4.0%)
Nasal dryness	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Breathing abnormalities (cont)				
Tachypnoea	0	0	0	0
Grade 1	0	0	0	0
Nasal disorders NEC	3 (12.5%)	1 (2.9%)	4 (6.8%)	5 (7.0%)
Grade 1	2 (8.3%)	1 (2.9%)	3 (5.1%)	4 (5.6%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Epistaxis	2 (8.3%)	1 (2.9%)	3 (5.1%)	4 (5.6%)
Grade 1	1 (4.2%)	1 (2.9%)	2 (3.4%)	3 (4.2%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Nasal dryness	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Upper respiratory tract signs and symptoms	1 (2.5%)	2 (4.1%)	3 (3.4%)	6 (6.1%)
Grade 1	1 (2.5%)	1 (2.0%)	2 (2.2%)	5 (5.1%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Dysphonia	1 (2.5%)	1 (2.0%)	2 (2.2%)	3 (3.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	2 (2.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Rhinorrhoea	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
Oropharyngeal discomfort	0	0	0	0
Grade 1	0	0	0	0
Oropharyngeal pain	0	1 (2.0%)	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Upper respiratory tract signs and symptoms	1 (4.2%)	1 (2.9%)	2 (3.4%)	3 (4.2%)
Grade 1	1 (4.2%)	1 (2.9%)	2 (3.4%)	3 (4.2%)
Grade 2	0	0	0	0
Dysphonia	0	0	0	1 (1.4%)
Grade 1	0	0	0	1 (1.4%)
Grade 2	0	0	0	0
Rhinorrhoea	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Oropharyngeal discomfort	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Oropharyngeal pain	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Upper respiratory tract signs and symptoms (cont)				
Oropharyngeal pain (cont)				
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Throat tightness	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
Bronchospasm and obstruction	3 (7.5%)	1 (2.0%)	4 (4.5%)	5 (5.1%)
Grade 1	3 (7.5%)	0	3 (3.4%)	3 (3.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	0	0	0	1 (1.0%)
Bronchitis chronic	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-ol.pdf 29AUG2023: 9:41

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Upper respiratory tract signs and symptoms (cont)				
Oropharyngeal pain (cont)				
Grade 1	0	0	0	0
Throat tightness	0	0	0	0
Grade 1	0	0	0	0
Bronchospasm and obstruction	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 3	0	0	0	0
Bronchitis chronic	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Bronchospasm and obstruction (cont)				
Chronic obstructive pulmonary disease	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	0	0	0	1 (1.0%)
Wheezing	2 (5.0%)	0	2 (2.2%)	2 (2.0%)
Grade 1	2 (5.0%)	0	2 (2.2%)	2 (2.0%)
Asthma	0	0	0	0
Grade 2	0	0	0	0
Pneumothorax and pleural effusions NEC	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Bronchospasm and obstruction (cont)				
Chronic obstructive pulmonary disease	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Wheezing	0	0	0	0
Grade 1	0	0	0	0
Asthma	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Pneumothorax and pleural effusions NEC	1 (4.2%)	3 (8.6%)	4 (6.8%)	4 (5.6%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	0	2 (5.7%)	2 (3.4%)	2 (2.8%)
Grade 3	0	1 (2.9%)	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Pneumothorax and pleural effusions NEC (cont)				
Pleural effusion	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Lower respiratory tract signs and symptoms	2 (5.0%)	0	2 (2.2%)	4 (4.0%)
Grade 1	2 (5.0%)	0	2 (2.2%)	3 (3.0%)
Grade 2	0	0	0	1 (1.0%)
Rales	1 (2.5%)	0	1 (1.1%)	3 (3.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	2 (2.0%)
Grade 2	0	0	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Pneumothorax and pleural effusions NEC (cont)				
Pleural effusion	1 (4.2%)	3 (8.6%)	4 (6.8%)	4 (5.6%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	0	2 (5.7%)	2 (3.4%)	2 (2.8%)
Grade 3	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Lower respiratory tract signs and symptoms	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Rales	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Lower respiratory tract signs and symptoms (cont)				
Hiccups	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Respiratory failures (excl neonatal)	1 (2.5%)	0	1 (1.1%)	2 (2.0%)
Grade 3	0	0	0	0
Grade 4	0	0	0	1 (1.0%)
Grade 5	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Respiratory failure	1 (2.5%)	0	1 (1.1%)	2 (2.0%)
Grade 3	0	0	0	0
Grade 4	0	0	0	1 (1.0%)
Grade 5	1 (2.5%)	0	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Lower respiratory tract signs and symptoms (cont)				
Hiccups	0	0	0	0
Grade 1	0	0	0	0
Respiratory failures (excl neonatal)	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Grade 3	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 4	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 5	0	0	0	0
Respiratory failure	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Grade 3	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 4	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 5	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Lower respiratory tract inflammatory and immunologic conditions	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Grade 1	0	0	0	0
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Alveolitis	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Pneumonia aspiration	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Pulmonary granuloma	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Lower respiratory tract inflammatory and immunologic conditions	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Alveolitis	0	0	0	0
Grade 2	0	0	0	0
Pneumonia aspiration	0	0	0	0
Grade 3	0	0	0	0
Pulmonary granuloma	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Pulmonary thrombotic and embolic conditions	2 (5.0%)	1 (2.0%)	3 (3.4%)	3 (3.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 5	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Pulmonary embolism	2 (5.0%)	1 (2.0%)	3 (3.4%)	3 (3.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 5	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Conditions associated with abnormal gas exchange	0	0	0	1 (1.0%)
Grade 4	0	0	0	1 (1.0%)
Hypoxia	0	0	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Pulmonary thrombotic and embolic conditions	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Grade 5	0	0	0	0
Pulmonary embolism	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Grade 5	0	0	0	0
Conditions associated with abnormal gas exchange	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 4	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Hypoxia	1 (4.2%)	0	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Conditions associated with abnormal gas exchange (cont)				
Hypoxia (cont)				
Grade 4	0	0	0	1 (1.0%)
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Laryngeal inflammation	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Reflux laryngitis	0	0	0	1 (1.0%)
Grade 2	0	0	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Conditions associated with abnormal gas exchange (cont)				
Hypoxia (cont)				
Grade 4	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)	0	0	0	0
Grade 2	0	0	0	0
Laryngeal inflammation	0	0	0	0
Grade 2	0	0	0	0
Reflux laryngitis	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Parenchymal lung disorders NEC	2 (5.0%)	0	2 (2.2%)	2 (2.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Emphysema	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Lung consolidation	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Pleural infections and inflammations	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	0	0	0
Pleurisy	0	1 (2.0%)	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Parenchymal lung disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Emphysema	0	0	0	0
Grade 1	0	0	0	0
Lung consolidation	0	0	0	0
Grade 2	0	0	0	0
Pleural infections and inflammations	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	0	0	0
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Pleurisy	0	1 (2.9%)	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-ol.pdf 29AUG2023: 9:41

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Pleural infections and inflammations (cont)				
Pleurisy (cont)				
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	0	0	0
Paranasal sinus disorders (excl infections and neoplasms)	0	0	0	0
Grade 1	0	0	0	0
Sinus congestion	0	0	0	0
Grade 1	0	0	0	0
Pharyngeal disorders (excl infections and neoplasms)	0	0	0	1 (1.0%)
Grade 3	0	0	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Pleural infections and inflammations (cont)				
Pleurisy (cont)				
Grade 1	0	0	0	0
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Paranasal sinus disorders (excl infections and neoplasms)	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Sinus congestion	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Pharyngeal disorders (excl infections and neoplasms)	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Pharyngeal disorders (excl infections and neoplasms) (cont)				
Pharyngeal ulceration	0	0	0	1 (1.0%)
Grade 3	0	0	0	1 (1.0%)
Pulmonary oedemas	0	0	0	0
Grade 2	0	0	0	0
Pulmonary oedema	0	0	0	0
Grade 2	0	0	0	0
Respiratory tract disorders NEC	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Lung disorder	0	1 (2.0%)	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Pharyngeal disorders (excl infections and neoplasms) (cont)				
Pharyngeal ulceration	0	0	0	0
Grade 3	0	0	0	0
Pulmonary oedemas	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Pulmonary oedema	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Respiratory tract disorders NEC	0	0	0	0
Grade 2	0	0	0	0
Lung disorder	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Respiratory tract disorders NEC (cont)				
Lung disorder (cont)				
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Nervous system disorders	18 (45.0%)	17 (34.7%)	35 (39.3%)	47 (47.5%)
Grade 1	8 (20.0%)	8 (16.3%)	16 (18.0%)	24 (24.2%)
Grade 2	3 (7.5%)	7 (14.3%)	10 (11.2%)	13 (13.1%)
Grade 3	6 (15.0%)	2 (4.1%)	8 (9.0%)	9 (9.1%)
Grade 4	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 5	0	0	0	0
Neurological signs and symptoms NEC	5 (12.5%)	8 (16.3%)	13 (14.6%)	22 (22.2%)
Grade 1	5 (12.5%)	7 (14.3%)	12 (13.5%)	20 (20.2%)
Grade 2	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Respiratory tract disorders NEC (cont)				
Lung disorder (cont)				
Grade 2	0	0	0	0
Nervous system disorders	9 (37.5%)	15 (42.9%)	24 (40.7%)	32 (45.1%)
Grade 1	5 (20.8%)	8 (22.9%)	13 (22.0%)	15 (21.1%)
Grade 2	2 (8.3%)	4 (11.4%)	6 (10.2%)	10 (14.1%)
Grade 3	1 (4.2%)	3 (8.6%)	4 (6.8%)	6 (8.5%)
Grade 4	0	0	0	0
Grade 5	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Neurological signs and symptoms NEC	2 (8.3%)	6 (17.1%)	8 (13.6%)	13 (18.3%)
Grade 1	1 (4.2%)	3 (8.6%)	4 (6.8%)	7 (9.9%)
Grade 2	1 (4.2%)	2 (5.7%)	3 (5.1%)	4 (5.6%)
Grade 3	0	1 (2.9%)	1 (1.7%)	2 (2.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Neurological signs and symptoms NEC (cont)				
Dizziness	5 (12.5%)	8 (16.3%)	13 (14.6%)	21 (21.2%)
Grade 1	5 (12.5%)	7 (14.3%)	12 (13.5%)	20 (20.2%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	0	0	0	0
Presyncope	0	0	0	2 (2.0%)
Grade 1	0	0	0	1 (1.0%)
Grade 2	0	0	0	1 (1.0%)
Grade 3	0	0	0	0
Peripheral neuropathies NEC	6 (15.0%)	9 (18.4%)	15 (16.9%)	20 (20.2%)
Grade 1	2 (5.0%)	4 (8.2%)	6 (6.7%)	10 (10.1%)
Grade 2	2 (5.0%)	3 (6.1%)	5 (5.6%)	6 (6.1%)
Grade 3	2 (5.0%)	2 (4.1%)	4 (4.5%)	4 (4.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Neurological signs and symptoms NEC (cont)				
Dizziness	1 (4.2%)	6 (17.1%)	7 (11.9%)	13 (18.3%)
Grade 1	1 (4.2%)	3 (8.6%)	4 (6.8%)	8 (11.3%)
Grade 2	0	2 (5.7%)	2 (3.4%)	4 (5.6%)
Grade 3	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Presyncope	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	0	0	0	0
Grade 2	1 (4.2%)	0	1 (1.7%)	0
Grade 3	0	0	0	1 (1.4%)
Peripheral neuropathies NEC	3 (12.5%)	4 (11.4%)	7 (11.9%)	11 (15.5%)
Grade 1	3 (12.5%)	2 (5.7%)	5 (8.5%)	7 (9.9%)
Grade 2	0	2 (5.7%)	2 (3.4%)	4 (5.6%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Peripheral neuropathies NEC (cont)				
Peripheral sensory neuropathy	4 (10.0%)	9 (18.4%)	13 (14.6%)	18 (18.2%)
Grade 1	2 (5.0%)	4 (8.2%)	6 (6.7%)	10 (10.1%)
Grade 2	1 (2.5%)	3 (6.1%)	4 (4.5%)	5 (5.1%)
Grade 3	1 (2.5%)	2 (4.1%)	3 (3.4%)	3 (3.0%)
Neuropathy peripheral	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Peripheral sensorimotor neuropathy	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Paraesthesias and dysaesthesias	4 (10.0%)	3 (6.1%)	7 (7.9%)	9 (9.1%)
Grade 1	2 (5.0%)	1 (2.0%)	3 (3.4%)	5 (5.1%)
Grade 2	1 (2.5%)	2 (4.1%)	3 (3.4%)	3 (3.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Peripheral neuropathies NEC (cont)				
Peripheral sensory neuropathy	3 (12.5%)	4 (11.4%)	7 (11.9%)	11 (15.5%)
Grade 1	3 (12.5%)	2 (5.7%)	5 (8.5%)	7 (9.9%)
Grade 2	0	2 (5.7%)	2 (3.4%)	4 (5.6%)
Grade 3	0	0	0	0
Neuropathy peripheral	0	0	0	0
Grade 2	0	0	0	0
Peripheral sensorimotor neuropathy	0	0	0	0
Grade 3	0	0	0	0
Paraesthesias and dysaesthesias	2 (8.3%)	4 (11.4%)	6 (10.2%)	9 (12.7%)
Grade 1	2 (8.3%)	2 (5.7%)	4 (6.8%)	7 (9.9%)
Grade 2	0	2 (5.7%)	2 (3.4%)	2 (2.8%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Paraesthesias and dysaesthesias (cont)				
Paraesthesia	3 (7.5%)	3 (6.1%)	6 (6.7%)	8 (8.1%)
Grade 1	2 (5.0%)	1 (2.0%)	3 (3.4%)	5 (5.1%)
Grade 2	0	2 (4.1%)	2 (2.2%)	2 (2.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Hypoaesthesia	3 (7.5%)	1 (2.0%)	4 (4.5%)	4 (4.0%)
Grade 1	2 (5.0%)	1 (2.0%)	3 (3.4%)	3 (3.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Burning sensation	0	0	0	0
Grade 2	0	0	0	0
Dysaesthesia	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Paraesthesias and dysaesthesias (cont)				
Paraesthesia	0	2 (5.7%)	2 (3.4%)	5 (7.0%)
Grade 1	0	1 (2.9%)	1 (1.7%)	4 (5.6%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 3	0	0	0	0
Hypoaesthesia	2 (8.3%)	1 (2.9%)	3 (5.1%)	3 (4.2%)
Grade 1	2 (8.3%)	0	2 (3.4%)	2 (2.8%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Burning sensation	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Dysaesthesia	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Headaches NEC	1 (2.5%)	1 (2.0%)	2 (2.2%)	8 (8.1%)
Grade 1	1 (2.5%)	0	1 (1.1%)	7 (7.1%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	0	0	0	0
Headache	1 (2.5%)	1 (2.0%)	2 (2.2%)	8 (8.1%)
Grade 1	1 (2.5%)	0	1 (1.1%)	7 (7.1%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	0	0	0	0
Sinus headache	0	0	0	0
Grade 1	0	0	0	0
Disturbances in consciousness NEC	2 (5.0%)	1 (2.0%)	3 (3.4%)	5 (5.1%)
Grade 1	0	0	0	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Headaches NEC	1 (4.2%)	3 (8.6%)	4 (6.8%)	8 (11.3%)
Grade 1	1 (4.2%)	2 (5.7%)	3 (5.1%)	4 (5.6%)
Grade 2	0	0	0	3 (4.2%)
Grade 3	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Headache	1 (4.2%)	2 (5.7%)	3 (5.1%)	7 (9.9%)
Grade 1	1 (4.2%)	1 (2.9%)	2 (3.4%)	3 (4.2%)
Grade 2	0	0	0	3 (4.2%)
Grade 3	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Sinus headache	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Disturbances in consciousness NEC	1 (4.2%)	2 (5.7%)	3 (5.1%)	4 (5.6%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-ol.pdf 29AUG2023: 9:41

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Disturbances in consciousness NEC (cont) (cont)				
Grade 3	2 (5.0%)	0	2 (2.2%)	3 (3.0%)
Syncope	1 (2.5%)	0	1 (1.1%)	2 (2.0%)
Grade 2	0	0	0	0
Grade 3	1 (2.5%)	0	1 (1.1%)	2 (2.0%)
Somnolence	1 (2.5%)	0	1 (1.1%)	2 (2.0%)
Grade 1	0	0	0	1 (1.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Lethargy	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Disturbances in consciousness NEC (cont) (cont)				
Grade 3	1 (4.2%)	0	1 (1.7%)	2 (2.8%)
Syncope	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 3	0	0	0	1 (1.4%)
Somnolence	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 3	0	0	0	0
Lethargy	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	0	0	0	0
Grade 3	1 (4.2%)	0	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Coordination and balance disturbances	2 (5.0%)	2 (4.1%)	4 (4.5%)	5 (5.1%)
Grade 1	1 (2.5%)	2 (4.1%)	3 (3.4%)	4 (4.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Balance disorder	2 (5.0%)	1 (2.0%)	3 (3.4%)	4 (4.0%)
Grade 1	1 (2.5%)	1 (2.0%)	2 (2.2%)	3 (3.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Ataxia	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Sensory abnormalities NEC	2 (5.0%)	0	2 (2.2%)	3 (3.0%)
Grade 1	2 (5.0%)	0	2 (2.2%)	3 (3.0%)
Dysgeusia	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Coordination and balance disturbances	1 (4.2%)	0	1 (1.7%)	2 (2.8%)
Grade 1	0	0	0	1 (1.4%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Balance disorder	1 (4.2%)	0	1 (1.7%)	2 (2.8%)
Grade 1	0	0	0	1 (1.4%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Ataxia	0	0	0	0
Grade 1	0	0	0	0
Sensory abnormalities NEC	0	3 (8.6%)	3 (5.1%)	4 (5.6%)
Grade 1	0	3 (8.6%)	3 (5.1%)	4 (5.6%)
Dysgeusia	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Sensory abnormalities NEC (cont)				
Sensory disturbance	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Taste disorder	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
Ageusia	0	0	0	0
Grade 1	0	0	0	0
Restless legs syndrome	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Sensory abnormalities NEC (cont)				
Sensory disturbance	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Taste disorder	0	0	0	1 (1.4%)
Grade 1	0	0	0	1 (1.4%)
Ageusia	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Restless legs syndrome	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Central nervous system haemorrhages and cerebrovascular accidents	2 (5.0%)	0	2 (2.2%)	3 (3.0%)
Grade 1	0	0	0	0
Grade 2	0	0	0	1 (1.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 4	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 5	0	0	0	0
Cerebrovascular accident	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	0	0	0	0
Grade 4	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Cerebellar stroke	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Cerebral ischaemia	0	0	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Central nervous system haemorrhages and cerebrovascular accidents	3 (12.5%)	0	3 (5.1%)	3 (4.2%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Grade 5	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Cerebrovascular accident	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 4	0	0	0	0
Cerebellar stroke	0	0	0	0
Grade 3	0	0	0	0
Cerebral ischaemia	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Central nervous system haemorrhages and cerebrovascular accidents (cont)				
Cerebral ischaemia (cont)				
Grade 2	0	0	0	1 (1.0%)
Haemorrhagic stroke	0	0	0	0
Grade 5	0	0	0	0
Lacunar infarction	0	0	0	0
Grade 1	0	0	0	0
Memory loss (excl dementia)	1 (2.5%)	1 (2.0%)	2 (2.2%)	4 (4.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	3 (3.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Amnesia	1 (2.5%)	1 (2.0%)	2 (2.2%)	3 (3.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Central nervous system haemorrhages and cerebrovascular accidents (cont)				
Cerebral ischaemia (cont)				
Grade 2	0	0	0	0
Haemorrhagic stroke	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 5	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Lacunar infarction	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Memory loss (excl dementia)	0	2 (5.7%)	2 (3.4%)	2 (2.8%)
Grade 1	0	0	0	0
Grade 2	0	2 (5.7%)	2 (3.4%)	2 (2.8%)
Amnesia	0	1 (2.9%)	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Memory loss (excl dementia) (cont)				
Amnesia (cont)				
Grade 1	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Memory impairment	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
Grade 2	0	0	0	0
Central nervous system vascular disorders NEC	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	0	0	0	0
Cerebral microangiopathy	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Memory loss (excl dementia) (cont)				
Amnesia (cont)				
Grade 1	0	0	0	0
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Memory impairment	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	0	0	0
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Central nervous system vascular disorders NEC	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	0	0	0
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Cerebral microangiopathy	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Central nervous system vascular disorders NEC (cont)				
Cerebrovascular insufficiency	0	0	0	0
Grade 2	0	0	0	0
Transient cerebrovascular events	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	0	0	0	0
Transient ischaemic attack	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	0	0	0	0
Dementia (excl Alzheimer's type)	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Central nervous system vascular disorders NEC (cont)				
Cerebrovascular insufficiency	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Transient cerebrovascular events	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	0	0	0
Grade 3	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Transient ischaemic attack	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	0	0	0
Grade 3	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Dementia (excl Alzheimer's type)	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Dementia (excl Alzheimer's type) (cont)				
Dementia	0	0	0	0
Grade 2	0	0	0	0
Demyelinating disorders NEC	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Demyelination	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Encephalopathies NEC	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Leukoencephalopathy	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Dementia (excl Alzheimer's type) (cont)				
Dementia	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Demyelinating disorders NEC	0	0	0	0
Grade 2	0	0	0	0
Demyelination	0	0	0	0
Grade 2	0	0	0	0
Encephalopathies NEC	0	0	0	0
Grade 2	0	0	0	0
Leukoencephalopathy	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Lumbar spinal cord and nerve root disorders	0	0	0	0
Grade 2	0	0	0	0
Sciatica	0	0	0	0
Grade 2	0	0	0	0
Muscle tone abnormal	0	0	0	0
Grade 1	0	0	0	0
Myotonia	0	0	0	0
Grade 1	0	0	0	0
Parkinson's disease and parkinsonism	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Parkinson's disease	1 (2.5%)	0	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Lumbar spinal cord and nerve root disorders	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Sciatica	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Muscle tone abnormal	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Myotonia	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Parkinson's disease and parkinsonism	0	0	0	0
Grade 2	0	0	0	0
Parkinson's disease	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Parkinson's disease and parkinsonism (cont)				
Parkinson's disease (cont)				
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Structural brain disorders NEC	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Cerebral atrophy	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Tremor (excl congenital)	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Tremor	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Parkinson's disease and parkinsonism (cont)				
Parkinson's disease (cont)				
Grade 2	0	0	0	0
Structural brain disorders NEC	0	0	0	0
Grade 2	0	0	0	0
Cerebral atrophy	0	0	0	0
Grade 2	0	0	0	0
Tremor (excl congenital)	0	0	0	0
Grade 1	0	0	0	0
Tremor	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders	15 (37.5%)	21 (42.9%)	36 (40.4%)	48 (48.5%)
Grade 1	5 (12.5%)	8 (16.3%)	13 (14.6%)	18 (18.2%)
Grade 2	4 (10.0%)	11 (22.4%)	15 (16.9%)	18 (18.2%)
Grade 3	4 (10.0%)	0	4 (4.5%)	7 (7.1%)
Grade 4	2 (5.0%)	2 (4.1%)	4 (4.5%)	5 (5.1%)
Disorders of purine metabolism	4 (10.0%)	6 (12.2%)	10 (11.2%)	15 (15.2%)
Grade 1	1 (2.5%)	3 (6.1%)	4 (4.5%)	7 (7.1%)
Grade 2	1 (2.5%)	1 (2.0%)	2 (2.2%)	3 (3.0%)
Grade 3	0	0	0	0
Grade 4	2 (5.0%)	2 (4.1%)	4 (4.5%)	5 (5.1%)
Hyperuricaemia	3 (7.5%)	5 (10.2%)	8 (9.0%)	12 (12.1%)
Grade 1	1 (2.5%)	3 (6.1%)	4 (4.5%)	7 (7.1%)
Grade 4	2 (5.0%)	2 (4.1%)	4 (4.5%)	5 (5.1%)
Gout	1 (2.5%)	1 (2.0%)	2 (2.2%)	3 (3.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders	11 (45.8%)	14 (40.0%)	25 (42.4%)	30 (42.3%)
Grade 1	5 (20.8%)	5 (14.3%)	10 (16.9%)	9 (12.7%)
Grade 2	3 (12.5%)	6 (17.1%)	9 (15.3%)	12 (16.9%)
Grade 3	2 (8.3%)	3 (8.6%)	5 (8.5%)	7 (9.9%)
Grade 4	1 (4.2%)	0	1 (1.7%)	2 (2.8%)
Disorders of purine metabolism	2 (8.3%)	3 (8.6%)	5 (8.5%)	6 (8.5%)
Grade 1	0	3 (8.6%)	3 (5.1%)	3 (4.2%)
Grade 2	0	0	0	0
Grade 3	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 4	1 (4.2%)	0	1 (1.7%)	2 (2.8%)
Hyperuricaemia	1 (4.2%)	3 (8.6%)	4 (6.8%)	5 (7.0%)
Grade 1	0	3 (8.6%)	3 (5.1%)	3 (4.2%)
Grade 4	1 (4.2%)	0	1 (1.7%)	2 (2.8%)
Gout	1 (4.2%)	0	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-ol.pdf 29AUG2023: 9:41

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Disorders of purine metabolism (cont)				
Gout (cont)				
Grade 2	1 (2.5%)	1 (2.0%)	2 (2.2%)	3 (3.0%)
Grade 3	0	0	0	0
Water soluble vitamin deficiencies	5 (12.5%)	4 (8.2%)	9 (10.1%)	12 (12.1%)
Grade 1	1 (2.5%)	3 (6.1%)	4 (4.5%)	6 (6.1%)
Grade 2	4 (10.0%)	1 (2.0%)	5 (5.6%)	6 (6.1%)
Vitamin B1 deficiency	5 (12.5%)	4 (8.2%)	9 (10.1%)	11 (11.1%)
Grade 1	1 (2.5%)	3 (6.1%)	4 (4.5%)	5 (5.1%)
Grade 2	4 (10.0%)	1 (2.0%)	5 (5.6%)	6 (6.1%)
Vitamin B complex deficiency	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Disorders of purine metabolism (cont)				
Gout (cont)				
Grade 2	0	0	0	0
Grade 3	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Water soluble vitamin deficiencies	3 (12.5%)	4 (11.4%)	7 (11.9%)	9 (12.7%)
Grade 1	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Grade 2	2 (8.3%)	3 (8.6%)	5 (8.5%)	7 (9.9%)
Vitamin B1 deficiency	2 (8.3%)	4 (11.4%)	6 (10.2%)	8 (11.3%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	2 (8.3%)	3 (8.6%)	5 (8.5%)	7 (9.9%)
Vitamin B complex deficiency	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-ol.pdf 29AUG2023: 9:41

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Potassium imbalance	6 (15.0%)	3 (6.1%)	9 (10.1%)	12 (12.1%)
Grade 1	2 (5.0%)	2 (4.1%)	4 (4.5%)	4 (4.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	3 (3.0%)
Grade 3	4 (10.0%)	0	4 (4.5%)	5 (5.1%)
Hyperkalaemia	6 (15.0%)	1 (2.0%)	7 (7.9%)	9 (9.1%)
Grade 1	2 (5.0%)	1 (2.0%)	3 (3.4%)	2 (2.0%)
Grade 2	0	0	0	2 (2.0%)
Grade 3	4 (10.0%)	0	4 (4.5%)	5 (5.1%)
Hypokalaemia	0	2 (4.1%)	2 (2.2%)	3 (3.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	0	0	0	0
Appetite disorders	3 (7.5%)	5 (10.2%)	8 (9.0%)	12 (12.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-ol.pdf 29AUG2023: 9:41

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Potassium imbalance	3 (12.5%)	1 (2.9%)	4 (6.8%)	6 (8.5%)
Grade 1	2 (8.3%)	1 (2.9%)	3 (5.1%)	3 (4.2%)
Grade 2	0	0	0	2 (2.8%)
Grade 3	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Hyperkalaemia	2 (8.3%)	0	2 (3.4%)	2 (2.8%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	0	0	0	0
Grade 3	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Hypokalaemia	2 (8.3%)	1 (2.9%)	3 (5.1%)	5 (7.0%)
Grade 1	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Grade 2	0	0	0	2 (2.8%)
Grade 3	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Appetite disorders	3 (12.5%)	2 (5.7%)	5 (8.5%)	5 (7.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Appetite disorders (cont)				
(cont)				
Grade 1	3 (7.5%)	2 (4.1%)	5 (5.6%)	8 (8.1%)
Grade 2	0	3 (6.1%)	3 (3.4%)	4 (4.0%)
Decreased appetite	3 (7.5%)	5 (10.2%)	8 (9.0%)	12 (12.1%)
Grade 1	3 (7.5%)	2 (4.1%)	5 (5.6%)	8 (8.1%)
Grade 2	0	3 (6.1%)	3 (3.4%)	4 (4.0%)
Magnesium metabolism disorders	0	0	0	3 (3.0%)
Grade 1	0	0	0	3 (3.0%)
Grade 2	0	0	0	0
Hypomagnesaemia	0	0	0	3 (3.0%)
Grade 1	0	0	0	3 (3.0%)
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Appetite disorders (cont)				
(cont)				
Grade 1	2 (8.3%)	1 (2.9%)	3 (5.1%)	3 (4.2%)
Grade 2	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Decreased appetite	3 (12.5%)	2 (5.7%)	5 (8.5%)	5 (7.0%)
Grade 1	2 (8.3%)	1 (2.9%)	3 (5.1%)	3 (4.2%)
Grade 2	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Magnesium metabolism disorders	1 (4.2%)	1 (2.9%)	2 (3.4%)	4 (5.6%)
Grade 1	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Grade 2	1 (4.2%)	0	1 (1.7%)	2 (2.8%)
Hypomagnesaemia	1 (4.2%)	1 (2.9%)	2 (3.4%)	4 (5.6%)
Grade 1	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Grade 2	1 (4.2%)	0	1 (1.7%)	2 (2.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Calcium metabolism disorders	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Hypocalcaemia	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Hypercalcaemia	0	0	0	0
Grade 2	0	0	0	0
Diabetes mellitus (incl subtypes)	0	3 (6.1%)	3 (3.4%)	3 (3.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	2 (4.1%)	2 (2.2%)	2 (2.0%)
Diabetes mellitus	0	3 (6.1%)	3 (3.4%)	3 (3.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	2 (4.1%)	2 (2.2%)	2 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Calcium metabolism disorders	1 (4.2%)	1 (2.9%)	2 (3.4%)	4 (5.6%)
Grade 2	1 (4.2%)	1 (2.9%)	2 (3.4%)	4 (5.6%)
Hypocalcaemia	1 (4.2%)	0	1 (1.7%)	3 (4.2%)
Grade 2	1 (4.2%)	0	1 (1.7%)	3 (4.2%)
Hypercalcaemia	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Diabetes mellitus (incl subtypes)	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	0	0	0
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Diabetes mellitus	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	0	0	0
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Fat soluble vitamin deficiencies and disorders	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Grade 1	0	0	0	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Vitamin D deficiency	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Grade 1	0	0	0	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Vitamin K deficiency	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
Hyperglycaemic conditions NEC	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Grade 1	0	0	0	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Fat soluble vitamin deficiencies and disorders	1 (4.2%)	0	1 (1.7%)	2 (2.8%)
Grade 1	1 (4.2%)	0	1 (1.7%)	2 (2.8%)
Grade 2	0	0	0	0
Vitamin D deficiency	1 (4.2%)	0	1 (1.7%)	2 (2.8%)
Grade 1	1 (4.2%)	0	1 (1.7%)	2 (2.8%)
Grade 2	0	0	0	0
Vitamin K deficiency	0	0	0	0
Grade 1	0	0	0	0
Hyperglycaemic conditions NEC	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Hyperglycaemic conditions NEC (cont)				
Hyperglycaemia	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Grade 1	0	0	0	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	0	0	0	0
Iron excess	1 (2.5%)	0	1 (1.1%)	2 (2.0%)
Grade 1	0	0	0	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	0	0	0	0
Iron overload	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	0	0	0	0
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Hyperglycaemic conditions NEC (cont)				
Hyperglycaemia	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Iron excess	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	0	0	0
Grade 3	0	0	0	1 (1.4%)
Iron overload	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	0	0	0
Grade 3	0	0	0	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Iron excess (cont)				
Haemosiderosis	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
Total fluid volume decreased	1 (2.5%)	2 (4.1%)	3 (3.4%)	4 (4.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	1 (2.5%)	1 (2.0%)	2 (2.2%)	3 (3.0%)
Dehydration	1 (2.5%)	2 (4.1%)	3 (3.4%)	4 (4.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	1 (2.5%)	1 (2.0%)	2 (2.2%)	3 (3.0%)
Protein metabolism disorders NEC	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Iron excess (cont)				
Haemosiderosis	0	0	0	0
Grade 1	0	0	0	0
Total fluid volume decreased	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Dehydration	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Protein metabolism disorders NEC	1 (4.2%)	0	1 (1.7%)	2 (2.8%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	0	0	0	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Protein metabolism disorders NEC (cont)				
Hypoalbuminaemia	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	0	0	0
Sodium imbalance	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Hyponatraemia	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Hypernatraemia	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Hypoglycaemic conditions NEC	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Protein metabolism disorders NEC (cont)				
Hypoalbuminaemia	1 (4.2%)	0	1 (1.7%)	2 (2.8%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	0	0	0	1 (1.4%)
Sodium imbalance	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Grade 3	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Hyponatraemia	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Grade 3	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Hypernatraemia	0	0	0	0
Grade 2	0	0	0	0
Hypoglycaemic conditions NEC	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Hypoglycaemic conditions NEC (cont)				
(cont)				
Grade 3	0	0	0	1 (1.0%)
Hypoglycaemia	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	0	0	0	1 (1.0%)
Total fluid volume increased	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	0	0	0	0
Fluid overload	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Fluid retention	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Hypoglycaemic conditions NEC (cont)				
(cont)				
Grade 3	0	0	0	0
Hypoglycaemia	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Total fluid volume increased	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	0	0	0	0
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Fluid overload	0	0	0	0
Grade 1	0	0	0	0
Fluid retention	1 (4.2%)	0	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Total fluid volume increased (cont)				
Fluid retention (cont)				
Grade 2	0	0	0	0
Electrolyte imbalance NEC	0	0	0	0
Grade 1	0	0	0	0
Electrolyte imbalance	0	0	0	0
Grade 1	0	0	0	0
Elevated triglycerides	0	0	0	0
Grade 3	0	0	0	0
Hypertriglyceridaemia	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Total fluid volume increased (cont)				
Fluid retention (cont)				
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Electrolyte imbalance NEC	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Electrolyte imbalance	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Elevated triglycerides	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 3	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Hypertriglyceridaemia	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 3	0	1 (2.9%)	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
General nutritional disorders NEC	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Abnormal loss of weight	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Iron deficiencies	0	0	0	0
Grade 2	0	0	0	0
Iron deficiency	0	0	0	0
Grade 2	0	0	0	0
Lipid metabolism and deposit disorders NEC	0	0	0	0
Grade 2	0	0	0	0
Dyslipidaemia	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-ol.pdf 29AUG2023: 9:41

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
General nutritional disorders NEC	0	0	0	0
Grade 2	0	0	0	0
Abnormal loss of weight	0	0	0	0
Grade 2	0	0	0	0
Iron deficiencies	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Iron deficiency	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Lipid metabolism and deposit disorders NEC	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Dyslipidaemia	1 (4.2%)	0	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Lipid metabolism and deposit disorders NEC (cont)				
Dyslipidaemia (cont)				
Grade 2	0	0	0	0
Phosphorus metabolism disorders	0	0	0	0
Grade 3	0	0	0	0
Hypophosphataemia	0	0	0	0
Grade 3	0	0	0	0
Skin and subcutaneous tissue disorders	16 (40.0%)	13 (26.5%)	29 (32.6%)	40 (40.4%)
Grade 1	12 (30.0%)	10 (20.4%)	22 (24.7%)	30 (30.3%)
Grade 2	3 (7.5%)	2 (4.1%)	5 (5.6%)	8 (8.1%)
Grade 3	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Lipid metabolism and deposit disorders NEC (cont)				
Dyslipidaemia (cont)				
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Phosphorus metabolism disorders	0	0	0	1 (1.4%)
Grade 3	0	0	0	1 (1.4%)
Hypophosphataemia	0	0	0	1 (1.4%)
Grade 3	0	0	0	1 (1.4%)
Skin and subcutaneous tissue disorders	8 (33.3%)	12 (34.3%)	20 (33.9%)	22 (31.0%)
Grade 1	5 (20.8%)	8 (22.9%)	13 (22.0%)	15 (21.1%)
Grade 2	3 (12.5%)	4 (11.4%)	7 (11.9%)	7 (9.9%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Rashes, eruptions and exanthems NEC	5 (12.5%)	6 (12.2%)	11 (12.4%)	15 (15.2%)
Grade 1	5 (12.5%)	6 (12.2%)	11 (12.4%)	14 (14.1%)
Grade 2	0	0	0	1 (1.0%)
Rash	4 (10.0%)	4 (8.2%)	8 (9.0%)	11 (11.1%)
Grade 1	4 (10.0%)	4 (8.2%)	8 (9.0%)	10 (10.1%)
Grade 2	0	0	0	1 (1.0%)
Rash maculo-papular	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Rash generalised	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Rash macular	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Rashes, eruptions and exanthems NEC	3 (12.5%)	3 (8.6%)	6 (10.2%)	8 (11.3%)
Grade 1	2 (8.3%)	3 (8.6%)	5 (8.5%)	7 (9.9%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Rash	3 (12.5%)	1 (2.9%)	4 (6.8%)	5 (7.0%)
Grade 1	2 (8.3%)	1 (2.9%)	3 (5.1%)	4 (5.6%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Rash maculo-papular	0	0	0	2 (2.8%)
Grade 1	0	0	0	2 (2.8%)
Rash generalised	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Rash macular	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Rashes, eruptions and exanthems NEC (cont)				
Rash papular	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Apocrine and eccrine gland disorders	5 (12.5%)	5 (10.2%)	10 (11.2%)	14 (14.1%)
Grade 1	5 (12.5%)	4 (8.2%)	9 (10.1%)	13 (13.1%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Night sweats	5 (12.5%)	2 (4.1%)	7 (7.9%)	11 (11.1%)
Grade 1	5 (12.5%)	1 (2.0%)	6 (6.7%)	10 (10.1%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Hyperhidrosis	0	2 (4.1%)	2 (2.2%)	2 (2.0%)
Grade 1	0	2 (4.1%)	2 (2.2%)	2 (2.0%)
Cold sweat	0	1 (2.0%)	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-ol.pdf 29AUG2023: 9:41

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Rashes, eruptions and exanthems NEC (cont)				
Rash papular	0	0	0	0
Grade 1	0	0	0	0
Apocrine and eccrine gland disorders	2 (8.3%)	3 (8.6%)	5 (8.5%)	5 (7.0%)
Grade 1	2 (8.3%)	2 (5.7%)	4 (6.8%)	4 (5.6%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Night sweats	2 (8.3%)	2 (5.7%)	4 (6.8%)	4 (5.6%)
Grade 1	2 (8.3%)	1 (2.9%)	3 (5.1%)	3 (4.2%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Hyperhidrosis	0	2 (5.7%)	2 (3.4%)	2 (2.8%)
Grade 1	0	2 (5.7%)	2 (3.4%)	2 (2.8%)
Cold sweat	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Apocrine and eccrine gland disorders (cont)				
Cold sweat (cont)				
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Pruritus NEC	2 (5.0%)	3 (6.1%)	5 (5.6%)	6 (6.1%)
Grade 1	0	3 (6.1%)	3 (3.4%)	4 (4.0%)
Grade 2	2 (5.0%)	0	2 (2.2%)	2 (2.0%)
Pruritus	2 (5.0%)	3 (6.1%)	5 (5.6%)	6 (6.1%)
Grade 1	0	3 (6.1%)	3 (3.4%)	4 (4.0%)
Grade 2	2 (5.0%)	0	2 (2.2%)	2 (2.0%)
Pruritus generalised	0	0	0	0
Grade 1	0	0	0	0
Purpura and related conditions	1 (2.5%)	0	1 (1.1%)	3 (3.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Apocrine and eccrine gland disorders (cont)				
Cold sweat (cont)				
Grade 1	0	0	0	0
Pruritus NEC	0	5 (14.3%)	5 (8.5%)	6 (8.5%)
Grade 1	0	4 (11.4%)	4 (6.8%)	5 (7.0%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Pruritus	0	5 (14.3%)	5 (8.5%)	5 (7.0%)
Grade 1	0	4 (11.4%)	4 (6.8%)	4 (5.6%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Pruritus generalised	0	0	0	1 (1.4%)
Grade 1	0	0	0	1 (1.4%)
Purpura and related conditions	2 (8.3%)	1 (2.9%)	3 (5.1%)	4 (5.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Purpura and related conditions (cont)				
(cont)				
Grade 1	0	0	0	2 (2.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Ecchymosis	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	0	0	0	0
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Petechiae	0	0	0	2 (2.0%)
Grade 1	0	0	0	2 (2.0%)
Purpura	0	0	0	0
Grade 1	0	0	0	0
Dermal and epidermal conditions NEC	2 (5.0%)	0	2 (2.2%)	3 (3.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Purpura and related conditions (cont)				
(cont)				
Grade 1	2 (8.3%)	1 (2.9%)	3 (5.1%)	4 (5.6%)
Grade 2	0	0	0	0
Ecchymosis	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Grade 1	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Grade 2	0	0	0	0
Petechiae	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Purpura	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Dermal and epidermal conditions NEC	1 (4.2%)	0	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Dermal and epidermal conditions NEC (cont)				
(cont)				
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	2 (2.0%)
Dermatosis	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Papule	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Skin disorder	0	0	0	0
Grade 1	0	0	0	0
Skin fragility	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Dermal and epidermal conditions NEC (cont)				
(cont)				
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	0	0	0	0
Dermatosis	0	0	0	0
Grade 2	0	0	0	0
Papule	0	0	0	0
Grade 1	0	0	0	0
Skin disorder	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Skin fragility	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Dermal and epidermal conditions NEC (cont)				
Skin lesion	0	0	0	1 (1.0%)
Grade 2	0	0	0	1 (1.0%)
Dermatitis and eczema	2 (5.0%)	0	2 (2.2%)	4 (4.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	3 (3.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Dermatitis contact	0	0	0	2 (2.0%)
Grade 1	0	0	0	2 (2.0%)
Dermatitis	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Dermatitis allergic	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Dermal and epidermal conditions NEC (cont)				
Skin lesion	0	0	0	0
Grade 2	0	0	0	0
Dermatitis and eczema	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Dermatitis contact	0	0	0	0
Grade 1	0	0	0	0
Dermatitis	0	0	0	0
Grade 1	0	0	0	0
Dermatitis allergic	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Erythemas	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Erythema	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Alopecias	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
Alopecia	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
Bullous conditions	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Erythemas	1 (4.2%)	1 (2.9%)	2 (3.4%)	3 (4.2%)
Grade 1	0	0	0	1 (1.4%)
Grade 2	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Erythema	1 (4.2%)	1 (2.9%)	2 (3.4%)	3 (4.2%)
Grade 1	0	0	0	1 (1.4%)
Grade 2	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Alopecias	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Alopecia	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Bullous conditions	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Bullous conditions (cont)				
(cont)				
Grade 2	0	0	0	0
Blister	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
Grade 2	0	0	0	0
Blood blister	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
Dermatitis ascribed to specific agent	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Grade 3	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Drug eruption	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Bullous conditions (cont)				
(cont)				
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Blister	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	0	0	0
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Blood blister	0	0	0	0
Grade 1	0	0	0	0
Dermatitis ascribed to specific agent	0	0	0	0
Grade 3	0	0	0	0
Drug eruption	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Dermatitis ascribed to specific agent (cont)				
Toxic skin eruption	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Hyperkeratoses	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	0	0	1 (1.0%)
Hyperkeratosis	0	0	0	1 (1.0%)
Grade 2	0	0	0	1 (1.0%)
Lichenoid keratosis	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Dermatitis ascribed to specific agent (cont)				
Toxic skin eruption	0	0	0	0
Grade 3	0	0	0	0
Hyperkeratoses	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Hyperkeratosis	0	0	0	0
Grade 2	0	0	0	0
Lichenoid keratosis	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-ol.pdf 29AUG2023: 9:41

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Nail and nail bed conditions (excl infections and infestations)	0	0	0	1 (1.0%)
Grade 1	0	0	0	0
Grade 2	0	0	0	1 (1.0%)
Ingrowing nail	0	0	0	1 (1.0%)
Grade 2	0	0	0	1 (1.0%)
Nail discolouration	0	0	0	0
Grade 1	0	0	0	0
Skin preneoplastic conditions NEC	2 (5.0%)	0	2 (2.2%)	2 (2.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Actinic keratosis	2 (5.0%)	0	2 (2.2%)	2 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Nail and nail bed conditions (excl infections and infestations)	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	0	0	0
Ingrowing nail	0	0	0	0
Grade 2	0	0	0	0
Nail discolouration	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Skin preneoplastic conditions NEC	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Actinic keratosis	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Skin preneoplastic conditions NEC (cont)				
Actinic keratosis (cont)				
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Exfoliative conditions	0	0	0	0
Grade 1	0	0	0	0
Skin exfoliation	0	0	0	0
Grade 1	0	0	0	0
Skin cysts and polyps	0	0	0	0
Grade 1	0	0	0	0
Dermal cyst	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Skin preneoplastic conditions NEC (cont)				
Actinic keratosis (cont)				
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Exfoliative conditions	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Skin exfoliation	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Skin cysts and polyps	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Dermal cyst	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Skin haemorrhages	0	0	0	0
Grade 2	0	0	0	0
Skin haemorrhage	0	0	0	0
Grade 2	0	0	0	0
Skin vasculitides	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Hypersensitivity vasculitis	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Telangiectasia and related conditions	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
Telangiectasia	0	0	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Skin haemorrhages	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Skin haemorrhage	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Skin vasculitides	0	0	0	0
Grade 2	0	0	0	0
Hypersensitivity vasculitis	0	0	0	0
Grade 2	0	0	0	0
Telangiectasia and related conditions	0	0	0	0
Grade 1	0	0	0	0
Telangiectasia	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Telangiectasia and related conditions (cont)				
Telangiectasia (cont)				
Grade 1	0	0	0	1 (1.0%)
Musculoskeletal and connective tissue disorders	12 (30.0%)	17 (34.7%)	29 (32.6%)	39 (39.4%)
Grade 1	3 (7.5%)	6 (12.2%)	9 (10.1%)	14 (14.1%)
Grade 2	9 (22.5%)	8 (16.3%)	17 (19.1%)	21 (21.2%)
Grade 3	0	3 (6.1%)	3 (3.4%)	4 (4.0%)
Musculoskeletal and connective tissue pain and discomfort	9 (22.5%)	11 (22.4%)	20 (22.5%)	29 (29.3%)
Grade 1	2 (5.0%)	4 (8.2%)	6 (6.7%)	12 (12.1%)
Grade 2	7 (17.5%)	7 (14.3%)	14 (15.7%)	16 (16.2%)
Grade 3	0	0	0	1 (1.0%)
Pain in extremity	6 (15.0%)	4 (8.2%)	10 (11.2%)	16 (16.2%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Telangiectasia and related conditions (cont)				
Telangiectasia (cont)				
Grade 1	0	0	0	0
Musculoskeletal and connective tissue disorders	4 (16.7%)	13 (37.1%)	17 (28.8%)	22 (31.0%)
Grade 1	1 (4.2%)	5 (14.3%)	6 (10.2%)	10 (14.1%)
Grade 2	3 (12.5%)	8 (22.9%)	11 (18.6%)	12 (16.9%)
Grade 3	0	0	0	0
Musculoskeletal and connective tissue pain and discomfort	3 (12.5%)	8 (22.9%)	11 (18.6%)	13 (18.3%)
Grade 1	2 (8.3%)	4 (11.4%)	6 (10.2%)	8 (11.3%)
Grade 2	1 (4.2%)	4 (11.4%)	5 (8.5%)	5 (7.0%)
Grade 3	0	0	0	0
Pain in extremity	1 (4.2%)	2 (5.7%)	3 (5.1%)	5 (7.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Musculoskeletal and connective tissue pain and discomfort (cont)				
Pain in extremity (cont)				
Grade 1	1 (2.5%)	2 (4.1%)	3 (3.4%)	7 (7.1%)
Grade 2	5 (12.5%)	2 (4.1%)	7 (7.9%)	9 (9.1%)
Back pain	2 (5.0%)	6 (12.2%)	8 (9.0%)	12 (12.1%)
Grade 1	1 (2.5%)	2 (4.1%)	3 (3.4%)	6 (6.1%)
Grade 2	1 (2.5%)	4 (8.2%)	5 (5.6%)	5 (5.1%)
Grade 3	0	0	0	1 (1.0%)
Musculoskeletal pain	1 (2.5%)	1 (2.0%)	2 (2.2%)	4 (4.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	3 (3.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Musculoskeletal and connective tissue pain and discomfort (cont)				
Pain in extremity (cont)				
Grade 1	0	2 (5.7%)	2 (3.4%)	4 (5.6%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Back pain	2 (8.3%)	5 (14.3%)	7 (11.9%)	8 (11.3%)
Grade 1	2 (8.3%)	2 (5.7%)	4 (6.8%)	5 (7.0%)
Grade 2	0	3 (8.6%)	3 (5.1%)	3 (4.2%)
Grade 3	0	0	0	0
Musculoskeletal pain	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	0	0	0
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-ol.pdf 29AUG2023: 9:41

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Musculoskeletal and connective tissue pain and discomfort (cont)				
Flank pain	0	0	0	0
Grade 1	0	0	0	0
Musculoskeletal chest pain	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
Neck pain	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Bone related signs and symptoms	4 (10.0%)	3 (6.1%)	7 (7.9%)	8 (8.1%)
Grade 1	2 (5.0%)	2 (4.1%)	4 (4.5%)	4 (4.0%)
Grade 2	2 (5.0%)	1 (2.0%)	3 (3.4%)	4 (4.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Musculoskeletal and connective tissue pain and discomfort (cont)				
Flank pain	0	0	0	1 (1.4%)
Grade 1	0	0	0	1 (1.4%)
Musculoskeletal chest pain	0	0	0	0
Grade 1	0	0	0	0
Neck pain	0	0	0	0
Grade 2	0	0	0	0
Bone related signs and symptoms	0	1 (2.9%)	1 (1.7%)	4 (5.6%)
Grade 1	0	0	0	3 (4.2%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Bone related signs and symptoms (cont)				
Bone pain	3 (7.5%)	2 (4.1%)	5 (5.6%)	5 (5.1%)
Grade 1	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Grade 2	2 (5.0%)	1 (2.0%)	3 (3.4%)	3 (3.0%)
Pain in jaw	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Spinal pain	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	0	0	1 (1.0%)
Joint related signs and symptoms	4 (10.0%)	1 (2.0%)	5 (5.6%)	7 (7.1%)
Grade 1	1 (2.5%)	0	1 (1.1%)	2 (2.0%)
Grade 2	3 (7.5%)	1 (2.0%)	4 (4.5%)	5 (5.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Bone related signs and symptoms (cont)				
Bone pain	0	1 (2.9%)	1 (1.7%)	3 (4.2%)
Grade 1	0	0	0	2 (2.8%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Pain in jaw	0	0	0	1 (1.4%)
Grade 1	0	0	0	1 (1.4%)
Spinal pain	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Joint related signs and symptoms	0	3 (8.6%)	3 (5.1%)	3 (4.2%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	2 (5.7%)	2 (3.4%)	2 (2.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Joint related signs and symptoms (cont)				
Arthralgia	4 (10.0%)	1 (2.0%)	5 (5.6%)	7 (7.1%)
Grade 1	1 (2.5%)	0	1 (1.1%)	2 (2.0%)
Grade 2	3 (7.5%)	1 (2.0%)	4 (4.5%)	5 (5.1%)
Joint effusion	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Joint swelling	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Muscle related signs and symptoms NEC	0	3 (6.1%)	3 (3.4%)	5 (5.1%)
Grade 1	0	1 (2.0%)	1 (1.1%)	3 (3.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Joint related signs and symptoms (cont)				
Arthralgia	0	3 (8.6%)	3 (5.1%)	3 (4.2%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	2 (5.7%)	2 (3.4%)	2 (2.8%)
Joint effusion	0	0	0	0
Grade 2	0	0	0	0
Joint swelling	0	0	0	0
Grade 2	0	0	0	0
Muscle related signs and symptoms NEC	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Muscle related signs and symptoms NEC (cont)				
Muscle spasms	0	2 (4.1%)	2 (2.2%)	4 (4.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	3 (3.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Muscle haemorrhage	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Arthropathies NEC	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	0	0	0	0
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Arthritis	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Muscle related signs and symptoms NEC (cont)				
Muscle spasms	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Muscle haemorrhage	0	0	0	0
Grade 3	0	0	0	0
Arthropathies NEC	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	0	0	0	0
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 3	0	0	0	0
Arthritis	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Arthropathies NEC (cont)				
Arthritis (cont)				
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Arthritis reactive	0	0	0	0
Grade 2	0	0	0	0
Muscle pains	1 (2.5%)	1 (2.0%)	2 (2.2%)	3 (3.0%)
Grade 1	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Grade 2	0	0	0	1 (1.0%)
Myalgia	1 (2.5%)	1 (2.0%)	2 (2.2%)	3 (3.0%)
Grade 1	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Grade 2	0	0	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Arthropathies NEC (cont)				
Arthritis (cont)				
Grade 3	0	0	0	0
Arthritis reactive	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Muscle pains	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Myalgia	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Muscle weakness conditions	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Muscular weakness	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Bone disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Bone lesion	0	0	0	0
Grade 1	0	0	0	0
Osteosclerosis	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Muscle weakness conditions	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Grade 2	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Muscular weakness	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Grade 2	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Bone disorders NEC	0	2 (5.7%)	2 (3.4%)	2 (2.8%)
Grade 1	0	2 (5.7%)	2 (3.4%)	2 (2.8%)
Bone lesion	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Osteosclerosis	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Musculoskeletal and connective tissue conditions NEC	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Mobility decreased	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Musculoskeletal stiffness	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Osteoarthropathies	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Musculoskeletal and connective tissue conditions NEC	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Mobility decreased	0	0	0	0
Grade 2	0	0	0	0
Musculoskeletal stiffness	0	0	0	0
Grade 1	0	0	0	0
Osteoarthropathies	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Osteoarthropathies (cont)				
Osteoarthritis	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Soft tissue disorders NEC	0	0	0	2 (2.0%)
Grade 1	0	0	0	2 (2.0%)
Groin pain	0	0	0	2 (2.0%)
Grade 1	0	0	0	2 (2.0%)
Bursal disorders	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
Bursal fluid accumulation	0	0	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Osteoarthropathies (cont)				
Osteoarthritis	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Soft tissue disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Groin pain	0	0	0	0
Grade 1	0	0	0	0
Bursal disorders	0	0	0	0
Grade 1	0	0	0	0
Bursal fluid accumulation	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Bursal disorders (cont)				
Bursal fluid accumulation (cont)				
Grade 1	0	0	0	1 (1.0%)
Cartilage disorders	0	0	0	0
Grade 2	0	0	0	0
Costochondritis	0	0	0	0
Grade 2	0	0	0	0
Crystal arthropathic disorders	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Chondrocalcinosis pyrophosphate	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Bursal disorders (cont)				
Bursal fluid accumulation (cont)				
Grade 1	0	0	0	0
Cartilage disorders	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Costochondritis	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Crystal arthropathic disorders	0	0	0	0
Grade 2	0	0	0	0
Chondrocalcinosis pyrophosphate	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Crystal arthropathic disorders (cont)				
Gouty arthritis	0	0	0	1 (1.0%)
Grade 2	0	0	0	1 (1.0%)
Intervertebral disc disorders NEC	0	0	0	0
Grade 2	0	0	0	0
Intervertebral disc protrusion	0	0	0	0
Grade 2	0	0	0	0
Joint related disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Rotator cuff syndrome	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-ol.pdf 29AUG2023: 9:41

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Crystal arthropathic disorders (cont)				
Gouty arthritis	0	0	0	0
Grade 2	0	0	0	0
Intervertebral disc disorders NEC	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Intervertebral disc protrusion	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Joint related disorders NEC	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Rotator cuff syndrome	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Metabolic bone disorders	0	0	0	0
Grade 2	0	0	0	0
Osteoporosis	0	0	0	0
Grade 2	0	0	0	0
Musculoskeletal and connective tissue infections and inflammations NEC	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Fasciitis	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Tendon disorders	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Metabolic bone disorders	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Osteoporosis	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Musculoskeletal and connective tissue infections and inflammations NEC	0	0	0	0
Grade 1	0	0	0	0
Fasciitis	0	0	0	0
Grade 1	0	0	0	0
Tendon disorders	0	0	0	1 (1.4%)
Grade 2	0	0	0	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Tendon disorders (cont)				
Tendonitis	0	0	0	0
Grade 2	0	0	0	0
Investigations	12 (30.0%)	11 (22.4%)	23 (25.8%)	32 (32.3%)
Grade 1	4 (10.0%)	4 (8.2%)	8 (9.0%)	12 (12.1%)
Grade 2	5 (12.5%)	7 (14.3%)	12 (13.5%)	14 (14.1%)
Grade 3	3 (7.5%)	0	3 (3.4%)	5 (5.1%)
Grade 4	0	0	0	1 (1.0%)
Liver function analyses	4 (10.0%)	5 (10.2%)	9 (10.1%)	15 (15.2%)
Grade 1	1 (2.5%)	1 (2.0%)	2 (2.2%)	6 (6.1%)
Grade 2	1 (2.5%)	4 (8.2%)	5 (5.6%)	5 (5.1%)
Grade 3	2 (5.0%)	0	2 (2.2%)	4 (4.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Tendon disorders (cont)				
Tendonitis	0	0	0	1 (1.4%)
Grade 2	0	0	0	1 (1.4%)
Investigations	5 (20.8%)	7 (20.0%)	12 (20.3%)	17 (23.9%)
Grade 1	0	4 (11.4%)	4 (6.8%)	5 (7.0%)
Grade 2	3 (12.5%)	3 (8.6%)	6 (10.2%)	8 (11.3%)
Grade 3	1 (4.2%)	0	1 (1.7%)	3 (4.2%)
Grade 4	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Liver function analyses	1 (4.2%)	3 (8.6%)	4 (6.8%)	8 (11.3%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	1 (4.2%)	2 (5.7%)	3 (5.1%)	5 (7.0%)
Grade 3	0	0	0	2 (2.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Liver function analyses (cont)				
Alanine aminotransferase increased	2 (5.0%)	3 (6.1%)	5 (5.6%)	8 (8.1%)
Grade 1	2 (5.0%)	2 (4.1%)	4 (4.5%)	6 (6.1%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	0	0	0	1 (1.0%)
Gamma-glutamyltransferase increased	1 (2.5%)	3 (6.1%)	4 (4.5%)	7 (7.1%)
Grade 1	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Grade 2	1 (2.5%)	2 (4.1%)	3 (3.4%)	4 (4.0%)
Grade 3	0	0	0	1 (1.0%)
Aspartate aminotransferase increased	1 (2.5%)	2 (4.1%)	3 (3.4%)	5 (5.1%)
Grade 1	1 (2.5%)	2 (4.1%)	3 (3.4%)	5 (5.1%)
Grade 3	0	0	0	0
Blood bilirubin increased	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Liver function analyses (cont)				
Alanine aminotransferase increased	1 (4.2%)	1 (2.9%)	2 (3.4%)	5 (7.0%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	1 (4.2%)	0	1 (1.7%)	2 (2.8%)
Grade 3	0	0	0	2 (2.8%)
Gamma-glutamyltransferase increased	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Grade 1	0	0	0	1 (1.4%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 3	0	0	0	0
Aspartate aminotransferase increased	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 3	0	0	0	1 (1.4%)
Blood bilirubin increased	0	1 (2.9%)	1 (1.7%)	2 (2.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-ol.pdf 29AUG2023: 9:41

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Liver function analyses (cont)				
Blood bilirubin increased (cont)				
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Transaminases increased	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Liver function test abnormal	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Renal function analyses	7 (17.5%)	2 (4.1%)	9 (10.1%)	10 (10.1%)
Grade 1	3 (7.5%)	0	3 (3.4%)	3 (3.0%)
Grade 2	4 (10.0%)	2 (4.1%)	6 (6.7%)	7 (7.1%)
Blood creatinine increased	5 (12.5%)	2 (4.1%)	7 (7.9%)	7 (7.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Liver function analyses (cont)				
Blood bilirubin increased (cont)				
Grade 2	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Grade 3	0	0	0	0
Transaminases increased	0	0	0	0
Grade 1	0	0	0	0
Liver function test abnormal	0	0	0	0
Grade 3	0	0	0	0
Renal function analyses	1 (4.2%)	4 (11.4%)	5 (8.5%)	6 (8.5%)
Grade 1	1 (4.2%)	3 (8.6%)	4 (6.8%)	5 (7.0%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Blood creatinine increased	1 (4.2%)	3 (8.6%)	4 (6.8%)	5 (7.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Renal function analyses (cont)				
Blood creatinine increased (cont)				
Grade 1	3 (7.5%)	0	3 (3.4%)	3 (3.0%)
Grade 2	2 (5.0%)	2 (4.1%)	4 (4.5%)	4 (4.0%)
Creatinine renal clearance decreased	2 (5.0%)	0	2 (2.2%)	3 (3.0%)
Grade 1	0	0	0	0
Grade 2	2 (5.0%)	0	2 (2.2%)	3 (3.0%)
Physical examination procedures and organ system status	2 (5.0%)	2 (4.1%)	4 (4.5%)	8 (8.1%)
Grade 1	1 (2.5%)	2 (4.1%)	3 (3.4%)	7 (7.1%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	0	0	0	0
Weight decreased	2 (5.0%)	1 (2.0%)	3 (3.4%)	5 (5.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Renal function analyses (cont)				
Blood creatinine increased (cont)				
Grade 1	1 (4.2%)	2 (5.7%)	3 (5.1%)	4 (5.6%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Creatinine renal clearance decreased	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	0	0	0
Physical examination procedures and organ system status	2 (8.3%)	0	2 (3.4%)	3 (4.2%)
Grade 1	0	0	0	1 (1.4%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 3	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Weight decreased	1 (4.2%)	0	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-ol.pdf 29AUG2023: 9:41

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Physical examination procedures and organ system status (cont)				
Weight decreased (cont)				
Grade 1	1 (2.5%)	1 (2.0%)	2 (2.2%)	4 (4.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	0	0	0	0
Weight increased	0	1 (2.0%)	1 (1.1%)	3 (3.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	3 (3.0%)
Grade 2	0	0	0	0
Lymph node palpable	0	0	0	0
Grade 1	0	0	0	0
Coagulation and bleeding analyses	0	2 (4.1%)	2 (2.2%)	2 (2.0%)
Grade 1	0	2 (4.1%)	2 (2.2%)	2 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Physical examination procedures and organ system status (cont)				
Weight decreased (cont)				
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Weight increased	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	0	0	0	0
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Lymph node palpable	0	0	0	1 (1.4%)
Grade 1	0	0	0	1 (1.4%)
Coagulation and bleeding analyses	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Coagulation and bleeding analyses (cont)				
Activated partial thromboplastin time prolonged	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
International normalised ratio increased	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Prothrombin time prolonged	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
ECG investigations	0	0	0	2 (2.0%)
Grade 1	0	0	0	1 (1.0%)
Grade 4	0	0	0	1 (1.0%)
Electrocardiogram QT prolonged	0	0	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Coagulation and bleeding analyses (cont)				
Activated partial thromboplastin time prolonged	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
International normalised ratio increased	0	0	0	0
Grade 1	0	0	0	0
Prothrombin time prolonged	0	0	0	0
Grade 1	0	0	0	0
ECG investigations	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	0	0	0	0
Grade 4	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Electrocardiogram QT prolonged	1 (4.2%)	0	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
ECG investigations (cont)				
Electrocardiogram QT prolonged (cont)				
Grade 4	0	0	0	1 (1.0%)
Electrocardiogram ST segment depression	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
Mineral and electrolyte analyses	1 (2.5%)	1 (2.0%)	2 (2.2%)	3 (3.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Blood bicarbonate decreased	0	0	0	1 (1.0%)
Grade 2	0	0	0	1 (1.0%)
Blood chloride increased	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
ECG investigations (cont)				
Electrocardiogram QT prolonged (cont)				
Grade 4	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Electrocardiogram ST segment depression	0	0	0	0
Grade 1	0	0	0	0
Mineral and electrolyte analyses	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Blood bicarbonate decreased	0	0	0	0
Grade 2	0	0	0	0
Blood chloride increased	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Mineral and electrolyte analyses (cont)				
Serum ferritin increased	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Tissue enzyme analyses NEC	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	0	0	0
Blood alkaline phosphatase increased	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Blood lactate dehydrogenase increased	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Protein analyses NEC	1 (2.5%)	0	1 (1.1%)	2 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Mineral and electrolyte analyses (cont)				
Serum ferritin increased	0	0	0	0
Grade 2	0	0	0	0
Tissue enzyme analyses NEC	0	0	0	2 (2.8%)
Grade 1	0	0	0	1 (1.4%)
Grade 2	0	0	0	1 (1.4%)
Blood alkaline phosphatase increased	0	0	0	2 (2.8%)
Grade 1	0	0	0	1 (1.4%)
Grade 2	0	0	0	1 (1.4%)
Blood lactate dehydrogenase increased	0	0	0	0
Grade 1	0	0	0	0
Protein analyses NEC	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Protein analyses NEC (cont)				
(cont)				
Grade 1	1 (2.5%)	0	1 (1.1%)	2 (2.0%)
Protein total increased	1 (2.5%)	0	1 (1.1%)	2 (2.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	2 (2.0%)
Vitamin analyses	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Blood folate decreased	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Vitamin B1 decreased	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Protein analyses NEC (cont)				
(cont)				
Grade 1	0	0	0	0
Protein total increased	0	0	0	0
Grade 1	0	0	0	0
Vitamin analyses	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Blood folate decreased	0	0	0	0
Grade 2	0	0	0	0
Vitamin B1 decreased	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Autoimmunity analyses	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Antiphospholipid antibodies positive	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Blood gas and acid base analyses	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
Blood lactic acid increased	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
Haematological analyses NEC	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Blast cell count increased	1 (2.5%)	0	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-ol.pdf 29AUG2023: 9:41

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Autoimmunity analyses	0	0	0	0
Grade 2	0	0	0	0
Antiphospholipid antibodies positive	0	0	0	0
Grade 2	0	0	0	0
Blood gas and acid base analyses	0	0	0	0
Grade 1	0	0	0	0
Blood lactic acid increased	0	0	0	0
Grade 1	0	0	0	0
Haematological analyses NEC	0	0	0	0
Grade 1	0	0	0	0
Blast cell count increased	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Haematological analyses NEC (cont)				
Blast cell count increased (cont)				
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Reproductive organ and breast imaging procedures	0	0	0	0
Grade 1	0	0	0	0
Computerised tomogram pelvis abnormal	0	0	0	0
Grade 1	0	0	0	0
Respiratory tract and thoracic imaging procedures	0	0	0	0
Grade 1	0	0	0	0
Chest X-ray abnormal	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Haematological analyses NEC (cont)				
Blast cell count increased (cont)				
Grade 1	0	0	0	0
Reproductive organ and breast imaging procedures	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Computerised tomogram pelvis abnormal	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Respiratory tract and thoracic imaging procedures	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Chest X-ray abnormal	0	1 (2.9%)	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Respiratory tract and thoracic imaging procedures (cont)				
Chest X-ray abnormal (cont)				
Grade 1	0	0	0	0
Skeletal and cardiac muscle analyses	0	0	0	0
Grade 1	0	0	0	0
Blood creatine phosphokinase increased	0	0	0	0
Grade 1	0	0	0	0
Vascular tests NEC (incl blood pressure)	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Blood pressure increased	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Respiratory tract and thoracic imaging procedures (cont)				
Chest X-ray abnormal (cont)				
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Skeletal and cardiac muscle analyses	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Blood creatine phosphokinase increased	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Vascular tests NEC (incl blood pressure)	0	0	0	0
Grade 3	0	0	0	0
Blood pressure increased	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders	10 (25.0%)	8 (16.3%)	18 (20.2%)	25 (25.3%)
Grade 1	5 (12.5%)	1 (2.0%)	6 (6.7%)	11 (11.1%)
Grade 2	3 (7.5%)	4 (8.2%)	7 (7.9%)	7 (7.1%)
Grade 3	1 (2.5%)	2 (4.1%)	3 (3.4%)	5 (5.1%)
Grade 4	0	0	0	0
Grade 5	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Renal failure and impairment	7 (17.5%)	4 (8.2%)	11 (12.4%)	14 (14.1%)
Grade 1	3 (7.5%)	0	3 (3.4%)	5 (5.1%)
Grade 2	3 (7.5%)	2 (4.1%)	5 (5.6%)	5 (5.1%)
Grade 3	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Grade 4	0	0	0	0
Grade 5	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Acute kidney injury	2 (5.0%)	1 (2.0%)	3 (3.4%)	5 (5.1%)
Grade 1	2 (5.0%)	0	2 (2.2%)	4 (4.0%)
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders	7 (29.2%)	8 (22.9%)	15 (25.4%)	19 (26.8%)
Grade 1	2 (8.3%)	2 (5.7%)	4 (6.8%)	5 (7.0%)
Grade 2	2 (8.3%)	2 (5.7%)	4 (6.8%)	5 (7.0%)
Grade 3	2 (8.3%)	4 (11.4%)	6 (10.2%)	6 (8.5%)
Grade 4	1 (4.2%)	0	1 (1.7%)	2 (2.8%)
Grade 5	0	0	0	1 (1.4%)
Renal failure and impairment	3 (12.5%)	4 (11.4%)	7 (11.9%)	9 (12.7%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	0	2 (5.7%)	2 (3.4%)	2 (2.8%)
Grade 3	2 (8.3%)	2 (5.7%)	4 (6.8%)	4 (5.6%)
Grade 4	0	0	0	1 (1.4%)
Grade 5	0	0	0	1 (1.4%)
Acute kidney injury	1 (4.2%)	2 (5.7%)	3 (5.1%)	3 (4.2%)
Grade 1	0	0	0	0
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal failure and impairment (cont)				
Acute kidney injury (cont)				
Grade 3	0	0	0	0
Grade 5	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Chronic kidney disease	2 (5.0%)	1 (2.0%)	3 (3.4%)	3 (3.0%)
Grade 2	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Grade 5	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Renal failure	1 (2.5%)	2 (4.1%)	3 (3.4%)	3 (3.0%)
Grade 2	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 5	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal failure and impairment (cont)				
Acute kidney injury (cont)				
Grade 3	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Grade 5	0	0	0	0
Chronic kidney disease	1 (4.2%)	1 (2.9%)	2 (3.4%)	3 (4.2%)
Grade 2	0	0	0	0
Grade 3	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Grade 4	0	0	0	1 (1.4%)
Grade 5	0	0	0	0
Renal failure	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 3	0	0	0	0
Grade 5	0	0	0	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal failure and impairment (cont)				
Renal impairment	2 (5.0%)	0	2 (2.2%)	4 (4.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	2 (2.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	0	0	0	1 (1.0%)
Bladder and urethral symptoms	0	1 (2.0%)	1 (1.1%)	4 (4.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Grade 2	0	0	0	1 (1.0%)
Grade 3	0	0	0	1 (1.0%)
Dysuria	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
Grade 2	0	0	0	0
Pollakiuria	0	0	0	2 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal failure and impairment (cont)				
Renal impairment	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Bladder and urethral symptoms	1 (4.2%)	1 (2.9%)	2 (3.4%)	4 (5.6%)
Grade 1	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Grade 2	1 (4.2%)	0	1 (1.7%)	2 (2.8%)
Grade 3	0	0	0	0
Dysuria	1 (4.2%)	1 (2.9%)	2 (3.4%)	3 (4.2%)
Grade 1	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Pollakiuria	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Bladder and urethral symptoms (cont)				
Pollakiuria (cont)				
Grade 1	0	0	0	1 (1.0%)
Grade 3	0	0	0	1 (1.0%)
Micturition disorder	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Urinary incontinence	0	0	0	0
Grade 2	0	0	0	0
Urinary retention	0	0	0	1 (1.0%)
Grade 2	0	0	0	1 (1.0%)
Urinary abnormalities	1 (2.5%)	2 (4.1%)	3 (3.4%)	4 (4.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	2 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Bladder and urethral symptoms (cont)				
Pollakiuria (cont)				
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Micturition disorder	0	0	0	0
Grade 1	0	0	0	0
Urinary incontinence	0	0	0	1 (1.4%)
Grade 2	0	0	0	1 (1.4%)
Urinary retention	0	0	0	0
Grade 2	0	0	0	0
Urinary abnormalities	2 (8.3%)	0	2 (3.4%)	2 (2.8%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Urinary abnormalities (cont)				
(cont)				
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Haematuria	1 (2.5%)	2 (4.1%)	3 (3.4%)	4 (4.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	2 (2.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Chromaturia	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
Proteinuria	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Urinary abnormalities (cont)				
(cont)				
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 3	0	0	0	0
Haematuria	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Chromaturia	0	0	0	0
Grade 1	0	0	0	0
Proteinuria	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Urinary tract signs and symptoms NEC	1 (2.5%)	1 (2.0%)	2 (2.2%)	4 (4.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	3 (3.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	0	0	0	0
Nocturia	1 (2.5%)	0	1 (1.1%)	3 (3.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	3 (3.0%)
Renal colic	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	0	0	0	0
Renal lithiasis	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
Nephrolithiasis	0	0	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Urinary tract signs and symptoms NEC	0	2 (5.7%)	2 (3.4%)	2 (2.8%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	0	0	0
Grade 3	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Nocturia	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Renal colic	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	0	0	0
Grade 3	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Renal lithiasis	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Nephrolithiasis	0	1 (2.9%)	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal lithiasis (cont)				
Nephrolithiasis (cont)				
Grade 1	0	0	0	1 (1.0%)
Nephropathies and tubular disorders NEC	0	0	0	0
Grade 4	0	0	0	0
Nephropathy	0	0	0	0
Grade 4	0	0	0	0
Renal disorders NEC	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Renal disorder	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal lithiasis (cont)				
Nephrolithiasis (cont)				
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Nephropathies and tubular disorders NEC	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 4	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Nephropathy	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 4	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Renal disorders NEC	0	0	0	0
Grade 3	0	0	0	0
Renal disorder	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-ol.pdf 29AUG2023: 9:41

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal hypertension and related conditions	0	0	0	0
Grade 3	0	0	0	0
Hypertensive nephropathy	0	0	0	0
Grade 3	0	0	0	0
Renal neoplasms	0	0	0	0
Grade 1	0	0	0	0
Renal cyst	0	0	0	0
Grade 1	0	0	0	0
Renal vascular and ischaemic conditions	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Renal tubular necrosis	1 (2.5%)	0	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal hypertension and related conditions	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 3	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Hypertensive nephropathy	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 3	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Renal neoplasms	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Renal cyst	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Renal vascular and ischaemic conditions	0	0	0	0
Grade 2	0	0	0	0
Renal tubular necrosis	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal vascular and ischaemic conditions (cont)				
Renal tubular necrosis (cont)				
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Vascular disorders	8 (20.0%)	9 (18.4%)	17 (19.1%)	23 (23.2%)
Grade 1	3 (7.5%)	3 (6.1%)	6 (6.7%)	8 (8.1%)
Grade 2	3 (7.5%)	3 (6.1%)	6 (6.7%)	8 (8.1%)
Grade 3	2 (5.0%)	3 (6.1%)	5 (5.6%)	7 (7.1%)
Vascular hypotensive disorders	1 (2.5%)	1 (2.0%)	2 (2.2%)	7 (7.1%)
Grade 1	0	0	0	2 (2.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	3 (3.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	2 (2.0%)
Hypotension	1 (2.5%)	1 (2.0%)	2 (2.2%)	7 (7.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal vascular and ischaemic conditions (cont)				
Renal tubular necrosis (cont)				
Grade 2	0	0	0	0
Vascular disorders	6 (25.0%)	7 (20.0%)	13 (22.0%)	20 (28.2%)
Grade 1	2 (8.3%)	2 (5.7%)	4 (6.8%)	9 (12.7%)
Grade 2	2 (8.3%)	4 (11.4%)	6 (10.2%)	7 (9.9%)
Grade 3	2 (8.3%)	1 (2.9%)	3 (5.1%)	4 (5.6%)
Vascular hypotensive disorders	2 (8.3%)	3 (8.6%)	5 (8.5%)	11 (15.5%)
Grade 1	0	1 (2.9%)	1 (1.7%)	5 (7.0%)
Grade 2	0	2 (5.7%)	2 (3.4%)	3 (4.2%)
Grade 3	2 (8.3%)	0	2 (3.4%)	3 (4.2%)
Hypotension	2 (8.3%)	2 (5.7%)	4 (6.8%)	10 (14.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-ol.pdf 29AUG2023: 9:41

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Vascular hypotensive disorders (cont)				
Hypotension (cont)				
Grade 1	0	0	0	2 (2.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	3 (3.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	2 (2.0%)
Orthostatic hypotension	0	0	0	0
Grade 2	0	0	0	0
Vascular hypertensive disorders NEC	2 (5.0%)	4 (8.2%)	6 (6.7%)	7 (7.1%)
Grade 1	0	2 (4.1%)	2 (2.2%)	2 (2.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	1 (2.5%)	2 (4.1%)	3 (3.4%)	4 (4.0%)
Hypertension	2 (5.0%)	4 (8.2%)	6 (6.7%)	7 (7.1%)
Grade 1	0	2 (4.1%)	2 (2.2%)	2 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Vascular hypotensive disorders (cont)				
Hypotension (cont)				
Grade 1	0	1 (2.9%)	1 (1.7%)	5 (7.0%)
Grade 2	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Grade 3	2 (8.3%)	0	2 (3.4%)	3 (4.2%)
Orthostatic hypotension	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Vascular hypertensive disorders NEC	3 (12.5%)	2 (5.7%)	5 (8.5%)	5 (7.0%)
Grade 1	0	0	0	0
Grade 2	3 (12.5%)	1 (2.9%)	4 (6.8%)	4 (5.6%)
Grade 3	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Hypertension	3 (12.5%)	2 (5.7%)	5 (8.5%)	5 (7.0%)
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Vascular hypertensive disorders NEC (cont)				
Hypertension (cont)				
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	1 (2.5%)	2 (4.1%)	3 (3.4%)	4 (4.0%)
Peripheral vascular disorders NEC	0	1 (2.0%)	1 (1.1%)	4 (4.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	4 (4.0%)
Grade 2	0	0	0	0
Flushing	0	1 (2.0%)	1 (1.1%)	3 (3.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	3 (3.0%)
Grade 2	0	0	0	0
Hot flush	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Vascular hypertensive disorders NEC (cont)				
Hypertension (cont)				
Grade 2	3 (12.5%)	1 (2.9%)	4 (6.8%)	4 (5.6%)
Grade 3	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Peripheral vascular disorders NEC	1 (4.2%)	1 (2.9%)	2 (3.4%)	4 (5.6%)
Grade 1	1 (4.2%)	1 (2.9%)	2 (3.4%)	3 (4.2%)
Grade 2	0	0	0	1 (1.4%)
Flushing	0	0	0	2 (2.8%)
Grade 1	0	0	0	1 (1.4%)
Grade 2	0	0	0	1 (1.4%)
Hot flush	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Grade 1	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Haemorrhages NEC	3 (7.5%)	1 (2.0%)	4 (4.5%)	5 (5.1%)
Grade 1	2 (5.0%)	1 (2.0%)	3 (3.4%)	4 (4.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Haematoma	3 (7.5%)	1 (2.0%)	4 (4.5%)	5 (5.1%)
Grade 1	2 (5.0%)	1 (2.0%)	3 (3.4%)	4 (4.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Aortic necrosis and vascular insufficiency	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Aortic stenosis	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-ol.pdf 29AUG2023: 9:41

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Haemorrhages NEC	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	0	0	0
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Haematoma	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	0	0	0
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Aortic necrosis and vascular insufficiency	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	0	0	0	0
Aortic stenosis	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-ol.pdf 29AUG2023: 9:41

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Aortic necrosis and vascular insufficiency (cont)				
Aortic arteriosclerosis	0	0	0	0
Grade 1	0	0	0	0
Non-site specific necrosis and vascular insufficiency NEC	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Arteriosclerosis	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Peripheral embolism and thrombosis	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Aortic necrosis and vascular insufficiency (cont)				
Aortic arteriosclerosis	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Non-site specific necrosis and vascular insufficiency NEC	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Arteriosclerosis	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Peripheral embolism and thrombosis	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Peripheral embolism and thrombosis (cont)				
Deep vein thrombosis	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Thrombophlebitis superficial	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Peripheral vasoconstriction, necrosis and vascular insufficiency	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	0	0	0
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Peripheral arterial occlusive disease	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	0	0	0
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Peripheral embolism and thrombosis (cont)				
Deep vein thrombosis	0	0	0	0
Grade 3	0	0	0	0
Thrombophlebitis superficial	0	0	0	0
Grade 2	0	0	0	0
Peripheral vasoconstriction, necrosis and vascular insufficiency	0	0	0	1 (1.4%)
Grade 1	0	0	0	1 (1.4%)
Grade 2	0	0	0	0
Peripheral arterial occlusive disease	0	0	0	1 (1.4%)
Grade 1	0	0	0	1 (1.4%)
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Non-site specific vascular disorders NEC	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
Poor venous access	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
Phlebitis NEC	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Phlebitis	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Non-site specific vascular disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Poor venous access	0	0	0	0
Grade 1	0	0	0	0
Phlebitis NEC	0	0	0	0
Grade 1	0	0	0	0
Phlebitis	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders	7 (17.5%)	6 (12.2%)	13 (14.6%)	20 (20.2%)
Grade 1	3 (7.5%)	0	3 (3.4%)	3 (3.0%)
Grade 2	1 (2.5%)	1 (2.0%)	2 (2.2%)	5 (5.1%)
Grade 3	2 (5.0%)	4 (8.2%)	6 (6.7%)	10 (10.1%)
Grade 4	0	0	0	0
Grade 5	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Supraventricular arrhythmias	4 (10.0%)	3 (6.1%)	7 (7.9%)	12 (12.1%)
Grade 1	2 (5.0%)	0	2 (2.2%)	3 (3.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	4 (4.0%)
Grade 3	2 (5.0%)	2 (4.1%)	4 (4.5%)	5 (5.1%)
Atrial fibrillation	3 (7.5%)	3 (6.1%)	6 (6.7%)	10 (10.1%)
Grade 1	1 (2.5%)	0	1 (1.1%)	2 (2.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	3 (3.0%)
Grade 3	2 (5.0%)	2 (4.1%)	4 (4.5%)	5 (5.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders	5 (20.8%)	7 (20.0%)	12 (20.3%)	15 (21.1%)
Grade 1	1 (4.2%)	3 (8.6%)	4 (6.8%)	5 (7.0%)
Grade 2	2 (8.3%)	0	2 (3.4%)	2 (2.8%)
Grade 3	2 (8.3%)	4 (11.4%)	6 (10.2%)	7 (9.9%)
Grade 4	0	0	0	1 (1.4%)
Grade 5	0	0	0	0
Supraventricular arrhythmias	4 (16.7%)	2 (5.7%)	6 (10.2%)	7 (9.9%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	2 (8.3%)	0	2 (3.4%)	2 (2.8%)
Grade 3	1 (4.2%)	2 (5.7%)	3 (5.1%)	4 (5.6%)
Atrial fibrillation	3 (12.5%)	2 (5.7%)	5 (8.5%)	6 (8.5%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	2 (8.3%)	0	2 (3.4%)	2 (2.8%)
Grade 3	0	2 (5.7%)	2 (3.4%)	3 (4.2%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Supraventricular arrhythmias (cont)				
Atrial flutter	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Grade 2	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Sinus bradycardia	0	0	0	0
Grade 3	0	0	0	0
Supraventricular extrasystoles	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Supraventricular tachycardia	0	0	0	1 (1.0%)
Grade 2	0	0	0	1 (1.0%)
Heart failures NEC	2 (5.0%)	1 (2.0%)	3 (3.4%)	5 (5.1%)
Grade 1	0	0	0	0
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-ol.pdf 29AUG2023: 9:41

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Supraventricular arrhythmias (cont)				
Atrial flutter	0	0	0	0
Grade 2	0	0	0	0
Sinus bradycardia	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 3	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Supraventricular extrasystoles	0	0	0	0
Grade 1	0	0	0	0
Supraventricular tachycardia	0	0	0	0
Grade 2	0	0	0	0
Heart failures NEC	1 (4.2%)	2 (5.7%)	3 (5.1%)	4 (5.6%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Heart failures NEC (cont)				
(cont)				
Grade 3	1 (2.5%)	0	1 (1.1%)	3 (3.0%)
Grade 5	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Cardiac failure	1 (2.5%)	1 (2.0%)	2 (2.2%)	3 (3.0%)
Grade 1	0	0	0	0
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	0	0	0	1 (1.0%)
Grade 5	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Cardiac failure congestive	1 (2.5%)	0	1 (1.1%)	2 (2.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	2 (2.0%)
Ischaemic coronary artery disorders	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Heart failures NEC (cont)				
(cont)				
Grade 3	1 (4.2%)	1 (2.9%)	2 (3.4%)	3 (4.2%)
Grade 5	0	0	0	0
Cardiac failure	1 (4.2%)	2 (5.7%)	3 (5.1%)	4 (5.6%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	0	0	0
Grade 3	1 (4.2%)	1 (2.9%)	2 (3.4%)	3 (4.2%)
Grade 5	0	0	0	0
Cardiac failure congestive	0	0	0	0
Grade 3	0	0	0	0
Ischaemic coronary artery disorders	0	2 (5.7%)	2 (3.4%)	3 (4.2%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Ischaemic coronary artery disorders (cont) (cont)				
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 4	0	0	0	0
Angina pectoris	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	0	0	0
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Acute myocardial infarction	0	0	0	0
Grade 4	0	0	0	0
Myocardial infarction	0	0	0	0
Grade 3	0	0	0	0
Cardiac signs and symptoms NEC	1 (2.5%)	0	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Ischaemic coronary artery disorders (cont) (cont)				
Grade 3	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 4	0	0	0	1 (1.4%)
Angina pectoris	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 3	0	0	0	1 (1.4%)
Acute myocardial infarction	0	0	0	1 (1.4%)
Grade 4	0	0	0	1 (1.4%)
Myocardial infarction	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 3	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Cardiac signs and symptoms NEC	0	1 (2.9%)	1 (1.7%)	2 (2.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Cardiac signs and symptoms NEC (cont)				
(cont)				
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Palpitations	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Rate and rhythm disorders NEC	1 (2.5%)	0	1 (1.1%)	3 (3.0%)
Grade 1	0	0	0	1 (1.0%)
Grade 2	0	0	0	1 (1.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Tachycardia	1 (2.5%)	0	1 (1.1%)	2 (2.0%)
Grade 2	0	0	0	1 (1.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Cardiac signs and symptoms NEC (cont) (cont)				
Grade 1	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Palpitations	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Grade 1	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Rate and rhythm disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Tachycardia	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Rate and rhythm disorders NEC (cont)				
Bradycardia	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Extrasystoles	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
Cardiac conduction disorders	1 (2.5%)	0	1 (1.1%)	2 (2.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	0	0	0	1 (1.0%)
Atrioventricular block complete	0	0	0	1 (1.0%)
Grade 3	0	0	0	1 (1.0%)
Atrioventricular block first degree	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Rate and rhythm disorders NEC (cont)				
Bradycardia	0	0	0	0
Grade 1	0	0	0	0
Extrasystoles	0	0	0	0
Grade 1	0	0	0	0
Cardiac conduction disorders	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Atrioventricular block complete	0	0	0	0
Grade 3	0	0	0	0
Atrioventricular block first degree	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Mitral valvular disorders	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	0	0	0
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Mitral valve incompetence	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	0	0	0
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Cardiac valve disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Cardiac valve disease	0	0	0	0
Grade 1	0	0	0	0
Cardiomyopathies	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Mitral valvular disorders	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 3	0	0	0	0
Mitral valve incompetence	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 3	0	0	0	0
Cardiac valve disorders NEC	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Cardiac valve disease	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Cardiomyopathies	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Cardiomyopathies (cont)				
Cardiomyopathy	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Myocardial disorders NEC	0	0	0	1 (1.0%)
Grade 2	0	0	0	1 (1.0%)
Cardiomegaly	0	0	0	1 (1.0%)
Grade 2	0	0	0	1 (1.0%)
Pericardial disorders NEC	0	0	0	1 (1.0%)
Grade 3	0	0	0	1 (1.0%)
Pericardial effusion	0	0	0	1 (1.0%)
Grade 3	0	0	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Cardiomyopathies (cont)				
Cardiomyopathy	0	0	0	0
Grade 3	0	0	0	0
Myocardial disorders NEC	0	0	0	0
Grade 2	0	0	0	0
Cardiomegaly	0	0	0	0
Grade 2	0	0	0	0
Pericardial disorders NEC	0	0	0	0
Grade 3	0	0	0	0
Pericardial effusion	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Ventricular arrhythmias and cardiac arrest	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 5	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Cardiac arrest	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 5	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Injury, poisoning and procedural complications	6 (15.0%)	8 (16.3%)	14 (15.7%)	21 (21.2%)
Grade 1	4 (10.0%)	2 (4.1%)	6 (6.7%)	11 (11.1%)
Grade 2	0	3 (6.1%)	3 (3.4%)	5 (5.1%)
Grade 3	2 (5.0%)	2 (4.1%)	4 (4.5%)	4 (4.0%)
Grade 5	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Skin injuries NEC	3 (7.5%)	3 (6.1%)	6 (6.7%)	11 (11.1%)
Grade 1	2 (5.0%)	2 (4.1%)	4 (4.5%)	9 (9.1%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-ol.pdf 29AUG2023: 9:41

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Ventricular arrhythmias and cardiac arrest	0	0	0	0
Grade 5	0	0	0	0
Cardiac arrest	0	0	0	0
Grade 5	0	0	0	0
Injury, poisoning and procedural complications	7 (29.2%)	4 (11.4%)	11 (18.6%)	13 (18.3%)
Grade 1	5 (20.8%)	1 (2.9%)	6 (10.2%)	6 (8.5%)
Grade 2	2 (8.3%)	2 (5.7%)	4 (6.8%)	5 (7.0%)
Grade 3	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Grade 5	0	0	0	0
Skin injuries NEC	2 (8.3%)	1 (2.9%)	3 (5.1%)	6 (8.5%)
Grade 1	2 (8.3%)	1 (2.9%)	3 (5.1%)	5 (7.0%)
Grade 2	0	0	0	1 (1.4%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Skin injuries NEC (cont)				
Contusion	2 (5.0%)	1 (2.0%)	3 (3.4%)	7 (7.1%)
Grade 1	2 (5.0%)	1 (2.0%)	3 (3.4%)	7 (7.1%)
Grade 2	0	0	0	0
Skin abrasion	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
Skin injury	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Skin laceration	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Subcutaneous haematoma	0	1 (2.0%)	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Skin injuries NEC (cont)				
Contusion	2 (8.3%)	1 (2.9%)	3 (5.1%)	6 (8.5%)
Grade 1	2 (8.3%)	1 (2.9%)	3 (5.1%)	5 (7.0%)
Grade 2	0	0	0	1 (1.4%)
Skin abrasion	0	0	0	0
Grade 1	0	0	0	0
Skin injury	0	0	0	0
Grade 3	0	0	0	0
Skin laceration	0	0	0	0
Grade 2	0	0	0	0
Subcutaneous haematoma	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Skin injuries NEC (cont)				
Subcutaneous haematoma (cont)				
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Non-site specific injuries NEC	2 (5.0%)	5 (10.2%)	7 (7.9%)	11 (11.1%)
Grade 1	1 (2.5%)	2 (4.1%)	3 (3.4%)	7 (7.1%)
Grade 2	1 (2.5%)	2 (4.1%)	3 (3.4%)	3 (3.0%)
Grade 5	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Fall	1 (2.5%)	5 (10.2%)	6 (6.7%)	10 (10.1%)
Grade 1	0	2 (4.1%)	2 (2.2%)	6 (6.1%)
Grade 2	1 (2.5%)	2 (4.1%)	3 (3.4%)	3 (3.0%)
Grade 5	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Wound	1 (2.5%)	0	1 (1.1%)	2 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Skin injuries NEC (cont)				
Subcutaneous haematoma (cont)				
Grade 1	0	0	0	0
Non-site specific injuries NEC	2 (8.3%)	1 (2.9%)	3 (5.1%)	3 (4.2%)
Grade 1	2 (8.3%)	0	2 (3.4%)	2 (2.8%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 5	0	0	0	0
Fall	2 (8.3%)	1 (2.9%)	3 (5.1%)	3 (4.2%)
Grade 1	2 (8.3%)	0	2 (3.4%)	2 (2.8%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 5	0	0	0	0
Wound	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Non-site specific injuries NEC (cont)				
Wound (cont)				
Grade 1	1 (2.5%)	0	1 (1.1%)	2 (2.0%)
Site specific injuries NEC	0	1 (2.0%)	1 (1.1%)	4 (4.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	3 (3.0%)
Grade 2	0	0	0	1 (1.0%)
Limb injury	0	0	0	2 (2.0%)
Grade 1	0	0	0	1 (1.0%)
Grade 2	0	0	0	1 (1.0%)
Head injury	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Non-site specific injuries NEC (cont)				
Wound (cont)				
Grade 1	0	0	0	0
Site specific injuries NEC	2 (8.3%)	1 (2.9%)	3 (5.1%)	3 (4.2%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Limb injury	2 (8.3%)	1 (2.9%)	3 (5.1%)	3 (4.2%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Head injury	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Site specific injuries NEC (cont)				
Limb crushing injury	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
Non-site specific procedural complications	1 (2.5%)	2 (4.1%)	3 (3.4%)	4 (4.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	0	0	0	1 (1.0%)
Grade 3	0	2 (4.1%)	2 (2.2%)	2 (2.0%)
Post procedural haemorrhage	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Procedural pain	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Site specific injuries NEC (cont)				
Limb crushing injury	0	0	0	0
Grade 1	0	0	0	0
Non-site specific procedural complications	0	0	0	2 (2.8%)
Grade 1	0	0	0	1 (1.4%)
Grade 2	0	0	0	0
Grade 3	0	0	0	1 (1.4%)
Post procedural haemorrhage	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Procedural pain	0	0	0	1 (1.4%)
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Non-site specific procedural complications (cont)				
Procedural pain (cont)				
Grade 3	0	0	0	0
Post procedural complication	0	0	0	1 (1.0%)
Grade 2	0	0	0	1 (1.0%)
Post procedural contusion	0	0	0	0
Grade 1	0	0	0	0
Post procedural inflammation	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Spinal fractures and dislocations	1 (2.5%)	0	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Non-site specific procedural complications (cont)				
Procedural pain (cont)				
Grade 3	0	0	0	1 (1.4%)
Post procedural complication	0	0	0	0
Grade 2	0	0	0	0
Post procedural contusion	0	0	0	1 (1.4%)
Grade 1	0	0	0	1 (1.4%)
Post procedural inflammation	0	0	0	0
Grade 3	0	0	0	0
Spinal fractures and dislocations	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Spinal fractures and dislocations (cont) (cont)				
Grade 2	0	0	0	0
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Spinal compression fracture	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	0	0	0	0
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Spinal fracture	0	0	0	0
Grade 2	0	0	0	0
Gastrointestinal and hepatobiliary procedural complications	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-ol.pdf 29AUG2023: 9:41

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Spinal fractures and dislocations (cont) (cont)				
Grade 2	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Grade 3	0	0	0	0
Spinal compression fracture	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 3	0	0	0	0
Spinal fracture	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Gastrointestinal and hepatobiliary procedural complications	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Gastrointestinal and hepatobiliary procedural complications (cont) (cont)				
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Dental restoration failure	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Procedural nausea	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Cerebral injuries NEC	0	0	0	0
Grade 1	0	0	0	0
Subdural haemorrhage	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Gastrointestinal and hepatobiliary procedural complications (cont) (cont)				
Grade 2	0	0	0	0
Dental restoration failure	0	0	0	0
Grade 1	0	0	0	0
Procedural nausea	0	0	0	0
Grade 2	0	0	0	0
Cerebral injuries NEC	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Subdural haemorrhage	1 (4.2%)	0	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Cerebral injuries NEC (cont)				
Subdural haemorrhage (cont)				
Grade 1	0	0	0	0
Chest and respiratory tract injuries NEC	0	0	0	0
Grade 3	0	0	0	0
Traumatic haemothorax	0	0	0	0
Grade 3	0	0	0	0
Limb fractures and dislocations	0	0	0	0
Grade 2	0	0	0	0
Patella fracture	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Cerebral injuries NEC (cont)				
Subdural haemorrhage (cont)				
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Chest and respiratory tract injuries NEC	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 3	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Traumatic haemothorax	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 3	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Limb fractures and dislocations	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Patella fracture	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Muscle, tendon and ligament injuries	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Muscle strain	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Skull fractures, facial bone fractures and dislocations	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Facial bones fracture	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Transfusion related complications	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Muscle, tendon and ligament injuries	0	0	0	0
Grade 2	0	0	0	0
Muscle strain	0	0	0	0
Grade 2	0	0	0	0
Skull fractures, facial bone fractures and dislocations	0	0	0	0
Grade 1	0	0	0	0
Facial bones fracture	0	0	0	0
Grade 1	0	0	0	0
Transfusion related complications	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Transfusion related complications (cont)				
Febrile nonhaemolytic transfusion reaction	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Eye disorders	7 (17.5%)	6 (12.2%)	13 (14.6%)	19 (19.2%)
Grade 1	5 (12.5%)	4 (8.2%)	9 (10.1%)	14 (14.1%)
Grade 2	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Grade 3	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Grade 4	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Cataract conditions	2 (5.0%)	2 (4.1%)	4 (4.5%)	6 (6.1%)
Grade 1	2 (5.0%)	1 (2.0%)	3 (3.4%)	4 (4.0%)
Grade 2	0	0	0	1 (1.0%)
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Transfusion related complications (cont)				
Febrile nonhaemolytic transfusion reaction	0	0	0	0
Grade 1	0	0	0	0
Eye disorders	7 (29.2%)	3 (8.6%)	10 (16.9%)	12 (16.9%)
Grade 1	5 (20.8%)	3 (8.6%)	8 (13.6%)	10 (14.1%)
Grade 2	0	0	0	0
Grade 3	2 (8.3%)	0	2 (3.4%)	2 (2.8%)
Grade 4	0	0	0	0
Cataract conditions	4 (16.7%)	1 (2.9%)	5 (8.5%)	5 (7.0%)
Grade 1	2 (8.3%)	1 (2.9%)	3 (5.1%)	3 (4.2%)
Grade 2	0	0	0	0
Grade 3	2 (8.3%)	0	2 (3.4%)	2 (2.8%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Cataract conditions (cont)				
Cataract cortical	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	0	0	1 (1.0%)
Grade 3	0	0	0	0
Cataract nuclear	2 (5.0%)	0	2 (2.2%)	2 (2.0%)
Grade 1	2 (5.0%)	0	2 (2.2%)	2 (2.0%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Cataract	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Grade 1	0	0	0	1 (1.0%)
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Cataract subcapsular	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Cataract conditions (cont)				
Cataract cortical	2 (8.3%)	1 (2.9%)	3 (5.1%)	3 (4.2%)
Grade 1	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Grade 2	0	0	0	0
Grade 3	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Cataract nuclear	3 (12.5%)	0	3 (5.1%)	3 (4.2%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 3	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Cataract	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Cataract subcapsular	1 (4.2%)	0	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-ol.pdf 29AUG2023: 9:41

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Cataract conditions (cont)				
Cataract subcapsular (cont)				
Grade 1	0	0	0	0
Visual disorders NEC	1 (2.5%)	1 (2.0%)	2 (2.2%)	4 (4.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	3 (3.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Vision blurred	1 (2.5%)	0	1 (1.1%)	3 (3.0%)
Grade 1	0	0	0	2 (2.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Diplopia	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Cataract conditions (cont)				
Cataract subcapsular (cont)				
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Visual disorders NEC	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Grade 1	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Grade 3	0	0	0	0
Vision blurred	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Grade 1	0	1 (2.9%)	1 (1.7%)	2 (2.8%)
Grade 3	0	0	0	0
Diplopia	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-ol.pdf 29AUG2023: 9:41

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Conjunctival and corneal bleeding and vascular disorders	2 (5.0%)	0	2 (2.2%)	2 (2.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Conjunctival haemorrhage	2 (5.0%)	0	2 (2.2%)	2 (2.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Lacrimation disorders	1 (2.5%)	1 (2.0%)	2 (2.2%)	4 (4.0%)
Grade 1	1 (2.5%)	1 (2.0%)	2 (2.2%)	4 (4.0%)
Dry eye	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Grade 1	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Lacrimation increased	0	0	0	2 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Conjunctival and corneal bleeding and vascular disorders	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Grade 1	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Grade 2	0	0	0	0
Conjunctival haemorrhage	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Grade 1	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Grade 2	0	0	0	0
Lacrimation disorders	0	0	0	0
Grade 1	0	0	0	0
Dry eye	0	0	0	0
Grade 1	0	0	0	0
Lacrimation increased	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Lacrimation disorders (cont)				
Lacrimation increased (cont)				
Grade 1	0	0	0	2 (2.0%)
Retinal bleeding and vascular disorders (excl retinopathy)	1 (2.5%)	0	1 (1.1%)	2 (2.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	2 (2.0%)
Retinal haemorrhage	1 (2.5%)	0	1 (1.1%)	2 (2.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	2 (2.0%)
Choroid and vitreous structural change, deposit and degeneration	1 (2.5%)	0	1 (1.1%)	2 (2.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	2 (2.0%)
Hyalosis asteroid	0	0	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Lacrimation disorders (cont)				
Lacrimation increased (cont)				
Grade 1	0	0	0	0
Retinal bleeding and vascular disorders (excl retinopathy)	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Retinal haemorrhage	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Choroid and vitreous structural change, deposit and degeneration	0	0	0	0
Grade 1	0	0	0	0
Hyalosis asteroid	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Choroid and vitreous structural change, deposit and degeneration (cont)				
Hyalosis asteroid (cont)				
Grade 1	0	0	0	1 (1.0%)
Vitreous floaters	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Corneal infections, oedemas and inflammations	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Grade 1	0	0	0	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Keratitis	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Grade 1	0	0	0	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Choroid and vitreous structural change, deposit and degeneration (cont)				
Hyalosis asteroid (cont)				
Grade 1	0	0	0	0
Vitreous floaters	0	0	0	0
Grade 1	0	0	0	0
Corneal infections, oedemas and inflammations	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Keratitis	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Lid, lash and lacrimal infections, irritations and inflammations	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Erythema of eyelid	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Eyelid oedema	0	0	0	0
Grade 1	0	0	0	0
Ocular bleeding and vascular disorders NEC	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	0	0	0	0
Grade 4	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Eye haemorrhage	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Lid, lash and lacrimal infections, irritations and inflammations	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Erythema of eyelid	0	0	0	0
Grade 1	0	0	0	0
Eyelid oedema	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Ocular bleeding and vascular disorders NEC	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 4	0	0	0	0
Eye haemorrhage	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Ocular bleeding and vascular disorders NEC (cont)				
Eye haemorrhage (cont)				
Grade 4	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Ocular disorders NEC	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	0	0	0	0
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Eye pain	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Periorbital oedema	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Ocular bleeding and vascular disorders NEC (cont)				
Eye haemorrhage (cont)				
Grade 4	0	0	0	0
Ocular disorders NEC	0	0	0	1 (1.4%)
Grade 1	0	0	0	1 (1.4%)
Grade 3	0	0	0	0
Eye pain	0	0	0	0
Grade 3	0	0	0	0
Periorbital oedema	0	0	0	1 (1.4%)
Grade 1	0	0	0	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Retinal structural change, deposit and degeneration	1 (2.5%)	0	1 (1.1%)	2 (2.0%)
Grade 1	0	0	0	1 (1.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Macular degeneration	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
Retinal detachment	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Visual impairment and blindness (excl colour blindness)	0	0	0	0
Grade 1	0	0	0	0
Visual acuity reduced	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Retinal structural change, deposit and degeneration	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Macular degeneration	0	0	0	0
Grade 1	0	0	0	0
Retinal detachment	0	0	0	0
Grade 3	0	0	0	0
Visual impairment and blindness (excl colour blindness)	1 (4.2%)	0	1 (1.7%)	2 (2.8%)
Grade 1	1 (4.2%)	0	1 (1.7%)	2 (2.8%)
Visual acuity reduced	0	0	0	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Visual impairment and blindness (excl colour blindness) (cont)				
Visual acuity reduced (cont)				
Grade 1	0	0	0	0
Visual impairment	0	0	0	0
Grade 1	0	0	0	0
Eyelid movement disorders	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Eyelid ptosis	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Visual impairment and blindness (excl colour blindness) (cont)				
Visual acuity reduced (cont)				
Grade 1	0	0	0	1 (1.4%)
Visual impairment	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Eyelid movement disorders	0	0	0	0
Grade 1	0	0	0	0
Eyelid ptosis	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10 (25.0%)	7 (14.3%)	17 (19.1%)	19 (19.2%)
Grade 1	1 (2.5%)	3 (6.1%)	4 (4.5%)	4 (4.0%)
Grade 2	3 (7.5%)	1 (2.0%)	4 (4.5%)	4 (4.0%)
Grade 3	6 (15.0%)	3 (6.1%)	9 (10.1%)	9 (9.1%)
Grade 4	0	0	0	2 (2.0%)
Grade 5	0	0	0	0
Leukaemias acute myeloid	3 (7.5%)	1 (2.0%)	4 (4.5%)	5 (5.1%)
Grade 3	3 (7.5%)	1 (2.0%)	4 (4.5%)	4 (4.0%)
Grade 4	0	0	0	1 (1.0%)
Acute myeloid leukaemia	3 (7.5%)	1 (2.0%)	4 (4.5%)	5 (5.1%)
Grade 3	3 (7.5%)	1 (2.0%)	4 (4.5%)	4 (4.0%)
Grade 4	0	0	0	1 (1.0%)
Transformation to acute myeloid leukaemia	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4 (16.7%)	4 (11.4%)	8 (13.6%)	9 (12.7%)
Grade 1	2 (8.3%)	1 (2.9%)	3 (5.1%)	3 (4.2%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 3	1 (4.2%)	1 (2.9%)	2 (3.4%)	3 (4.2%)
Grade 4	0	0	0	0
Grade 5	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Leukaemias acute myeloid	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 3	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 4	0	0	0	0
Acute myeloid leukaemia	0	0	0	0
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Transformation to acute myeloid leukaemia	1 (4.2%)	0	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Leukaemias acute myeloid (cont)				
Transformation to acute myeloid leukaemia (cont)				
Grade 3	0	0	0	0
Skin neoplasms malignant and unspecified (excl melanoma)	3 (7.5%)	2 (4.1%)	5 (5.6%)	5 (5.1%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	3 (7.5%)	1 (2.0%)	4 (4.5%)	4 (4.0%)
Basal cell carcinoma	2 (5.0%)	0	2 (2.2%)	2 (2.0%)
Grade 2	2 (5.0%)	0	2 (2.2%)	2 (2.0%)
Squamous cell carcinoma of skin	1 (2.5%)	2 (4.1%)	3 (3.4%)	3 (3.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Leukaemias acute myeloid (cont)				
Transformation to acute myeloid leukaemia (cont)				
Grade 3	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Skin neoplasms malignant and unspecified (excl melanoma)	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	0	0	0
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Basal cell carcinoma	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Squamous cell carcinoma of skin	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Skin neoplasms malignant and unspecified (excl melanoma) (cont)				
Squamous cell carcinoma of skin (cont)				
Grade 2	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Bowen's disease	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Skin neoplasms benign	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Grade 1	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Seborrhoeic keratosis	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Skin papilloma	1 (2.5%)	0	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Skin neoplasms malignant and unspecified (excl melanoma) (cont)				
Squamous cell carcinoma of skin (cont)				
Grade 2	0	0	0	0
Bowen's disease	0	0	0	0
Grade 2	0	0	0	0
Skin neoplasms benign	0	0	0	0
Grade 1	0	0	0	0
Seborrhoeic keratosis	0	0	0	0
Grade 1	0	0	0	0
Skin papilloma	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Skin neoplasms benign (cont)				
Skin papilloma (cont)				
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Uterine neoplasms malignant NEC	0	0	0	0
Grade 3	0	0	0	0
Grade 5	0	0	0	0
Uterine cancer	0	0	0	0
Grade 3	0	0	0	0
Grade 5	0	0	0	0
Bone neoplasms benign (excl cysts)	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Data Extracted: CRF data: 01JUL2019
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Skin neoplasms benign (cont)				
Skin papilloma (cont)				
Grade 1	0	0	0	0
Uterine neoplasms malignant NEC	1 (4.2%)	0	1 (1.7%)	2 (2.8%)
Grade 3	0	0	0	1 (1.4%)
Grade 5	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Uterine cancer	1 (4.2%)	0	1 (1.7%)	2 (2.8%)
Grade 3	0	0	0	1 (1.4%)
Grade 5	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Bone neoplasms benign (excl cysts)	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Bone neoplasms benign (excl cysts) (cont)				
Haemangioma of bone	0	0	0	0
Grade 1	0	0	0	0
Colorectal neoplasms malignant	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Rectal cancer	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Histiocytoses	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Langerhans cell sarcoma	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Bone neoplasms benign (excl cysts) (cont)				
Haemangioma of bone	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Colorectal neoplasms malignant	0	0	0	0
Grade 3	0	0	0	0
Rectal cancer	0	0	0	0
Grade 3	0	0	0	0
Histiocytoses	0	0	0	0
Grade 3	0	0	0	0
Langerhans cell sarcoma	0	0	0	0
Grade 3	0	0	0	0

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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Leukaemias chronic myeloid	0	0	0	0
Grade 3	0	0	0	0
Chronic myeloid leukaemia	0	0	0	0
Grade 3	0	0	0	0
Myeloproliferative disorders (excl leukaemias)	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Leukoerythroblastosis	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Nasal and paranasal sinus neoplasms benign	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Leukaemias chronic myeloid	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 3	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Chronic myeloid leukaemia	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 3	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Myeloproliferative disorders (excl leukaemias)	0	0	0	0
Grade 3	0	0	0	0
Leukoerythroblastosis	0	0	0	0
Grade 3	0	0	0	0
Nasal and paranasal sinus neoplasms benign	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
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SAF-Anemic Analysis Set

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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Nasal and paranasal sinus neoplasms benign (cont)				
Sinonasal papilloma	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Neoplasms malignant site unspecified NEC	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Metastatic squamous cell carcinoma	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Ocular neoplasms malignancy unspecified	0	0	0	0
Grade 1	0	0	0	0
Eyelid tumour	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
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Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Nasal and paranasal sinus neoplasms benign (cont)				
Sinonasal papilloma	0	0	0	0
Grade 3	0	0	0	0
Neoplasms malignant site unspecified NEC	0	0	0	0
Grade 1	0	0	0	0
Metastatic squamous cell carcinoma	0	0	0	0
Grade 1	0	0	0	0
Ocular neoplasms malignancy unspecified	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Eyelid tumour	0	1 (2.9%)	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Ocular neoplasms malignancy unspecified (cont)				
Eyelid tumour (cont)				
Grade 1	0	0	0	0
Oncologic complications and emergencies	0	0	0	0
Grade 1	0	0	0	0
Tumour associated fever	0	0	0	0
Grade 1	0	0	0	0
Ovarian neoplasms malignant (excl germ cell)	0	0	0	0
Grade 3	0	0	0	0
Ovarian clear cell carcinoma	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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SAF-Anemic Analysis Set

(Continued)	Female			
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Ocular neoplasms malignancy unspecified (cont)				
Eyelid tumour (cont)				
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Oncologic complications and emergencies	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Tumour associated fever	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Ovarian neoplasms malignant (excl germ cell)	0	0	0	1 (1.4%)
Grade 3	0	0	0	1 (1.4%)
Ovarian clear cell carcinoma	0	0	0	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Ovarian neoplasms malignant (excl germ cell) (cont)				
Ovarian clear cell carcinoma (cont)				
Grade 3	0	0	0	0
Skin melanomas (excl ocular)	0	0	0	0
Grade 5	0	0	0	0
Malignant melanoma	0	0	0	0
Grade 5	0	0	0	0
Soft tissue neoplasms benign NEC	0	0	0	0
Grade 1	0	0	0	0
Angiomyolipoma	0	0	0	0

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Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Ovarian neoplasms malignant (excl germ cell) (cont)				
Ovarian clear cell carcinoma (cont)				
Grade 3	0	0	0	1 (1.4%)
Skin melanomas (excl ocular)	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 5	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Malignant melanoma	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 5	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Soft tissue neoplasms benign NEC	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Angiomyolipoma	1 (4.2%)	0	1 (1.7%)	1 (1.4%)

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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Soft tissue neoplasms benign NEC (cont)				
Angiomyolipoma (cont)				
Grade 1	0	0	0	0
Splenic marginal zone lymphomas	0	0	0	1 (1.0%)
Grade 4	0	0	0	1 (1.0%)
Splenic marginal zone lymphoma	0	0	0	1 (1.0%)
Grade 4	0	0	0	1 (1.0%)
Testicular neoplasms malignant	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Seminoma	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Soft tissue neoplasms benign NEC (cont)				
Angiomyolipoma (cont)				
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Splenic marginal zone lymphomas	0	0	0	0
Grade 4	0	0	0	0
Splenic marginal zone lymphoma	0	0	0	0
Grade 4	0	0	0	0
Testicular neoplasms malignant	0	0	0	0
Grade 3	0	0	0	0
Seminoma	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Uterine neoplasms benign	0	0	0	0
Grade 1	0	0	0	0
Uterine leiomyoma	0	0	0	0
Grade 1	0	0	0	0
Psychiatric disorders	7 (17.5%)	7 (14.3%)	14 (15.7%)	17 (17.2%)
Grade 1	3 (7.5%)	3 (6.1%)	6 (6.7%)	8 (8.1%)
Grade 2	4 (10.0%)	4 (8.2%)	8 (9.0%)	9 (9.1%)
Grade 3	0	0	0	0
Disturbances in initiating and maintaining sleep	4 (10.0%)	3 (6.1%)	7 (7.9%)	8 (8.1%)
Grade 1	1 (2.5%)	1 (2.0%)	2 (2.2%)	3 (3.0%)
Grade 2	3 (7.5%)	2 (4.1%)	5 (5.6%)	5 (5.1%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Uterine neoplasms benign	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Uterine leiomyoma	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Psychiatric disorders	7 (29.2%)	2 (5.7%)	9 (15.3%)	10 (14.1%)
Grade 1	3 (12.5%)	1 (2.9%)	4 (6.8%)	4 (5.6%)
Grade 2	3 (12.5%)	1 (2.9%)	4 (6.8%)	5 (7.0%)
Grade 3	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Disturbances in initiating and maintaining sleep	3 (12.5%)	1 (2.9%)	4 (6.8%)	4 (5.6%)
Grade 1	3 (12.5%)	1 (2.9%)	4 (6.8%)	4 (5.6%)
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Disturbances in initiating and maintaining sleep (cont)				
Insomnia	4 (10.0%)	3 (6.1%)	7 (7.9%)	8 (8.1%)
Grade 1	1 (2.5%)	1 (2.0%)	2 (2.2%)	3 (3.0%)
Grade 2	3 (7.5%)	2 (4.1%)	5 (5.6%)	5 (5.1%)
Depressive disorders	2 (5.0%)	0	2 (2.2%)	3 (3.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	2 (2.0%)
Grade 3	0	0	0	0
Depression	2 (5.0%)	0	2 (2.2%)	3 (3.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	2 (2.0%)
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Disturbances in initiating and maintaining sleep (cont)				
Insomnia	3 (12.5%)	1 (2.9%)	4 (6.8%)	4 (5.6%)
Grade 1	3 (12.5%)	1 (2.9%)	4 (6.8%)	4 (5.6%)
Grade 2	0	0	0	0
Depressive disorders	3 (12.5%)	1 (2.9%)	4 (6.8%)	4 (5.6%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Grade 3	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Depression	3 (12.5%)	1 (2.9%)	4 (6.8%)	4 (5.6%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Grade 3	1 (4.2%)	0	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-ol.pdf 29AUG2023: 9:41

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Anxiety symptoms	2 (5.0%)	0	2 (2.2%)	2 (2.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Anxiety	2 (5.0%)	0	2 (2.2%)	2 (2.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Confusion and disorientation	0	2 (4.1%)	2 (2.2%)	3 (3.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Confusional state	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Grade 1	0	0	0	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Anxiety symptoms	1 (4.2%)	0	1 (1.7%)	4 (5.6%)
Grade 1	0	0	0	1 (1.4%)
Grade 2	1 (4.2%)	0	1 (1.7%)	3 (4.2%)
Anxiety	1 (4.2%)	0	1 (1.7%)	4 (5.6%)
Grade 1	0	0	0	1 (1.4%)
Grade 2	1 (4.2%)	0	1 (1.7%)	3 (4.2%)
Confusion and disorientation	2 (8.3%)	0	2 (3.4%)	2 (2.8%)
Grade 1	2 (8.3%)	0	2 (3.4%)	2 (2.8%)
Grade 2	0	0	0	0
Confusional state	2 (8.3%)	0	2 (3.4%)	2 (2.8%)
Grade 1	2 (8.3%)	0	2 (3.4%)	2 (2.8%)
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Confusion and disorientation (cont)				
Disorientation	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Sexual desire disorders	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Libido decreased	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Delusional symptoms	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Delusion	0	1 (2.0%)	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Confusion and disorientation (cont)				
Disorientation	0	0	0	0
Grade 1	0	0	0	0
Sexual desire disorders	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Libido decreased	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Delusional symptoms	0	0	0	0
Grade 1	0	0	0	0
Delusion	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Delusional symptoms (cont)				
Delusion (cont)				
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Hallucinations (excl sleep-related)	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
Hallucination	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
Mental disorders NEC	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)
Mental status changes	0	0	0	1 (1.0%)
Grade 1	0	0	0	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Delusional symptoms (cont)				
Delusion (cont)				
Grade 1	0	0	0	0
Hallucinations (excl sleep-related)	0	0	0	0
Grade 1	0	0	0	0
Hallucination	0	0	0	0
Grade 1	0	0	0	0
Mental disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Mental status changes	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Sleep disorders NEC	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Sleep disorder	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Suicidal and self-injurious behaviour	0	0	0	0
Grade 2	0	0	0	0
Suicidal ideation	0	0	0	0
Grade 2	0	0	0	0
Ear and labyrinth disorders	2 (5.0%)	3 (6.1%)	5 (5.6%)	6 (6.1%)
Grade 1	0	2 (4.1%)	2 (2.2%)	3 (3.0%)
Grade 2	2 (5.0%)	1 (2.0%)	3 (3.4%)	3 (3.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Sleep disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Sleep disorder	0	0	0	0
Grade 1	0	0	0	0
Suicidal and self-injurious behaviour	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Suicidal ideation	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Ear and labyrinth disorders	2 (8.3%)	3 (8.6%)	5 (8.5%)	8 (11.3%)
Grade 1	2 (8.3%)	1 (2.9%)	3 (5.1%)	4 (5.6%)
Grade 2	0	2 (5.7%)	2 (3.4%)	4 (5.6%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-ol.pdf 29AUG2023: 9:41

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Ear and labyrinth disorders (cont)				
Inner ear signs and symptoms	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Grade 2	0	0	0	0
Vertigo	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	2 (2.0%)
Grade 2	0	0	0	0
Motion sickness	0	0	0	0
Grade 1	0	0	0	0
Hearing losses	2 (5.0%)	2 (4.1%)	4 (4.5%)	4 (4.0%)
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	2 (5.0%)	1 (2.0%)	3 (3.4%)	3 (3.0%)
Hypoacusis	0	1 (2.0%)	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Ear and labyrinth disorders (cont)				
Inner ear signs and symptoms	2 (8.3%)	3 (8.6%)	5 (8.5%)	7 (9.9%)
Grade 1	2 (8.3%)	1 (2.9%)	3 (5.1%)	4 (5.6%)
Grade 2	0	2 (5.7%)	2 (3.4%)	3 (4.2%)
Vertigo	1 (4.2%)	3 (8.6%)	4 (6.8%)	6 (8.5%)
Grade 1	1 (4.2%)	1 (2.9%)	2 (3.4%)	3 (4.2%)
Grade 2	0	2 (5.7%)	2 (3.4%)	3 (4.2%)
Motion sickness	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Hearing losses	0	0	0	1 (1.4%)
Grade 1	0	0	0	0
Grade 2	0	0	0	1 (1.4%)
Hypoacusis	0	0	0	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Ear and labyrinth disorders (cont)				
Hearing losses (cont)				
Hypoacusis (cont)				
Grade 1	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	0	0	0
Deafness	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Deafness unilateral	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Sudden hearing loss	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 2	1 (2.5%)	0	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Ear and labyrinth disorders (cont)				
Hearing losses (cont)				
Hypoacusis (cont)				
Grade 1	0	0	0	0
Grade 2	0	0	0	1 (1.4%)
Deafness	0	0	0	0
Grade 2	0	0	0	0
Deafness unilateral	0	0	0	0
Grade 2	0	0	0	0
Sudden hearing loss	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Hepatobiliary disorders	3 (7.5%)	3 (6.1%)	6 (6.7%)	6 (6.1%)
Grade 1	2 (5.0%)	1 (2.0%)	3 (3.4%)	3 (3.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Cholecystitis and cholelithiasis	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Cholelithiasis	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Cholestasis and jaundice	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Grade 1	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Ocular icterus	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Hepatobiliary disorders	2 (8.3%)	2 (5.7%)	4 (6.8%)	4 (5.6%)
Grade 1	1 (4.2%)	2 (5.7%)	3 (5.1%)	3 (4.2%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 3	0	0	0	0
Cholecystitis and cholelithiasis	2 (8.3%)	1 (2.9%)	3 (5.1%)	3 (4.2%)
Grade 1	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Cholelithiasis	2 (8.3%)	1 (2.9%)	3 (5.1%)	3 (4.2%)
Grade 1	1 (4.2%)	1 (2.9%)	2 (3.4%)	2 (2.8%)
Grade 2	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Cholestasis and jaundice	0	0	0	0
Grade 1	0	0	0	0
Ocular icterus	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Hepatobiliary disorders (cont)				
Cholestasis and jaundice (cont)				
Ocular icterus (cont)				
Grade 1	1 (2.5%)	1 (2.0%)	2 (2.2%)	2 (2.0%)
Hepatic and hepatobiliary disorders NEC	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	0	0	0	0
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Liver disorder	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	0	0	0	0
Grade 3	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Hepatic vascular disorders	0	2 (4.1%)	2 (2.2%)	2 (2.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Hepatobiliary disorders (cont)				
Cholestasis and jaundice (cont)				
Ocular icterus (cont)				
Grade 1	0	0	0	0
Hepatic and hepatobiliary disorders NEC	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 3	0	0	0	0
Liver disorder	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 3	0	0	0	0
Hepatic vascular disorders	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Hepatobiliary disorders (cont)				
Hepatic vascular disorders (cont)				
Portal hypertension	0	2 (4.1%)	2 (2.2%)	2 (2.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Hepatic enzymes and function abnormalities	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Hepatic function abnormal	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Grade 1	1 (2.5%)	0	1 (1.1%)	1 (1.0%)
Hepatocellular damage and hepatitis NEC	0	0	0	0
Grade 1	0	0	0	0
Hepatic steatosis	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Hepatobiliary disorders (cont)				
Hepatic vascular disorders (cont)				
Portal hypertension	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Hepatic enzymes and function abnormalities	0	0	0	0
Grade 1	0	0	0	0
Hepatic function abnormal	0	0	0	0
Grade 1	0	0	0	0
Hepatocellular damage and hepatitis NEC	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Hepatic steatosis	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Reproductive system and breast disorders	2 (5.0%)	3 (6.1%)	5 (5.6%)	6 (6.1%)
Grade 1	0	0	0	1 (1.0%)
Grade 2	2 (5.0%)	2 (4.1%)	4 (4.5%)	4 (4.0%)
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Prostatic neoplasms and hypertrophy	2 (5.0%)	3 (6.1%)	5 (5.6%)	6 (6.1%)
Grade 1	0	0	0	1 (1.0%)
Grade 2	2 (5.0%)	2 (4.1%)	4 (4.5%)	4 (4.0%)
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Benign prostatic hyperplasia	2 (5.0%)	3 (6.1%)	5 (5.6%)	6 (6.1%)
Grade 1	0	0	0	1 (1.0%)
Grade 2	2 (5.0%)	2 (4.1%)	4 (4.5%)	4 (4.0%)
Grade 3	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Menopausal effects on the genitourinary tract	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Reproductive system and breast disorders	1 (4.2%)	1 (2.9%)	2 (3.4%)	4 (5.6%)
Grade 1	1 (4.2%)	0	1 (1.7%)	3 (4.2%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 3	0	0	0	0
Prostatic neoplasms and hypertrophy	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Benign prostatic hyperplasia	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Menopausal effects on the genitourinary tract	0	1 (2.9%)	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
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Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Reproductive system and breast disorders (cont)				
Menopausal effects on the genitourinary tract (cont) (cont)				
Grade 2	0	0	0	0
Postmenopausal haemorrhage	0	0	0	0
Grade 2	0	0	0	0
Uterine disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Uterine haemorrhage	0	0	0	0
Grade 1	0	0	0	0
Vulvovaginal disorders NEC	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Reproductive system and breast disorders (cont)				
Menopausal effects on the genitourinary tract (cont) (cont)				
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Postmenopausal haemorrhage	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Uterine disorders NEC	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Uterine haemorrhage	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Vulvovaginal disorders NEC	0	0	0	1 (1.4%)
Grade 1	0	0	0	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Reproductive system and breast disorders (cont)				
Vulvovaginal disorders NEC (cont)				
Vaginal haemorrhage	0	0	0	0
Grade 1	0	0	0	0
Vulvovaginal signs and symptoms	0	0	0	0
Grade 1	0	0	0	0
Vulvovaginal pain	0	0	0	0
Grade 1	0	0	0	0
Endocrine disorders	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	0	0	0
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 3	0	0	0	0
Acute and chronic thyroiditis	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Reproductive system and breast disorders (cont)				
Vulvovaginal disorders NEC (cont)				
Vaginal haemorrhage	0	0	0	1 (1.4%)
Grade 1	0	0	0	1 (1.4%)
Vulvovaginal signs and symptoms	0	0	0	1 (1.4%)
Grade 1	0	0	0	1 (1.4%)
Vulvovaginal pain	0	0	0	1 (1.4%)
Grade 1	0	0	0	1 (1.4%)
Endocrine disorders	0	2 (5.7%)	2 (3.4%)	2 (2.8%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 2	0	0	0	0
Grade 3	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Acute and chronic thyroiditis	0	1 (2.9%)	1 (1.7%)	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Endocrine disorders (cont)				
Acute and chronic thyroiditis (cont)				
(cont)				
Grade 3	0	0	0	0
Thyroiditis	0	0	0	0
Grade 3	0	0	0	0
Thyroid disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Goitre	0	0	0	0
Grade 1	0	0	0	0
Thyroid hypofunction disorders	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Endocrine disorders (cont)				
Acute and chronic thyroiditis (cont)				
(cont)				
Grade 3	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Thyroiditis	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 3	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Thyroid disorders NEC	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Goitre	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Grade 1	0	1 (2.9%)	1 (1.7%)	1 (1.4%)
Thyroid hypofunction disorders	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Endocrine disorders (cont)				
Thyroid hypofunction disorders (cont)				
Hypothyroidism	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Immune system disorders	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 1	0	0	0	0
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Allergies to foods, food additives, drugs and other chemicals	0	0	0	0
Grade 1	0	0	0	0
Drug hypersensitivity	0	0	0	0
Grade 1	0	0	0	0
Atopic disorders	0	1 (2.0%)	1 (1.1%)	1 (1.0%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-ol.pdf 29AUG2023: 9:41

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Endocrine disorders (cont)				
Thyroid hypofunction disorders (cont)				
Hypothyroidism	0	0	0	0
Grade 2	0	0	0	0
Immune system disorders	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 2	0	0	0	0
Allergies to foods, food additives, drugs and other chemicals	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Drug hypersensitivity	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Grade 1	1 (4.2%)	0	1 (1.7%)	1 (1.4%)
Atopic disorders	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019
Source: t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-ol.pdf 29AUG2023: 9:41

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

	Male			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=40)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=49)	OL Phase (Week 24 Onward) Total (N=89)	Overall Exposed to MMB Total (N=99)
Number of Subjects with Any Treatment-Emergent AE	39 (97.5%)	49 (100.0%)	88 (98.9%)	98 (99.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Immune system disorders (cont)				
Atopic disorders (cont)				
(cont)				
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Seasonal allergy	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Grade 2	0	1 (2.0%)	1 (1.1%)	1 (1.0%)
Surgical and medical procedures	0	0	0	0
Grade 1	0	0	0	0
Dental and gingival therapeutic procedures	0	0	0	0
Grade 1	0	0	0	0
Tooth extraction	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 3.0802: TEAEs by SOC, High-Level Term, and PT by Gender and Severity
Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period
SAF-Anemic Analysis Set

(Continued)	Female			
	OL Phase (Week 24 Onward) Continuing (MMB->MMB) (N=24)	OL Phase (Week 24 Onward) Switch (RUX->MMB) (N=35)	OL Phase (Week 24 Onward) Total (N=59)	Overall Exposed to MMB Total (N=71)
Number of Subjects with Any Treatment-Emergent AE	20 (83.3%)	34 (97.1%)	54 (91.5%)	68 (95.8%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Immune system disorders (cont)				
Atopic disorders (cont)				
(cont)				
Grade 2	0	0	0	0
Seasonal allergy	0	0	0	0
Grade 2	0	0	0	0
Surgical and medical procedures	0	0	0	1 (1.4%)
Grade 1	0	0	0	1 (1.4%)
Dental and gingival therapeutic procedures	0	0	0	1 (1.4%)
Grade 1	0	0	0	1 (1.4%)
Tooth extraction	0	0	0	1 (1.4%)
Grade 1	0	0	0	1 (1.4%)

SAF-Anemic Analysis includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term

Data Extracted: CRF data: 01JUL2019

Table 2.0201: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years	
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)
All Strata Combined: Splenic Response Rate at Week 24				
Responder, n(%)	1 (4.2%)	0	5 (11.9%)	2 (6.7%)
95% Exact CI	0.0011, 0.2112	0.0000, 0.3363	0.0398, 0.2563	0.0082, 0.2207
Proportion Difference - Stratified CMH Method (95% CI)	0.02 (-0.30, 0.35)		0.07 (-0.11, 0.24)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.04 (-0.14, 0.22)		0.05 (-0.09, 0.19)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.04 (-0.34, 0.42)		0.05 (-0.18, 0.28)	
Non-Responder, n(%)	23 (95.8%)	9 (100.0%)	37 (88.1%)	28 (93.3%)
Baseline spleen volume not available	0	0	0	0
Spleen volume at Week 24 not available	9 (37.5%)	3 (33.3%)	13 (31.0%)	6 (20.0%)
>0% spleen volume increase at Week 24	8 (33.3%)	3 (33.3%)	12 (28.6%)	12 (40.0%)
<35% spleen volume reduction at Week 24	14 (58.3%)	6 (66.7%)	24 (57.1%)	22 (73.3%)
Last participation date < Day 141 in RT phase	7 (29.2%)	3 (33.3%)	8 (19.0%)	4 (13.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/adhoc/2023/G-BA-Dec2023/prod/tfls/t-subgrp-srr24.sas V.03.05 Output file: t-subgrp-srr24-age.pdf 14DEC2023:10:50

Table 2.0201: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years	
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)
All Strata Combined: Splenic Response Rate at Week 12				
Responder, n(%)	0	0	3 (7.1%)	0
95% Exact CI	0.0000, 0.1425	0.0000, 0.3363	0.0150, 0.1948	0.0000, 0.1157
Proportion Difference - Stratified CMH Method (95% CI)	0.00 (-0.32, 0.32)		0.06 (-0.08, 0.21)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.00 (-0.16, 0.16)		0.07 (-0.02, 0.17)	
Proportion Difference - Unstratified Exact Method (95% CI)	NA		0.07 (-0.16, 0.30)	
Non-Responder, n(%)	24 (100.0%)	9 (100.0%)	39 (92.9%)	30 (100.0%)
Spleen volume at Week 12 not available	6 (25.0%)	4 (44.4%)	7 (16.7%)	4 (13.3%)
>0% spleen volume increase at Week 12	7 (29.2%)	3 (33.3%)	17 (40.5%)	13 (43.3%)
<35% spleen volume reduction at Week 12	18 (75.0%)	5 (55.6%)	32 (76.2%)	26 (86.7%)
Last participation date < Day 57 in RT phase	1 (4.2%)	1 (11.1%)	4 (9.5%)	3 (10.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 25JUN2019

Table 2.0208: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by DIPSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk	
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)
All Strata Combined: Splenic Response Rate at Week 24				
Responder, n(%)	5 (10.2%)	2 (6.5%)	1 (5.9%)	0
95% Exact CI	0.0340, 0.2223	0.0079, 0.2142	0.0015, 0.2869	0.0000, 0.3694
Proportion Difference - Stratified CMH Method (95% CI)	0.02 (-0.15, 0.18)		0.05 (-0.23, 0.33)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.04 (-0.09, 0.17)		0.06 (-0.16, 0.28)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.04 (-0.19, 0.26)		0.06 (-0.34, 0.45)	
Non-Responder, n(%)	44 (89.8%)	29 (93.5%)	16 (94.1%)	8 (100.0%)
Baseline spleen volume not available	0	0	0	0
Spleen volume at Week 24 not available	14 (28.6%)	7 (22.6%)	8 (47.1%)	2 (25.0%)
>0% spleen volume increase at Week 24	16 (32.7%)	12 (38.7%)	4 (23.5%)	3 (37.5%)
<35% spleen volume reduction at Week 24	30 (61.2%)	22 (71.0%)	8 (47.1%)	6 (75.0%)
Last participation date < Day 141 in RT phase	9 (18.4%)	6 (19.4%)	6 (35.3%)	1 (12.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
DIPSS = Dynamic International Prognostic Scoring System;
CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 25JUN2019

Table 2.0208: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by DIPSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk	
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)
All Strata Combined: Splenic Response Rate at Week 12				
Responder, n(%)	3 (6.1%)	0	0	0
95% Exact CI	0.0128, 0.1687	0.0000, 0.1122	0.0000, 0.1951	0.0000, 0.3694
Proportion Difference - Stratified CMH Method (95% CI)	0.05 (-0.08, 0.19)		0.00 (-0.28, 0.28)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.06 (-0.02, 0.15)		0.00 (-0.19, 0.19)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.06 (-0.16, 0.28)		NA	
Non-Responder, n(%)	46 (93.9%)	31 (100.0%)	17 (100.0%)	8 (100.0%)
Spleen volume at Week 12 not available	8 (16.3%)	7 (22.6%)	5 (29.4%)	1 (12.5%)
>0% spleen volume increase at Week 12	17 (34.7%)	13 (41.9%)	7 (41.2%)	3 (37.5%)
<35% spleen volume reduction at Week 12	38 (77.6%)	24 (77.4%)	12 (70.6%)	7 (87.5%)
Last participation date < Day 57 in RT phase	2 (4.1%)	3 (9.7%)	3 (17.6%)	1 (12.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
DIPSS = Dynamic International Prognostic Scoring System;
CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 25JUN2019

Table 2.0207: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by Hemoglobin Level at Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	< 8 g/dL		>= 8 g/dL	
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)
All Strata Combined: Splenic Response Rate at Week 24				
Responder, n(%)	4 (14.8%)	0	2 (5.1%)	2 (6.1%)
95% Exact CI	0.0419, 0.3373	0.0000, 0.4593	0.0063, 0.1732	0.0074, 0.2023
Proportion Difference - Stratified CMH Method (95% CI)	0.14 (-0.21, 0.50)		-0.02 (-0.17, 0.14)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.15 (-0.12, 0.41)		-0.01 (-0.13, 0.11)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.15 (-0.30, 0.58)		-0.01 (-0.24, 0.22)	
Non-Responder, n(%)	23 (85.2%)	6 (100.0%)	37 (94.9%)	31 (93.9%)
Baseline spleen volume not available	0	0	0	0
Spleen volume at Week 24 not available	8 (29.6%)	2 (33.3%)	14 (35.9%)	7 (21.2%)
>0% spleen volume increase at Week 24	7 (25.9%)	2 (33.3%)	13 (33.3%)	13 (39.4%)
<35% spleen volume reduction at Week 24	15 (55.6%)	4 (66.7%)	23 (59.0%)	24 (72.7%)
Last participation date < Day 141 in RT phase	6 (22.2%)	2 (33.3%)	9 (23.1%)	5 (15.2%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/adhoc/2023/G-BA-Dec2023/prod/tfls/t-subgrp-srr24.sas V.03.05 Output file: t-subgrp-srr24-hgb.pdf 14DEC2023:11:02

Table 2.0207: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by Hemoglobin Level at Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	< 8 g/dL		>= 8 g/dL	
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)
All Strata Combined: Splenic Response Rate at Week 12				
Responder, n(%)	3 (11.1%)	0	0	0
95% Exact CI	0.0235, 0.2916	0.0000, 0.4593	0.0000, 0.0903	0.0000, 0.1058
Proportion Difference - Stratified CMH Method (95% CI)	0.11 (-0.24, 0.46)		0.00 (-0.11, 0.11)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.11 (-0.15, 0.37)		0.00 (-0.05, 0.05)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.11 (-0.34, 0.54)		NA	
Non-Responder, n(%)	24 (88.9%)	6 (100.0%)	39 (100.0%)	33 (100.0%)
Spleen volume at Week 12 not available	4 (14.8%)	2 (33.3%)	9 (23.1%)	6 (18.2%)
>0% spleen volume increase at Week 12	11 (40.7%)	3 (50.0%)	13 (33.3%)	13 (39.4%)
<35% spleen volume reduction at Week 12	20 (74.1%)	4 (66.7%)	30 (76.9%)	27 (81.8%)
Last participation date < Day 57 in RT phase	2 (7.4%)	2 (33.3%)	3 (7.7%)	2 (6.1%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 25JUN2019

Table 2.0212: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by Highest Dose of Ruxolitinib Received Since Randomization
Randomized Treatment Phase
ITT-Anemic Analysis Set on BAT Treatment Group

	< 20 mg BID (N=28)	>= 20 mg BID (N=6)	Not Taking Rux (N=5)
Splenic Response Rate at Week 24			
Responder, n(%)	1 (3.6%)	1 (16.7%)	0
95% Exact CI	0.0009, 0.1835	0.0042, 0.6412	0.0000, 0.5218
Non-Responder, n(%)	27 (96.4%)	5 (83.3%)	5 (100.0%)
Baseline spleen volume not available	0	0	0
Spleen volume at week 24 not available	7 (25.0%)	1 (16.7%)	1 (20.0%)
>0% spleen volume increase at Week 24	8 (28.6%)	3 (50.0%)	4 (80.0%)
<35% spleen volume reduction at week 24	20 (71.4%)	4 (66.7%)	4 (80.0%)
Last participation date < Day 141 in RT phase	6 (21.4%)	1 (16.7%)	0
Splenic Response Rate at Week 12			
Responder, n(%)	0	0	0
95% Exact CI	0.0000, 0.1234	0.0000, 0.4593	0.0000, 0.5218
Non-Responder, n(%)	28 (100.0%)	6 (100.0%)	5 (100.0%)
Baseline spleen volume not available	0	0	0
Spleen volume at week 12 not available	6 (21.4%)	1 (16.7%)	1 (20.0%)
>0% spleen volume increase at Week 12	9 (32.1%)	4 (66.7%)	3 (60.0%)
<35% spleen volume reduction at week 12	22 (78.6%)	5 (83.3%)	4 (80.0%)
Last participation date < Day 57 in RT phase	4 (14.3%)	0	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 25JUN2019

Table 2.0209: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by JAKV617F Mutation
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Yes		No	
	MMB (N=43)	BAT (N=27)	MMB (N=22)	BAT (N=9)
All Strata Combined: Splenic Response Rate at Week 24				
Responder, n(%)	3 (7.0%)	2 (7.4%)	3 (13.6%)	0
95% Exact CI	0.0146, 0.1906	0.0091, 0.2429	0.0291, 0.3491	0.0000, 0.3363
Proportion Difference - Stratified CMH Method (95% CI)	0.00 (-0.18, 0.18)		0.12 (-0.15, 0.40)	
Proportion Difference - Unstratified CMH Method (95% CI)	-0.00 (-0.14, 0.13)		0.14 (-0.08, 0.35)	
Proportion Difference - Unstratified Exact Method (95% CI)	-0.00 (-0.24, 0.23)		0.14 (-0.25, 0.50)	
Non-Responder, n(%)	40 (93.0%)	25 (92.6%)	19 (86.4%)	9 (100.0%)
Baseline spleen volume not available	0	0	0	0
Spleen volume at Week 24 not available	17 (39.5%)	5 (18.5%)	5 (22.7%)	3 (33.3%)
>0% spleen volume increase at Week 24	12 (27.9%)	9 (33.3%)	7 (31.8%)	5 (55.6%)
<35% spleen volume reduction at Week 24	23 (53.5%)	20 (74.1%)	14 (63.6%)	6 (66.7%)
Last participation date < Day 141 in RT phase	13 (30.2%)	4 (14.8%)	2 (9.1%)	3 (33.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/adhoc/2023/G-BA-Dec2023/prod/tfls/t-subgrp-srr24.sas V.03.05 Output file: t-subgrp-srr24-jak.pdf 14DEC2023:11:02

Table 2.0209: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by JAKV617F Mutation
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Yes		No	
	MMB (N=43)	BAT (N=27)	MMB (N=22)	BAT (N=9)
All Strata Combined: Splenic Response Rate at Week 12				
Responder, n(%)	2 (4.7%)	0	1 (4.5%)	0
95% Exact CI	0.0057, 0.1581	0.0000, 0.1277	0.0012, 0.2284	0.0000, 0.3363
Proportion Difference - Stratified CMH Method (95% CI)	0.04 (-0.10, 0.18)		0.06 (-0.21, 0.33)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.05 (-0.04, 0.13)		0.05 (-0.14, 0.23)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.05 (-0.19, 0.28)		0.05 (-0.34, 0.42)	
Non-Responder, n(%)	41 (95.3%)	27 (100.0%)	21 (95.5%)	9 (100.0%)
Spleen volume at Week 12 not available	12 (27.9%)	5 (18.5%)	1 (4.5%)	3 (33.3%)
>0% spleen volume increase at Week 12	16 (37.2%)	10 (37.0%)	8 (36.4%)	5 (55.6%)
<35% spleen volume reduction at Week 12	29 (67.4%)	22 (81.5%)	20 (90.9%)	6 (66.7%)
Last participation date < Day 57 in RT phase	5 (11.6%)	2 (7.4%)	0	2 (22.2%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/adhoc/2023/G-BA-Dec2023/prod/tfls/t-subgrp-srr24.sas V.03.05 Output file: t-subgrp-srr24-jak.pdf 14DEC2023:11:02

Table 2.0211: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by Disease Type
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis		Post-PV Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)	MMB (N=8)	BAT (N=8)
All Strata Combined: Splenic Response Rate at Week 24						
Responder, n(%)	3 (6.7%)	1 (4.3%)	3 (23.1%)	0	0	1 (12.5%)
95% Exact CI	0.0140, 0.1827	0.0011, 0.2195	0.0504, 0.5381	0.0000, 0.3694	0.0000, 0.3694	0.0032, 0.5265
Proportion Difference - Stratified CMH Method (95% CI)	0.02 (-0.14, 0.18)		0.31 (-0.08, 0.70)		-0.22 (-0.79, 0.35)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.02 (-0.10, 0.15)		0.23 (-0.07, 0.53)		-0.13 (-0.45, 0.20)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.02 (-0.23, 0.27)		0.23 (-0.21, 0.62)		-0.13 (-0.60, 0.40)	
Non-Responder, n(%)	42 (93.3%)	22 (95.7%)	10 (76.9%)	8 (100.0%)	8 (100.0%)	7 (87.5%)
Baseline spleen volume not available	0	0	0	0	0	0
Spleen volume at Week 24 not available	16 (35.6%)	5 (21.7%)	4 (30.8%)	3 (37.5%)	2 (25.0%)	1 (12.5%)
>0% spleen volume increase at Week 24	13 (28.9%)	12 (52.2%)	4 (30.8%)	2 (25.0%)	3 (37.5%)	1 (12.5%)
<35% spleen volume reduction at Week 24	26 (57.8%)	17 (73.9%)	6 (46.2%)	5 (62.5%)	6 (75.0%)	6 (75.0%)
Last participation date < Day 141 in RT phase	10 (22.2%)	4 (17.4%)	3 (23.1%)	2 (25.0%)	2 (25.0%)	1 (12.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/adhoc/2023/G-BA-Dec2023/prod/tfls/t-subgrp-srr24.sas V.03.05 Output file: t-subgrp-srr24-mf.pdf 14DEC2023:11:03

Table 2.0211: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by Disease Type
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis		Post-PV Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)	MMB (N=8)	BAT (N=8)
All Strata Combined: Splenic Response Rate at Week 12						
Responder, n(%)	1 (2.2%)	0	2 (15.4%)	0	0	0
95% Exact CI	0.0006, 0.1177	0.0000, 0.1482	0.0192, 0.4545	0.0000, 0.3694	0.0000, 0.3694	0.0000, 0.3694
Proportion Difference - Stratified CMH Method (95% CI)	0.03 (-0.12, 0.17)		0.13 (-0.26, 0.52)		0.00 (-0.49, 0.49)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.02 (-0.06, 0.10)		0.15 (-0.12, 0.43)		0.00 (-0.24, 0.24)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.02 (-0.23, 0.27)		0.15 (-0.29, 0.56)		NA	
Non-Responder, n(%)	44 (97.8%)	23 (100.0%)	11 (84.6%)	8 (100.0%)	8 (100.0%)	8 (100.0%)
Spleen volume at Week 12 not available	10 (22.2%)	5 (21.7%)	3 (23.1%)	2 (25.0%)	0	1 (12.5%)
>0% spleen volume increase at Week 12	16 (35.6%)	12 (52.2%)	5 (38.5%)	3 (37.5%)	3 (37.5%)	1 (12.5%)
<35% spleen volume reduction at Week 12	34 (75.6%)	18 (78.3%)	8 (61.5%)	6 (75.0%)	8 (100.0%)	7 (87.5%)
Last participation date < Day 57 in RT phase	4 (8.9%)	2 (8.7%)	1 (7.7%)	1 (12.5%)	0	1 (12.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/adhoc/2023/G-BA-Dec2023/prod/tfls/t-subgrp-srr24.sas V.03.05 Output file: t-subgrp-srr24-mf.pdf 14DEC2023:11:03

Table 2.0203: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by Race
Randomized Treatment Phase
ITT-Anemic Analysis Set

	White		All Other Races	
	MMB (N=54)	BAT (N=34)	MMB (N=5)	BAT (N=0)
All Strata Combined: Splenic Response Rate at Week 24				
Responder, n(%)	5 (9.3%)	2 (5.9%)	0	0
95% Exact CI	0.0308, 0.2030	0.0072, 0.1968	0.0000, 0.5218	NA, NA
Proportion Difference - Stratified CMH Method (95% CI)	0.03 (-0.12, 0.17)		NA	
Proportion Difference - Unstratified CMH Method (95% CI)	0.03 (-0.09, 0.15)		NA	
Proportion Difference - Unstratified Exact Method (95% CI)	0.03 (-0.18, 0.25)		NA	
Non-Responder, n(%)	49 (90.7%)	32 (94.1%)	5 (100.0%)	0
Baseline spleen volume not available	0	0	0	0
Spleen volume at Week 24 not available	17 (31.5%)	9 (26.5%)	2 (40.0%)	0
>0% spleen volume increase at Week 24	18 (33.3%)	14 (41.2%)	2 (40.0%)	0
<35% spleen volume reduction at Week 24	32 (59.3%)	23 (67.6%)	3 (60.0%)	0
Last participation date < Day 141 in RT phase	12 (22.2%)	7 (20.6%)	2 (40.0%)	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 25JUN2019

Table 2.0203: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by Race
Randomized Treatment Phase
ITT-Anemic Analysis Set

	White		All Other Races	
	MMB (N=54)	BAT (N=34)	MMB (N=5)	BAT (N=0)
All Strata Combined: Splenic Response Rate at Week 12				
Responder, n(%)	2 (3.7%)	0	0	0
95% Exact CI	0.0045, 0.1275	0.0000, 0.1028	0.0000, 0.5218	NA, NA
Proportion Difference - Stratified CMH Method (95% CI)	0.03 (-0.07, 0.13)		NA	
Proportion Difference - Unstratified CMH Method (95% CI)	0.04 (-0.03, 0.11)		NA	
Proportion Difference - Unstratified Exact Method (95% CI)	0.04 (-0.18, 0.25)		NA	
Non-Responder, n(%)	52 (96.3%)	34 (100.0%)	5 (100.0%)	0
Spleen volume at Week 12 not available	11 (20.4%)	8 (23.5%)	1 (20.0%)	0
>0% spleen volume increase at Week 12	20 (37.0%)	14 (41.2%)	2 (40.0%)	0
<35% spleen volume reduction at Week 12	41 (75.9%)	26 (76.5%)	4 (80.0%)	0
Last participation date < Day 57 in RT phase	3 (5.6%)	4 (11.8%)	1 (20.0%)	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 25JUN2019

Table 2.0210: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by Duration of Ruxolitinib Received Prior to Randomization
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<12 weeks		>=12 weeks	
	MMB (N=13)	BAT (N=8)	MMB (N=47)	BAT (N=24)
All Strata Combined: Splenic Response Rate at Week 24				
Responder, n(%)	0	0	5 (10.6%)	1 (4.2%)
95% Exact CI	0.0000, 0.2471	0.0000, 0.3694	0.0355, 0.2310	0.0011, 0.2112
Proportion Difference - Stratified CMH Method (95% CI)	0.00 (-0.28, 0.28)		0.04 (-0.13, 0.22)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.00 (-0.20, 0.20)		0.06 (-0.07, 0.20)	
Proportion Difference - Unstratified Exact Method (95% CI)	NA		0.06 (-0.18, 0.30)	
Non-Responder, n(%)	13 (100.0%)	8 (100.0%)	42 (89.4%)	23 (95.8%)
Baseline spleen volume not available	0	0	0	0
Spleen volume at Week 24 not available	4 (30.8%)	3 (37.5%)	16 (34.0%)	4 (16.7%)
>0% spleen volume increase at Week 24	3 (23.1%)	3 (37.5%)	16 (34.0%)	10 (41.7%)
<35% spleen volume reduction at Week 24	9 (69.2%)	5 (62.5%)	26 (55.3%)	19 (79.2%)
Last participation date < Day 141 in RT phase	3 (23.1%)	3 (37.5%)	10 (21.3%)	3 (12.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 25JUN2019

Table 2.0210: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by Duration of Ruxolitinib Received Prior to Randomization
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<12 weeks		>=12 weeks	
	MMB (N=13)	BAT (N=8)	MMB (N=47)	BAT (N=24)
All Strata Combined: Splenic Response Rate at Week 12				
Responder, n(%)	0	0	3 (6.4%)	0
95% Exact CI	0.0000, 0.2471	0.0000, 0.3694	0.0134, 0.1754	0.0000, 0.1425
Proportion Difference - Stratified CMH Method (95% CI)	0.00 (-0.28, 0.28)		0.06 (-0.09, 0.20)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.00 (-0.20, 0.20)		0.06 (-0.03, 0.16)	
Proportion Difference - Unstratified Exact Method (95% CI)	NA		0.06 (-0.18, 0.30)	
Non-Responder, n(%)	13 (100.0%)	8 (100.0%)	44 (93.6%)	24 (100.0%)
Spleen volume at Week 12 not available	2 (15.4%)	4 (50.0%)	10 (21.3%)	3 (12.5%)
>0% spleen volume increase at Week 12	5 (38.5%)	4 (50.0%)	18 (38.3%)	10 (41.7%)
<35% spleen volume reduction at Week 12	11 (84.6%)	4 (50.0%)	34 (72.3%)	21 (87.5%)
Last participation date < Day 57 in RT phase	2 (15.4%)	2 (25.0%)	3 (6.4%)	2 (8.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 25JUN2019

Table 2.0202: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female	
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)
All Strata Combined: Splenic Response Rate at Week 24				
Responder, n(%)	4 (7.7%)	1 (5.6%)	2 (14.3%)	1 (4.8%)
95% Exact CI	0.0214, 0.1854	0.0014, 0.2729	0.0178, 0.4281	0.0012, 0.2382
Proportion Difference - Stratified CMH Method (95% CI)	0.02 (-0.17, 0.22)		0.02 (-0.26, 0.30)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.02 (-0.13, 0.17)		0.10 (-0.14, 0.33)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.02 (-0.24, 0.29)		0.10 (-0.25, 0.43)	
Non-Responder, n(%)	48 (92.3%)	17 (94.4%)	12 (85.7%)	20 (95.2%)
Baseline spleen volume not available	0	0	0	0
Spleen volume at Week 24 not available	19 (36.5%)	6 (33.3%)	3 (21.4%)	3 (14.3%)
>0% spleen volume increase at Week 24	16 (30.8%)	7 (38.9%)	4 (28.6%)	8 (38.1%)
<35% spleen volume reduction at Week 24	29 (55.8%)	11 (61.1%)	9 (64.3%)	17 (81.0%)
Last participation date < Day 141 in RT phase	11 (21.2%)	4 (22.2%)	4 (28.6%)	3 (14.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/adhoc/2023/G-BA-Dec2023/prod/tfls/t-subgrp-srr24.sas V.03.05 Output file: t-subgrp-srr24-sex.pdf 14DEC2023:11:00

Table 2.0202: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female	
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)
All Strata Combined: Splenic Response Rate at Week 12				
Responder, n(%)	2 (3.8%)	0	1 (7.1%)	0
95% Exact CI	0.0047, 0.1321	0.0000, 0.1853	0.0018, 0.3387	0.0000, 0.1611
Proportion Difference - Stratified CMH Method (95% CI)	0.04 (-0.13, 0.21)		0.06 (-0.17, 0.28)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.04 (-0.06, 0.13)		0.07 (-0.10, 0.25)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.04 (-0.23, 0.30)		0.07 (-0.27, 0.40)	
Non-Responder, n(%)	50 (96.2%)	18 (100.0%)	13 (92.9%)	21 (100.0%)
Spleen volume at Week 12 not available	11 (21.2%)	5 (27.8%)	2 (14.3%)	3 (14.3%)
>0% spleen volume increase at Week 12	17 (32.7%)	7 (38.9%)	7 (50.0%)	9 (42.9%)
<35% spleen volume reduction at Week 12	39 (75.0%)	13 (72.2%)	11 (78.6%)	18 (85.7%)
Last participation date < Day 57 in RT phase	4 (7.7%)	3 (16.7%)	1 (7.1%)	1 (4.8%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/adhoc/2023/G-BA-Dec2023/prod/tfls/t-subgrp-srr24.sas V.03.05 Output file: t-subgrp-srr24-sex.pdf 14DEC2023:11:00

Table 2.0205: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by Spleen Volume at Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3	
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)
All Strata Combined: Splenic Response Rate at Week 24				
Responder, n(%)	3 (10.7%)	2 (8.3%)	3 (7.9%)	0
95% Exact CI	0.0227, 0.2823	0.0103, 0.2700	0.0166, 0.2138	0.0000, 0.2180
Proportion Difference - Stratified CMH Method (95% CI)	0.02 (-0.19, 0.23)		0.06 (-0.20, 0.32)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.02 (-0.15, 0.20)		0.08 (-0.05, 0.21)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.02 (-0.25, 0.29)		0.08 (-0.22, 0.37)	
Non-Responder, n(%)	25 (89.3%)	22 (91.7%)	35 (92.1%)	15 (100.0%)
Baseline spleen volume not available	0	0	0	0
Spleen volume at Week 24 not available	5 (17.9%)	3 (12.5%)	17 (44.7%)	6 (40.0%)
>0% spleen volume increase at Week 24	13 (46.4%)	11 (45.8%)	7 (18.4%)	4 (26.7%)
<35% spleen volume reduction at Week 24	20 (71.4%)	19 (79.2%)	18 (47.4%)	9 (60.0%)
Last participation date < Day 141 in RT phase	4 (14.3%)	2 (8.3%)	11 (28.9%)	5 (33.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/adhoc/2023/G-BA-Dec2023/prod/tfls/t-subgrp-srr24.sas V.03.05 Output file: t-subgrp-srr24-svb.pdf 14DEC2023:11:01

Table 2.0205: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by Spleen Volume at Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3	
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)
All Strata Combined: Splenic Response Rate at Week 12				
Responder, n(%)	1 (3.6%)	0	2 (5.3%)	0
95% Exact CI	0.0009, 0.1835	0.0000, 0.1425	0.0064, 0.1775	0.0000, 0.2180
Proportion Difference - Stratified CMH Method (95% CI)	0.03 (-0.14, 0.20)		0.05 (-0.21, 0.31)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.04 (-0.07, 0.14)		0.05 (-0.07, 0.17)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.04 (-0.24, 0.31)		0.05 (-0.24, 0.34)	
Non-Responder, n(%)	27 (96.4%)	24 (100.0%)	36 (94.7%)	15 (100.0%)
Spleen volume at Week 12 not available	3 (10.7%)	3 (12.5%)	10 (26.3%)	5 (33.3%)
>0% spleen volume increase at Week 12	13 (46.4%)	13 (54.2%)	11 (28.9%)	3 (20.0%)
<35% spleen volume reduction at Week 12	24 (85.7%)	21 (87.5%)	26 (68.4%)	10 (66.7%)
Last participation date < Day 57 in RT phase	1 (3.6%)	2 (8.3%)	4 (10.5%)	2 (13.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 25JUN2019

Table 2.0204: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by Transfusion Dependence at Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Yes		No	
	MMB (N=52)	BAT (N=25)	MMB (N=14)	BAT (N=14)
All Strata Combined: Splenic Response Rate at Week 24				
Responder, n(%)	5 (9.6%)	1 (4.0%)	1 (7.1%)	1 (7.1%)
95% Exact CI	0.0320, 0.2103	0.0010, 0.2035	0.0018, 0.3387	0.0018, 0.3387
Proportion Difference - Stratified CMH Method (95% CI)	0.05 (-0.09, 0.19)		-0.00 (-0.27, 0.27)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.06 (-0.07, 0.18)		0.00 (-0.23, 0.23)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.06 (-0.19, 0.29)		0.00 (-0.39, 0.39)	
Non-Responder, n(%)	47 (90.4%)	24 (96.0%)	13 (92.9%)	13 (92.9%)
Baseline spleen volume not available	0	0	0	0
Spleen volume at Week 24 not available	15 (28.8%)	6 (24.0%)	7 (50.0%)	3 (21.4%)
>0% spleen volume increase at Week 24	17 (32.7%)	10 (40.0%)	3 (21.4%)	5 (35.7%)
<35% spleen volume reduction at Week 24	32 (61.5%)	18 (72.0%)	6 (42.9%)	10 (71.4%)
Last participation date < Day 141 in RT phase	9 (17.3%)	4 (16.0%)	6 (42.9%)	3 (21.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Stratification factor is total symptom score (< 18 vs. >=18) at baseline.
CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 25JUN2019

Table 2.0204: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by Transfusion Dependence at Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Yes		No	
	MMB (N=52)	BAT (N=25)	MMB (N=14)	BAT (N=14)
All Strata Combined: Splenic Response Rate at Week 12				
Responder, n(%)	3 (5.8%)	0	0	0
95% Exact CI	0.0121, 0.1595	0.0000, 0.1372	0.0000, 0.2316	0.0000, 0.2316
Proportion Difference - Stratified CMH Method (95% CI)	0.06 (-0.05, 0.16)		0.00 (-0.20, 0.20)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.06 (-0.03, 0.15)		0.00 (-0.14, 0.14)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.06 (-0.18, 0.30)		NA	
Non-Responder, n(%)	49 (94.2%)	25 (100.0%)	14 (100.0%)	14 (100.0%)
Spleen volume at Week 12 not available	8 (15.4%)	5 (20.0%)	5 (35.7%)	3 (21.4%)
>0% spleen volume increase at Week 12	21 (40.4%)	10 (40.0%)	3 (21.4%)	6 (42.9%)
<35% spleen volume reduction at Week 12	41 (78.8%)	20 (80.0%)	9 (64.3%)	11 (78.6%)
Last participation date < Day 57 in RT phase	2 (3.8%)	4 (16.0%)	3 (21.4%)	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Stratification factor is total symptom score (< 18 vs. >=18) at baseline.
CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 25JUN2019

Table 2.0206: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by TSS at Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18	
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)
All Strata Combined: Splenic Response Rate at Week 24				
Responder, n(%)	4 (9.5%)	2 (10.0%)	2 (8.3%)	0
95% Exact CI	0.0266, 0.2262	0.0123, 0.3170	0.0103, 0.2700	0.0000, 0.1765
Proportion Difference - Stratified CMH Method (95% CI)	-0.01 (-0.19, 0.17)		0.09 (-0.08, 0.26)	
Proportion Difference - Unstratified CMH Method (95% CI)	-0.00 (-0.18, 0.17)		0.08 (-0.06, 0.23)	
Proportion Difference - Unstratified Exact Method (95% CI)	-0.00 (-0.27, 0.26)		0.08 (-0.21, 0.37)	
Non-Responder, n(%)	38 (90.5%)	18 (90.0%)	22 (91.7%)	19 (100.0%)
Baseline spleen volume not available	0	0	0	0
Spleen volume at Week 24 not available	13 (31.0%)	4 (20.0%)	9 (37.5%)	5 (26.3%)
>0% spleen volume increase at Week 24	15 (35.7%)	8 (40.0%)	5 (20.8%)	7 (36.8%)
<35% spleen volume reduction at Week 24	25 (59.5%)	14 (70.0%)	13 (54.2%)	14 (73.7%)
Last participation date < Day 141 in RT phase	8 (19.0%)	3 (15.0%)	7 (29.2%)	4 (21.1%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Stratification factor is transfusion dependence (Yes vs. No) at baseline.
CMH = Cochran-Mantel-Haenszel;
TSS = Total Symptom Score;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/adhoc/2023/G-BA-Dec2023/prod/tfls/t-subgrp-srr24.sas V.03.05 Output file: t-subgrp-srr24-tss.pdf 14DEC2023:11:01

Table 2.0206: Subgroup Analysis of Splenic Response Rate at Week 24 and at Week 12 by TSS at Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18	
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)
All Strata Combined: Splenic Response Rate at Week 12				
Responder, n(%)	2 (4.8%)	0	1 (4.2%)	0
95% Exact CI	0.0058, 0.1616	0.0000, 0.1684	0.0011, 0.2112	0.0000, 0.1765
Proportion Difference - Stratified CMH Method (95% CI)	0.04 (-0.08, 0.17)		0.04 (-0.11, 0.19)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.05 (-0.05, 0.15)		0.04 (-0.08, 0.16)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.05 (-0.22, 0.31)		0.04 (-0.25, 0.33)	
Non-Responder, n(%)	40 (95.2%)	20 (100.0%)	23 (95.8%)	19 (100.0%)
Spleen volume at Week 12 not available	7 (16.7%)	2 (10.0%)	6 (25.0%)	6 (31.6%)
>0% spleen volume increase at Week 12	18 (42.9%)	10 (50.0%)	6 (25.0%)	6 (31.6%)
<35% spleen volume reduction at Week 12	33 (78.6%)	18 (90.0%)	17 (70.8%)	13 (68.4%)
Last participation date < Day 57 in RT phase	2 (4.8%)	2 (10.0%)	3 (12.5%)	2 (10.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Stratification factor is transfusion dependence (Yes vs. No) at baseline.
CMH = Cochran-Mantel-Haenszel;
TSS = Total Symptom Score;

Data Extracted: CRF data: 25JUN2019

Table 2.1601: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years	
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)
Total Symptom Score Status				
Missing TSS at baseline (excluded from rate calculation)	0	0	0	0
TSS = 0 at baseline	0	2 (22.2%)	1 (2.4%)	1 (3.3%)
TSS > 0 at baseline	24 (100.0%)	7 (77.8%)	41 (97.6%)	29 (96.7%)
Response Rate of Total Symptom Score at Week 24				
Subjects Evaluable at Week 24, n	24	9	41	29
TSS = 0 at baseline and TSS >0 or missing at Week 24	0	2 (22.2%)	0	0
Responder, n(%)	5 (20.8%)	0	16 (39.0%)	1 (3.4%)
95% Exact CI	0.0713, 0.4215	0.0000, 0.3363	0.2420, 0.5550	0.0009, 0.1776
Proportion Difference - Stratified CMH Method (95% CI)	0.23 (-0.13, 0.59)		0.36 (0.16, 0.56)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.21 (-0.02, 0.44)		0.36 (0.18, 0.53)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.21 (-0.18, 0.57)		0.36 (0.12, 0.56)	
Non-Responder, n(%)	19 (79.2%)	9 (100.0%)	25 (61.0%)	28 (96.6%)
Last participation date < Day 162 in RT phase	8 (33.3%)	3 (33.3%)	10 (24.4%)	4 (13.8%)
Last participation date >= Day 162 and TSS at Week 24 not available	0	1 (11.1%)	1 (2.4%)	2 (6.9%)
>0% increase from baseline at Week 24	6 (25.0%)	4 (44.4%)	9 (22.0%)	13 (44.8%)
<50% reduction from baseline at Week 24	11 (45.8%)	4 (44.4%)	14 (34.1%)	22 (75.9%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-age.pdf 24AUG2023:16:25

Table 2.1601: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years	
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)
Response Rate of Total Symptom Score at Week 12				
Subjects Evaluable at Week 12, n	24	8	41	30
TSS = 0 at baseline and TSS >0 or missing at Week 12	0	1 (12.5%)	0	1 (3.3%)
Responder, n(%)	4 (16.7%)	0	15 (36.6%)	3 (10.0%)
95% Exact CI	0.0474, 0.3738	0.0000, 0.3694	0.2212, 0.5306	0.0211, 0.2653
Proportion Difference - Stratified CMH Method (95% CI)	0.20 (-0.11, 0.51)		0.25 (0.03, 0.47)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.17 (-0.06, 0.40)		0.27 (0.08, 0.45)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.17 (-0.25, 0.55)		0.27 (0.03, 0.48)	
Non-Responder, n(%)	20 (83.3%)	8 (100.0%)	26 (63.4%)	27 (90.0%)
Last participation date < Day 78 in RT phase	2 (8.3%)	3 (37.5%)	5 (12.2%)	3 (10.0%)
Last participation date >= Day 78 and TSS at Week 12 not available	1 (4.2%)	0	0	0
>0% increase from baseline at Week 12	9 (37.5%)	4 (50.0%)	10 (24.4%)	12 (40.0%)
<50% reduction from baseline at Week 12	17 (70.8%)	4 (50.0%)	21 (51.2%)	23 (76.7%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-age.pdf 24AUG2023:16:25

Table 2.1608: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by DIPSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk	
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)
Total Symptom Score Status				
Missing TSS at baseline (excluded from rate calculation)	0	0	0	0
TSS = 0 at baseline	1 (2.0%)	3 (9.7%)	0	0
TSS > 0 at baseline	48 (98.0%)	28 (90.3%)	17 (100.0%)	8 (100.0%)
Response Rate of Total Symptom Score at Week 24				
Subjects Evaluable at Week 24, n	48	30	17	8
TSS = 0 at baseline and TSS >0 or missing at Week 24	0	2 (6.7%)	0	0
Responder, n(%)	14 (29.2%)	1 (3.3%)	7 (41.2%)	0
95% Exact CI	0.1695, 0.4406	0.0008, 0.1722	0.1844, 0.6708	0.0000, 0.3694
Proportion Difference - Stratified CMH Method (95% CI)	0.24 (0.07, 0.42)		0.43 (0.06, 0.80)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.26 (0.11, 0.41)		0.41 (0.12, 0.71)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.26 (0.03, 0.47)		0.41 (0.01, 0.76)	
Non-Responder, n(%)	34 (70.8%)	29 (96.7%)	10 (58.8%)	8 (100.0%)
Last participation date < Day 162 in RT phase	12 (25.0%)	6 (20.0%)	6 (35.3%)	1 (12.5%)
Last participation date >= Day 162 and TSS at Week 24 not available	1 (2.1%)	1 (3.3%)	0	2 (25.0%)
>0% increase from baseline at Week 24	11 (22.9%)	13 (43.3%)	4 (23.5%)	4 (50.0%)
<50% reduction from baseline at Week 24	21 (43.8%)	21 (70.0%)	4 (23.5%)	5 (62.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
DIPSS = Dynamic International Prognostic Scoring System;
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-dipss.pdf 24AUG2023:16:26

Table 2.1608: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by DIPSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk	
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)
Response Rate of Total Symptom Score at Week 12				
Subjects Evaluable at Week 12, n	48	30	17	8
TSS = 0 at baseline and TSS >0 or missing at Week 12	0	2 (6.7%)	0	0
Responder, n(%)	13 (27.1%)	1 (3.3%)	6 (35.3%)	2 (25.0%)
95% Exact CI	0.1528, 0.4185	0.0008, 0.1722	0.1421, 0.6167	0.0319, 0.6509
Proportion Difference - Stratified CMH Method (95% CI)	0.22 (0.05, 0.40)		0.10 (-0.34, 0.54)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.24 (0.09, 0.39)		0.10 (-0.30, 0.51)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.24 (0.01, 0.45)		0.10 (-0.32, 0.50)	
Non-Responder, n(%)	35 (72.9%)	29 (96.7%)	11 (64.7%)	6 (75.0%)
Last participation date < Day 78 in RT phase	4 (8.3%)	5 (16.7%)	3 (17.6%)	1 (12.5%)
Last participation date >= Day 78 and TSS at Week 12 not available	1 (2.1%)	0	0	0
>0% increase from baseline at Week 12	15 (31.3%)	14 (46.7%)	4 (23.5%)	2 (25.0%)
<50% reduction from baseline at Week 12	30 (62.5%)	22 (73.3%)	8 (47.1%)	5 (62.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
DIPSS = Dynamic International Prognostic Scoring System;
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 25JUN2019

Table 2.1607: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by Hemoglobin Level at Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<8 g/dL		>=8 g/dL	
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)
Total Symptom Score Status				
Missing TSS at baseline (excluded from rate calculation)	0	0	0	0
TSS = 0 at baseline	0	1 (16.7%)	1 (2.6%)	2 (6.1%)
TSS > 0 at baseline	27 (100.0%)	5 (83.3%)	38 (97.4%)	31 (93.9%)
Response Rate of Total Symptom Score at Week 24				
Subjects Evaluable at Week 24, n	27	6	38	32
TSS = 0 at baseline and TSS >0 or missing at Week 24	0	1 (16.7%)	0	1 (3.1%)
Responder, n(%)	11 (40.7%)	0	10 (26.3%)	1 (3.1%)
95% Exact CI	0.2239, 0.6120	0.0000, 0.4593	0.1340, 0.4310	0.0008, 0.1622
Proportion Difference - Stratified CMH Method (95% CI)	0.41 (0.03, 0.79)		0.23 (0.05, 0.41)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.41 (0.11, 0.70)		0.23 (0.07, 0.39)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.41 (-0.04, 0.78)		0.23 (-0.00, 0.45)	
Non-Responder, n(%)	16 (59.3%)	6 (100.0%)	28 (73.7%)	31 (96.9%)
Last participation date < Day 162 in RT phase	8 (29.6%)	2 (33.3%)	10 (26.3%)	5 (15.6%)
Last participation date >= Day 162 and TSS at Week 24 not available	0	3 (50.0%)	1 (2.6%)	0
>0% increase from baseline at Week 24	4 (14.8%)	0	11 (28.9%)	17 (53.1%)
<50% reduction from baseline at Week 24	8 (29.6%)	1 (16.7%)	17 (44.7%)	25 (78.1%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-hgb.pdf 24AUG2023:16:25

Table 2.1607: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by Hemoglobin Level at Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<8 g/dL		>=8 g/dL	
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)
Response Rate of Total Symptom Score at Week 12				
Subjects Evaluable at Week 12, n	27	6	38	32
TSS = 0 at baseline and TSS >0 or missing at Week 12	0	1 (16.7%)	0	1 (3.1%)
Responder, n(%)	9 (33.3%)	2 (33.3%)	10 (26.3%)	1 (3.1%)
95% Exact CI	0.1652, 0.5396	0.0433, 0.7772	0.1340, 0.4310	0.0008, 0.1622
Proportion Difference - Stratified CMH Method (95% CI)	-0.01 (-0.52, 0.50)		0.24 (0.05, 0.42)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.00 (-0.46, 0.46)		0.23 (0.07, 0.39)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.00 (-0.46, 0.46)		0.23 (-0.00, 0.45)	
Non-Responder, n(%)	18 (66.7%)	4 (66.7%)	28 (73.7%)	31 (96.9%)
Last participation date < Day 78 in RT phase	3 (11.1%)	2 (33.3%)	4 (10.5%)	4 (12.5%)
Last participation date >= Day 78 and TSS at Week 12 not available	0	0	1 (2.6%)	0
>0% increase from baseline at Week 12	7 (25.9%)	0	12 (31.6%)	16 (50.0%)
<50% reduction from baseline at Week 12	15 (55.6%)	1 (16.7%)	23 (60.5%)	26 (81.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-hgb.pdf 24AUG2023:16:25

Table 2.1612: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by Highest Dose of Ruxolitinib Received Since Randomization
Randomized Treatment Phase
ITT-Anemic Analysis Set on BAT Treatment Group

	< 20 mg BID (N=28)	>= 20 mg BID (N=6)	Not Taking Rux (N=5)
Total Symptom Score Status			
Missing TSS at baseline (excluded from rate calculation)	0	0	0
TSS = 0 at baseline	3 (10.7%)	0	0
TSS > 0 at baseline	25 (89.3%)	6 (100.0%)	5 (100.0%)
Response Rate of Total Symptom Score at Week 24			
Subjects Evaluable at Week 24, n	27	6	5
TSS = 0 at baseline and TSS >0 or missing at Week 24	2 (7.4%)	0	0
Responder, n(%)	0	0	1 (20.0%)
95% Exact CI	0.0000, 0.1277	0.0000, 0.4593	0.0051, 0.7164
Non-Responder, n(%)	27 (100.0%)	6 (100.0%)	4 (80.0%)
Last participation date < Day 162 in RT phase	6 (22.2%)	1 (16.7%)	0
Last participation date >= Day 162 and TSS at Week 24 not available	2 (7.4%)	0	1 (20.0%)
>0% increase from baseline at Week 24	11 (40.7%)	3 (50.0%)	3 (60.0%)
<50% reduction from baseline at Week 24	18 (66.7%)	5 (83.3%)	3 (60.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-inc4.pdf 24AUG2023:16:26

Table 2.1612: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by Highest Dose of Ruxolitinib Received Since Randomization
Randomized Treatment Phase
ITT-Anemic Analysis Set on BAT Treatment Group

	< 20 mg BID (N=28)	>= 20 mg BID (N=6)	Not Taking Rux (N=5)
Response Rate of Total Symptom Score at Week 12			
Subjects Evaluable at Week 12, n	27	6	5
TSS = 0 at baseline and TSS >0 or missing at Week 12	2 (7.4%)	0	0
Responder, n(%)	1 (3.7%)	0	2 (40.0%)
95% Exact CI	0.0009, 0.1897	0.0000, 0.4593	0.0527, 0.8534
Non-Responder, n(%)	26 (96.3%)	6 (100.0%)	3 (60.0%)
Last participation date < Day 78 in RT phase	5 (18.5%)	1 (16.7%)	0
Last participation date >= Day 78 and TSS at Week 12 not available	0	0	0
>0% increase from baseline at Week 12	11 (40.7%)	2 (33.3%)	3 (60.0%)
<50% reduction from baseline at Week 12	19 (70.4%)	5 (83.3%)	3 (60.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-inc4.pdf 24AUG2023:16:26

Table 2.1609: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by JAK2V617F Mutation
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Positive		Negative	
	MMB (N=43)	BAT (N=27)	MMB (N=22)	BAT (N=9)
Total Symptom Score Status				
Missing TSS at baseline (excluded from rate calculation)	0	0	0	0
TSS = 0 at baseline	1 (2.3%)	1 (3.7%)	0	2 (22.2%)
TSS > 0 at baseline	42 (97.7%)	26 (96.3%)	22 (100.0%)	7 (77.8%)
Response Rate of Total Symptom Score at Week 24				
Subjects Evaluable at Week 24, n	42	27	22	8
TSS = 0 at baseline and TSS >0 or missing at Week 24	0	1 (3.7%)	0	1 (12.5%)
Responder, n(%)	12 (28.6%)	1 (3.7%)	9 (40.9%)	0
95% Exact CI	0.1572, 0.4458	0.0009, 0.1897	0.2071, 0.6365	0.0000, 0.3694
Proportion Difference - Stratified CMH Method (95% CI)	0.25 (0.06, 0.44)		0.43 (0.10, 0.76)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.25 (0.08, 0.41)		0.41 (0.14, 0.68)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.25 (0.00, 0.47)		0.41 (0.00, 0.76)	
Non-Responder, n(%)	30 (71.4%)	26 (96.3%)	13 (59.1%)	8 (100.0%)
Last participation date < Day 162 in RT phase	15 (35.7%)	4 (14.8%)	3 (13.6%)	3 (37.5%)
Last participation date >= Day 162 and TSS at Week 24 not available	1 (2.4%)	2 (7.4%)	0	1 (12.5%)
>0% increase from baseline at Week 24	8 (19.0%)	10 (37.0%)	6 (27.3%)	4 (50.0%)
<50% reduction from baseline at Week 24	14 (33.3%)	19 (70.4%)	10 (45.5%)	4 (50.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-jak.pdf 24AUG2023:16:26

Table 2.1609: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by JAK2V617F Mutation
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Positive		Negative	
	MMB (N=43)	BAT (N=27)	MMB (N=22)	BAT (N=9)
Response Rate of Total Symptom Score at Week 12				
Subjects Evaluable at Week 12, n	42	26	22	9
TSS = 0 at baseline and TSS >0 or missing at Week 12	0	0	0	2 (22.2%)
Responder, n(%)	10 (23.8%)	3 (11.5%)	9 (40.9%)	0
95% Exact CI	0.1205, 0.3945	0.0245, 0.3015	0.2071, 0.6365	0.0000, 0.3363
Proportion Difference - Stratified CMH Method (95% CI)	0.14 (-0.08, 0.36)		0.40 (0.09, 0.70)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.12 (-0.06, 0.31)		0.41 (0.15, 0.67)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.12 (-0.12, 0.36)		0.41 (0.02, 0.73)	
Non-Responder, n(%)	32 (76.2%)	23 (88.5%)	13 (59.1%)	9 (100.0%)
Last participation date < Day 78 in RT phase	7 (16.7%)	3 (11.5%)	0	3 (33.3%)
Last participation date >= Day 78 and TSS at Week 12 not available	1 (2.4%)	0	0	0
>0% increase from baseline at Week 12	10 (23.8%)	10 (38.5%)	8 (36.4%)	3 (33.3%)
<50% reduction from baseline at Week 12	24 (57.1%)	20 (76.9%)	13 (59.1%)	4 (44.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 25JUN2019

Table 2.1611: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by Disease Type
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis		Post-PV Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)	MMB (N=8)	BAT (N=8)
Total Symptom Score Status						
Missing TSS at baseline (excluded from rate calculation)	0	0	0	0	0	0
TSS = 0 at baseline	1 (2.2%)	2 (8.7%)	0	0	0	1 (12.5%)
TSS > 0 at baseline	44 (97.8%)	21 (91.3%)	13 (100.0%)	8 (100.0%)	8 (100.0%)	7 (87.5%)
Response Rate of Total Symptom Score at Week 24						
Subjects Evaluable at Week 24, n	44	22	13	8	8	8
TSS = 0 at baseline and TSS >0 or missing at Week 24	0	1 (4.5%)	0	0	0	1 (12.5%)
Responder, n(%)	13 (29.5%)	1 (4.5%)	4 (30.8%)	0	4 (50.0%)	0
95% Exact CI	0.1676, 0.4520	0.0012, 0.2284	0.0909, 0.6143	0.0000, 0.3694	0.1570, 0.8430	0.0000, 0.3694
Proportion Difference - Stratified CMH Method (95% CI)	0.26 (0.05, 0.46)		0.38 (-0.02, 0.78)		0.48 (-0.08, 1.05)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.25 (0.08, 0.42)		0.31 (-0.01, 0.62)		0.50 (0.09, 0.91)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.25 (-0.02, 0.49)		0.31 (-0.14, 0.68)		0.50 (-0.05, 0.85)	
Non-Responder, n(%)	31 (70.5%)	21 (95.5%)	9 (69.2%)	8 (100.0%)	4 (50.0%)	8 (100.0%)
Last participation date < Day 162 in RT phase	12 (27.3%)	4 (18.2%)	4 (30.8%)	2 (25.0%)	2 (25.0%)	1 (12.5%)
Last participation date >= Day 162 and TSS at Week 24 not available	1 (2.3%)	3 (13.6%)	0	0	0	0
>0% increase from baseline at Week 24	11 (25.0%)	9 (40.9%)	3 (23.1%)	5 (62.5%)	1 (12.5%)	3 (37.5%)
<50% reduction from baseline at Week 24	18 (40.9%)	14 (63.6%)	5 (38.5%)	6 (75.0%)	2 (25.0%)	6 (75.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-mf.pdf 24AUG2023:16:26

Table 2.1611: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by Disease Type
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis		Post-PV Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)	MMB (N=8)	BAT (N=8)
Response Rate of Total Symptom Score at Week 12						
Subjects Evaluable at Week 12, n	44	23	13	8	8	7
TSS = 0 at baseline and TSS >0 or missing at Week 12	0	2 (8.7%)	0	0	0	0
Responder, n(%)	12 (27.3%)	3 (13.0%)	3 (23.1%)	0	4 (50.0%)	0
95% Exact CI	0.1496, 0.4279	0.0278, 0.3359	0.0504, 0.5381	0.0000, 0.3694	0.1570, 0.8430	0.0000, 0.4096
Proportion Difference - Stratified CMH Method (95% CI)	0.15 (-0.07, 0.37)		0.31 (-0.08, 0.70)		0.40 (-0.08, 0.88)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.14 (-0.06, 0.34)		0.23 (-0.07, 0.53)		0.50 (0.08, 0.92)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.14 (-0.11, 0.39)		0.23 (-0.21, 0.62)		0.50 (0.02, 0.85)	
Non-Responder, n(%)	32 (72.7%)	20 (87.0%)	10 (76.9%)	8 (100.0%)	4 (50.0%)	7 (100.0%)
Last participation date < Day 78 in RT phase	5 (11.4%)	3 (13.0%)	2 (15.4%)	2 (25.0%)	0	1 (14.3%)
Last participation date >= Day 78 and TSS at Week 12 not available	1 (2.3%)	0	0	0	0	0
>0% increase from baseline at Week 12	13 (29.5%)	8 (34.8%)	4 (30.8%)	5 (62.5%)	2 (25.0%)	3 (42.9%)
<50% reduction from baseline at Week 12	26 (59.1%)	15 (65.2%)	8 (61.5%)	6 (75.0%)	4 (50.0%)	6 (85.7%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-mf.pdf 24AUG2023:16:26

Table 2.1603: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by Race
Randomized Treatment Phase
ITT-Anemic Analysis Set

	White		All Other Races	
	MMB (N=54)	BAT (N=34)	MMB (N=5)	BAT (N=0)
Total Symptom Score Status				
Missing TSS at baseline (excluded from rate calculation)	0	0	0	0
TSS = 0 at baseline	1 (1.9%)	2 (5.9%)	0	0
TSS > 0 at baseline	53 (98.1%)	32 (94.1%)	5 (100.0%)	0
Response Rate of Total Symptom Score at Week 24				
Subjects Evaluable at Week 24, n	53	34	5	0
TSS = 0 at baseline and TSS >0 or missing at Week 24	0	2 (5.9%)	0	0
Responder, n(%)	17 (32.1%)	1 (2.9%)	2 (40.0%)	0
95% Exact CI	0.1992, 0.4632	0.0007, 0.1533	0.0527, 0.8534	NA, NA
Proportion Difference - Stratified CMH Method (95% CI)	0.28 (0.12, 0.45)		NA	
Proportion Difference - Unstratified CMH Method (95% CI)	0.29 (0.15, 0.44)		NA	
Proportion Difference - Unstratified Exact Method (95% CI)	0.29 (0.08, 0.49)		NA	
Non-Responder, n(%)	36 (67.9%)	33 (97.1%)	3 (60.0%)	0
Last participation date < Day 162 in RT phase	13 (24.5%)	7 (20.6%)	2 (40.0%)	0
Last participation date >= Day 162 and TSS at Week 24 not available	1 (1.9%)	3 (8.8%)	0	0
>0% increase from baseline at Week 24	13 (24.5%)	14 (41.2%)	0	0
<50% reduction from baseline at Week 24	22 (41.5%)	22 (64.7%)	1 (20.0%)	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-race.pdf 24AUG2023:16:25

Table 2.1603: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by Race
Randomized Treatment Phase
ITT-Anemic Analysis Set

	White		All Other Races	
	MMB (N=54)	BAT (N=34)	MMB (N=5)	BAT (N=0)
Response Rate of Total Symptom Score at Week 12				
Subjects Evaluable at Week 12, n	53	33	5	0
TSS = 0 at baseline and TSS >0 or missing at Week 12	0	1 (3.0%)	0	0
Responder, n(%)	15 (28.3%)	3 (9.1%)	3 (60.0%)	0
95% Exact CI	0.1679, 0.4235	0.0192, 0.2433	0.1466, 0.9473	NA, NA
Proportion Difference - Stratified CMH Method (95% CI)	0.18 (0.00, 0.36)		NA	
Proportion Difference - Unstratified CMH Method (95% CI)	0.19 (0.03, 0.35)		NA	
Proportion Difference - Unstratified Exact Method (95% CI)	0.19 (-0.02, 0.40)		NA	
Non-Responder, n(%)	38 (71.7%)	30 (90.9%)	2 (40.0%)	0
Last participation date < Day 78 in RT phase	5 (9.4%)	6 (18.2%)	1 (20.0%)	0
Last participation date >= Day 78 and TSS at Week 12 not available	1 (1.9%)	0	0	0
>0% increase from baseline at Week 12	14 (26.4%)	13 (39.4%)	1 (20.0%)	0
<50% reduction from baseline at Week 12	32 (60.4%)	23 (69.7%)	1 (20.0%)	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-race.pdf 24AUG2023:16:25

Table 2.1610: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by Duration of Ruxolitinib Received Prior to Randomization
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<12 weeks		>=12 weeks	
	MMB (N=13)	BAT (N=8)	MMB (N=47)	BAT (N=24)
Total Symptom Score Status				
Missing TSS at baseline (excluded from rate calculation)	0	0	0	0
TSS = 0 at baseline	0	0	1 (2.1%)	3 (12.5%)
TSS > 0 at baseline	13 (100.0%)	8 (100.0%)	46 (97.9%)	21 (87.5%)
Response Rate of Total Symptom Score at Week 24				
Subjects Evaluable at Week 24, n	13	8	46	23
TSS = 0 at baseline and TSS >0 or missing at Week 24	0	0	0	2 (8.7%)
Responder, n(%)	4 (30.8%)	0	14 (30.4%)	0
95% Exact CI	0.0909, 0.6143	0.0000, 0.3694	0.1774, 0.4575	0.0000, 0.1482
Proportion Difference - Stratified CMH Method (95% CI)	0.31 (-0.04, 0.66)		0.29 (0.11, 0.48)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.31 (-0.01, 0.62)		0.30 (0.16, 0.45)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.31 (-0.14, 0.68)		0.30 (0.04, 0.54)	
Non-Responder, n(%)	9 (69.2%)	8 (100.0%)	32 (69.6%)	23 (100.0%)
Last participation date < Day 162 in RT phase	4 (30.8%)	3 (37.5%)	12 (26.1%)	3 (13.0%)
Last participation date >= Day 162 and TSS at Week 24 not available	0	1 (12.5%)	1 (2.2%)	2 (8.7%)
>0% increase from baseline at Week 24	2 (15.4%)	2 (25.0%)	12 (26.1%)	12 (52.2%)
<50% reduction from baseline at Week 24	5 (38.5%)	4 (50.0%)	19 (41.3%)	17 (73.9%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-ruxDur.pdf 24AUG2023:16:26

Table 2.1610: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by Duration of Ruxolitinib Received Prior to Randomization
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<12 weeks		>=12 weeks	
	MMB (N=13)	BAT (N=8)	MMB (N=47)	BAT (N=24)
Response Rate of Total Symptom Score at Week 12				
Subjects Evaluable at Week 12, n	13	8	46	23
TSS = 0 at baseline and TSS >0 or missing at Week 12	0	0	0	2 (8.7%)
Responder, n(%)	3 (23.1%)	1 (12.5%)	13 (28.3%)	1 (4.3%)
95% Exact CI	0.0504, 0.5381	0.0032, 0.5265	0.1599, 0.4346	0.0011, 0.2195
Proportion Difference - Stratified CMH Method (95% CI)	0.09 (-0.28, 0.47)		0.23 (0.02, 0.43)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.11 (-0.26, 0.47)		0.24 (0.07, 0.41)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.11 (-0.33, 0.51)		0.24 (-0.02, 0.48)	
Non-Responder, n(%)	10 (76.9%)	7 (87.5%)	33 (71.7%)	22 (95.7%)
Last participation date < Day 78 in RT phase	2 (15.4%)	2 (25.0%)	5 (10.9%)	3 (13.0%)
Last participation date >= Day 78 and TSS at Week 12 not available	0	0	1 (2.2%)	0
>0% increase from baseline at Week 12	3 (23.1%)	2 (25.0%)	15 (32.6%)	11 (47.8%)
<50% reduction from baseline at Week 12	8 (61.5%)	5 (62.5%)	27 (58.7%)	17 (73.9%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-ruxDur.pdf 24AUG2023:16:26

Table 2.1602: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female	
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)
Total Symptom Score Status				
Missing TSS at baseline (excluded from rate calculation)	0	0	0	0
TSS = 0 at baseline	1 (1.9%)	2 (11.1%)	0	1 (4.8%)
TSS > 0 at baseline	51 (98.1%)	16 (88.9%)	14 (100.0%)	20 (95.2%)
Response Rate of Total Symptom Score at Week 24				
Subjects Evaluable at Week 24, n	51	17	14	21
TSS = 0 at baseline and TSS >0 or missing at Week 24	0	1 (5.9%)	0	1 (4.8%)
Responder, n(%)	17 (33.3%)	1 (5.9%)	4 (28.6%)	0
95% Exact CI	0.2076, 0.4792	0.0015, 0.2869	0.0839, 0.5810	0.0000, 0.1611
Proportion Difference - Stratified CMH Method (95% CI)	0.29 (0.08, 0.50)		0.25 (-0.03, 0.54)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.27 (0.09, 0.46)		0.29 (0.03, 0.54)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.27 (-0.01, 0.53)		0.29 (-0.06, 0.59)	
Non-Responder, n(%)	34 (66.7%)	16 (94.1%)	10 (71.4%)	21 (100.0%)
Last participation date < Day 162 in RT phase	14 (27.5%)	4 (23.5%)	4 (28.6%)	3 (14.3%)
Last participation date >= Day 162 and TSS at Week 24 not available	1 (2.0%)	3 (17.6%)	0	0
>0% increase from baseline at Week 24	11 (21.6%)	5 (29.4%)	4 (28.6%)	12 (57.1%)
<50% reduction from baseline at Week 24	19 (37.3%)	9 (52.9%)	6 (42.9%)	17 (81.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-sex.pdf 24AUG2023:16:25

Table 2.1602: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female	
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)
Response Rate of Total Symptom Score at Week 12				
Subjects Evaluable at Week 12, n	51	18	14	20
TSS = 0 at baseline and TSS >0 or missing at Week 12	0	2 (11.1%)	0	0
Responder, n(%)	16 (31.4%)	3 (16.7%)	3 (21.4%)	0
95% Exact CI	0.1911, 0.4589	0.0358, 0.4142	0.0466, 0.5080	0.0000, 0.1684
Proportion Difference - Stratified CMH Method (95% CI)	0.16 (-0.10, 0.41)		0.16 (-0.10, 0.41)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.15 (-0.08, 0.37)		0.21 (-0.03, 0.45)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.15 (-0.12, 0.41)		0.21 (-0.14, 0.52)	
Non-Responder, n(%)	35 (68.6%)	15 (83.3%)	11 (78.6%)	20 (100.0%)
Last participation date < Day 78 in RT phase	6 (11.8%)	4 (22.2%)	1 (7.1%)	2 (10.0%)
Last participation date >= Day 78 and TSS at Week 12 not available	1 (2.0%)	0	0	0
>0% increase from baseline at Week 12	17 (33.3%)	5 (27.8%)	2 (14.3%)	11 (55.0%)
<50% reduction from baseline at Week 12	28 (54.9%)	9 (50.0%)	10 (71.4%)	18 (90.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-sex.pdf 24AUG2023:16:25

Table 2.1605: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by Spleen Volume at Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3	
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)
Total Symptom Score Status				
Missing TSS at baseline (excluded from rate calculation)	0	0	0	0
TSS = 0 at baseline	1 (3.6%)	3 (12.5%)	0	0
TSS > 0 at baseline	27 (96.4%)	21 (87.5%)	38 (100.0%)	15 (100.0%)
Response Rate of Total Symptom Score at Week 24				
Subjects Evaluable at Week 24, n	27	23	38	15
TSS = 0 at baseline and TSS >0 or missing at Week 24	0	2 (8.7%)	0	0
Responder, n(%)	12 (44.4%)	1 (4.3%)	9 (23.7%)	0
95% Exact CI	0.2548, 0.6467	0.0011, 0.2195	0.1144, 0.4024	0.0000, 0.2180
Proportion Difference - Stratified CMH Method (95% CI)	0.39 (0.15, 0.62)		0.21 (-0.07, 0.48)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.40 (0.18, 0.62)		0.24 (0.07, 0.40)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.40 (0.13, 0.63)		0.24 (-0.06, 0.51)	
Non-Responder, n(%)	15 (55.6%)	22 (95.7%)	29 (76.3%)	15 (100.0%)
Last participation date < Day 162 in RT phase	5 (18.5%)	2 (8.7%)	13 (34.2%)	5 (33.3%)
Last participation date >= Day 162 and TSS at Week 24 not available	0	3 (13.0%)	1 (2.6%)	0
>0% increase from baseline at Week 24	6 (22.2%)	10 (43.5%)	9 (23.7%)	7 (46.7%)
<50% reduction from baseline at Week 24	10 (37.0%)	16 (69.6%)	15 (39.5%)	10 (66.7%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-svb.pdf 24AUG2023:16:25

Table 2.1605: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by Spleen Volume at Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3	
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)
Response Rate of Total Symptom Score at Week 12				
Subjects Evaluable at Week 12, n	27	23	38	15
TSS = 0 at baseline and TSS >0 or missing at Week 12	0	2 (8.7%)	0	0
Responder, n(%)	12 (44.4%)	3 (13.0%)	7 (18.4%)	0
95% Exact CI	0.2548, 0.6467	0.0278, 0.3359	0.0774, 0.3433	0.0000, 0.2180
Proportion Difference - Stratified CMH Method (95% CI)	0.28 (0.01, 0.54)		0.16 (-0.11, 0.43)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.31 (0.07, 0.56)		0.18 (0.03, 0.34)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.31 (0.04, 0.56)		0.18 (-0.11, 0.46)	
Non-Responder, n(%)	15 (55.6%)	20 (87.0%)	31 (81.6%)	15 (100.0%)
Last participation date < Day 78 in RT phase	1 (3.7%)	2 (8.7%)	6 (15.8%)	4 (26.7%)
Last participation date >= Day 78 and TSS at Week 12 not available	0	0	1 (2.6%)	0
>0% increase from baseline at Week 12	6 (22.2%)	8 (34.8%)	13 (34.2%)	8 (53.3%)
<50% reduction from baseline at Week 12	14 (51.9%)	16 (69.6%)	24 (63.2%)	11 (73.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-svb.pdf 24AUG2023:16:25

Table 2.1604: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by Transfusion Dependence at Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Yes		No	
	MMB (N=52)	BAT (N=25)	MMB (N=14)	BAT (N=14)
Total Symptom Score Status				
Missing TSS at baseline (excluded from rate calculation)	0	0	0	0
TSS = 0 at baseline	0	2 (8.0%)	1 (7.1%)	1 (7.1%)
TSS > 0 at baseline	52 (100.0%)	23 (92.0%)	13 (92.9%)	13 (92.9%)
Response Rate of Total Symptom Score at Week 24				
Subjects Evaluable at Week 24, n	52	25	13	13
TSS = 0 at baseline and TSS >0 or missing at Week 24	0	2 (8.0%)	0	0
Responder, n(%)	18 (34.6%)	0	3 (23.1%)	1 (7.7%)
95% Exact CI	0.2197, 0.4909	0.0000, 0.1372	0.0504, 0.5381	0.0019, 0.3603
Proportion Difference - Stratified CMH Method (95% CI)	0.35 (0.19, 0.50)		0.16 (-0.16, 0.49)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.35 (0.20, 0.49)		0.15 (-0.15, 0.45)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.35 (0.11, 0.56)		0.15 (-0.26, 0.53)	
Non-Responder, n(%)	34 (65.4%)	25 (100.0%)	10 (76.9%)	12 (92.3%)
Last participation date < Day 162 in RT phase	12 (23.1%)	4 (16.0%)	6 (46.2%)	3 (23.1%)
Last participation date >= Day 162 and TSS at Week 24 not available	1 (1.9%)	3 (12.0%)	0	0
>0% increase from baseline at Week 24	13 (25.0%)	14 (56.0%)	2 (15.4%)	3 (23.1%)
<50% reduction from baseline at Week 24	21 (40.4%)	17 (68.0%)	4 (30.8%)	9 (69.2%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Stratification factor is total symptom score (< 18 vs. >=18) at baseline.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-tf.pdf 24AUG2023:16:25

Table 2.1604: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by Transfusion Dependence at Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Yes		No	
	MMB (N=52)	BAT (N=25)	MMB (N=14)	BAT (N=14)
Response Rate of Total Symptom Score at Week 12				
Subjects Evaluable at Week 12, n	52	24	13	14
TSS = 0 at baseline and TSS >0 or missing at Week 12	0	1 (4.2%)	0	1 (7.1%)
Responder, n(%)	15 (28.8%)	2 (8.3%)	4 (30.8%)	1 (7.1%)
95% Exact CI	0.1713, 0.4308	0.0103, 0.2700	0.0909, 0.6143	0.0018, 0.3387
Proportion Difference - Stratified CMH Method (95% CI)	0.20 (0.01, 0.38)		0.24 (-0.09, 0.57)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.21 (0.03, 0.38)		0.24 (-0.07, 0.55)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.21 (-0.04, 0.43)		0.24 (-0.15, 0.55)	
Non-Responder, n(%)	37 (71.2%)	22 (91.7%)	9 (69.2%)	13 (92.9%)
Last participation date < Day 78 in RT phase	4 (7.7%)	4 (16.7%)	3 (23.1%)	2 (14.3%)
Last participation date >= Day 78 and TSS at Week 12 not available	1 (1.9%)	0	0	0
>0% increase from baseline at Week 12	15 (28.8%)	12 (50.0%)	4 (30.8%)	4 (28.6%)
<50% reduction from baseline at Week 12	32 (61.5%)	17 (70.8%)	6 (46.2%)	10 (71.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Stratification factor is total symptom score (< 18 vs. >=18) at baseline.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 25JUN2019

Table 2.1606: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by TSS at Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18	
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)
Total Symptom Score Status				
Missing TSS at baseline (excluded from rate calculation)	0	0	0	0
TSS = 0 at baseline	1 (2.4%)	3 (15.0%)	0	0
TSS > 0 at baseline	41 (97.6%)	17 (85.0%)	24 (100.0%)	19 (100.0%)
Response Rate of Total Symptom Score at Week 24				
Subjects Evaluable at Week 24, n	41	19	24	19
TSS = 0 at baseline and TSS >0 or missing at Week 24	0	2 (10.5%)	0	0
Responder, n(%)	13 (31.7%)	0	8 (33.3%)	1 (5.3%)
95% Exact CI	0.1808, 0.4809	0.0000, 0.1765	0.1563, 0.5532	0.0013, 0.2603
Proportion Difference - Stratified CMH Method (95% CI)	0.31 (0.13, 0.48)		0.28 (0.05, 0.52)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.32 (0.16, 0.48)		0.28 (0.05, 0.51)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.32 (0.04, 0.57)		0.28 (-0.02, 0.55)	
Non-Responder, n(%)	28 (68.3%)	19 (100.0%)	16 (66.7%)	18 (94.7%)
Last participation date < Day 162 in RT phase	9 (22.0%)	3 (15.8%)	9 (37.5%)	4 (21.1%)
Last participation date >= Day 162 and TSS at Week 24 not available	1 (2.4%)	2 (10.5%)	0	1 (5.3%)
>0% increase from baseline at Week 24	12 (29.3%)	8 (42.1%)	3 (12.5%)	9 (47.4%)
<50% reduction from baseline at Week 24	18 (43.9%)	13 (68.4%)	7 (29.2%)	13 (68.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Stratification factor is transfusion dependence (Yes vs. No) at baseline.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-tss.pdf 24AUG2023:16:25

Table 2.1606: Subgroup Analysis of Response Rate in TSS at Week 24 and at Week 12 by TSS at Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18	
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)
Response Rate of Total Symptom Score at Week 12				
Subjects Evaluable at Week 12, n	41	19	24	19
TSS = 0 at baseline and TSS >0 or missing at Week 12	0	2 (10.5%)	0	0
Responder, n(%)	12 (29.3%)	1 (5.3%)	7 (29.2%)	2 (10.5%)
95% Exact CI	0.1613, 0.4554	0.0013, 0.2603	0.1262, 0.5109	0.0130, 0.3314
Proportion Difference - Stratified CMH Method (95% CI)	0.22 (0.01, 0.43)		0.20 (-0.06, 0.46)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.24 (0.05, 0.43)		0.19 (-0.06, 0.43)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.24 (-0.04, 0.49)		0.19 (-0.11, 0.46)	
Non-Responder, n(%)	29 (70.7%)	18 (94.7%)	17 (70.8%)	17 (89.5%)
Last participation date < Day 78 in RT phase	3 (7.3%)	2 (10.5%)	4 (16.7%)	4 (21.1%)
Last participation date >= Day 78 and TSS at Week 12 not available	1 (2.4%)	0	0	0
>0% increase from baseline at Week 12	14 (34.1%)	8 (42.1%)	5 (20.8%)	8 (42.1%)
<50% reduction from baseline at Week 12	25 (61.0%)	14 (73.7%)	13 (54.2%)	13 (68.4%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Stratification factor is transfusion dependence (Yes vs. No) at baseline.
TSS rate analysis at one visit only include subjects with TSS >0 at baseline or with TSS =0 at baseline but with TSS > 0 or missing at that visit.
TSS = Total Symptom Score; CMH = Cochran-Mantel-Haenszel;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-tss24.sas V.03.05 Output file: t-subgrp-tss24-tss.pdf 24AUG2023:16:25

Table 2.2501: Subgroup Analysis of Rate of RBC Transfusion by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	< 65 years		>= 65 years	
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)
RBC Transfusion Rate in RT phase (units/month)				
N	24	9	42	30
Mean (SD)	1.9 (1.69)	2.0 (2.26)	2.2 (2.34)	2.0 (1.92)
Median	1.9	1.8	1.4	1.4
Q1, Q3	0.4, 3.1	1.1, 1.8	0.3, 3.3	0.5, 3.0
Min, Max	0.0, 6.0	0.0, 7.6	0.0, 8.2	0.0, 7.2
Negative Binomial Model				
Adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	1.48 (0.90, 2.42)	1.12 (0.52, 2.43)	1.54 (1.02, 2.32)	1.46 (0.95, 2.23)
Ratio of Rate for RBC Transfusion with 95% CI	1.31 (0.53, 3.23)		1.06 (0.63, 1.78)	
p-value	0.55		0.83	
Un-adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	1.85 (1.17, 2.95)	1.74 (0.78, 3.91)	2.21 (1.55, 3.13)	1.98 (1.31, 3.00)
Ratio of Rate for RBC Transfusion with 95% CI	1.06 (0.42, 2.70)		1.11 (0.65, 1.92)	
p-value	0.90		0.70	
Proportional Means Model - Supportive Analysis				
Stratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	1.36 (0.89, 2.07)		0.91 (0.59, 1.41)	
p-value	0.16		0.68	
Unstratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	1.30 (0.76, 2.22)		1.09 (0.68, 1.73)	
p-value	0.34		0.73	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-age.pdf 24AUG2023:15:03

Table 2.2501: Subgroup Analysis of Rate of RBC Transfusion by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	< 65 years		>= 65 years	
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)
Total number of RBC Transfusion unit in RT phase				
N	24	9	42	30
Mean (SD)	8.6 (8.23)	5.9 (3.92)	10.1 (11.27)	9.6 (9.13)
Median	6.5	6.0	6.0	8.0
Q1, Q3	1.0, 13.5	5.0, 10.0	2.0, 13.0	3.0, 14.0
Min, Max	0.0, 28.0	0.0, 10.0	0.0, 38.0	0.0, 40.0
Duration of RBC Transfusion in RT phase (months)				
N	24	9	42	30
Mean (SD)	4.85 (1.326)	4.27 (1.960)	4.91 (1.474)	5.08 (1.371)
Median	5.50	5.42	5.55	5.55
Q1, Q3	3.98, 5.73	2.46, 5.55	5.42, 5.62	5.49, 5.62
Min, Max	0.95, 5.78	0.66, 5.72	0.92, 5.78	0.43, 5.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-age.pdf 24AUG2023:15:03

Table 2.2508: Subgroup Analysis of Rate of RBC Transfusion by DIPSS at Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk	
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)
RBC Transfusion Rate in RT phase (units/month)				
N	49	31	17	8
Mean (SD)	2.0 (2.03)	1.8 (1.86)	2.4 (2.41)	2.5 (2.43)
Median	1.3	1.4	2.0	1.8
Q1, Q3	0.4, 2.9	0.5, 2.5	0.0, 3.3	0.7, 3.8
Min, Max	0.0, 8.2	0.0, 7.6	0.0, 6.6	0.0, 7.2
Negative Binomial Model				
Adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	1.42 (0.99, 2.04)	1.37 (0.93, 2.01)	1.88 (1.03, 3.43)	1.65 (0.63, 4.32)
Ratio of Rate for RBC Transfusion with 95% CI	1.04 (0.64, 1.69)		1.14 (0.40, 3.26)	
p-value	0.88		0.81	
Un-adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	1.97 (1.44, 2.70)	1.74 (1.16, 2.61)	2.37 (1.30, 4.33)	2.59 (1.09, 6.16)
Ratio of Rate for RBC Transfusion with 95% CI	1.13 (0.68, 1.89)		0.92 (0.32, 2.62)	
p-value	0.63		0.87	
Proportional Means Model - Supportive Analysis				
Stratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	1.04 (0.72, 1.51)		0.93 (0.44, 1.96)	
p-value	0.82		0.85	
Unstratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	1.20 (0.80, 1.80)		0.86 (0.39, 1.91)	
p-value	0.37		0.71	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
DIPSS = Dynamic International Prognostic Scoring System;
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-dipss.pdf 24AUG2023:15:03

Table 2.2508: Subgroup Analysis of Rate of RBC Transfusion by DIPSS at Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk	
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)
Total number of RBC Transfusion unit in RT phase				
N	49	31	17	8
Mean (SD)	9.3 (9.29)	7.5 (6.13)	10.4 (12.83)	13.8 (13.41)
Median	6.0	7.0	4.0	10.0
Q1, Q3	2.0, 13.0	3.0, 10.0	0.0, 13.0	4.0, 21.0
Min, Max	0.0, 38.0	0.0, 25.0	0.0, 38.0	0.0, 40.0
Duration of RBC Transfusion in RT phase (months)				
N	49	31	17	8
Mean (SD)	5.06 (1.201)	4.89 (1.489)	4.38 (1.845)	4.93 (1.827)
Median	5.55	5.55	5.52	5.55
Q1, Q3	5.45, 5.72	5.42, 5.62	3.19, 5.59	5.40, 5.67
Min, Max	0.95, 5.78	0.66, 5.78	0.92, 5.75	0.43, 5.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
DIPSS = Dynamic International Prognostic Scoring System;
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-dipss.pdf 24AUG2023:15:03

Table 2.2507: Subgroup Analysis of Rate of RBC Transfusion by Hemoglobin Level at Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	< 8 g/dL		>= 8 g/dL	
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)
RBC Transfusion Rate in RT phase (units/month)				
N	27	6	39	33
Mean (SD)	2.5 (2.46)	3.7 (2.69)	1.8 (1.82)	1.7 (1.69)
Median	1.3	3.0	1.7	1.4
Q1, Q3	0.5, 4.5	1.1, 6.2	0.0, 2.9	0.4, 2.4
Min, Max	0.0, 8.2	1.0, 7.6	0.0, 6.8	0.0, 7.2
Negative Binomial Model				
Adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	2.54 (1.74, 3.70)	3.32 (1.49, 7.39)	1.60 (1.08, 2.37)	1.34 (0.89, 2.02)
Ratio of Rate for RBC Transfusion with 95% CI	0.76 (0.32, 1.85)		1.19 (0.69, 2.07)	
p-value	0.55		0.54	
Un-adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	2.47 (1.69, 3.60)	3.41 (1.49, 7.81)	1.80 (1.22, 2.65)	1.69 (1.11, 2.57)
Ratio of Rate for RBC Transfusion with 95% CI	0.72 (0.29, 1.80)		1.07 (0.60, 1.89)	
p-value	0.49		0.82	
Proportional Means Model - Supportive Analysis				
Stratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	0.92 (0.52, 1.62)		1.03 (0.66, 1.59)	
p-value	0.76		0.91	
Unstratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	0.91 (0.52, 1.59)		1.04 (0.64, 1.69)	
p-value	0.73		0.87	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-hgb.pdf 24AUG2023:15:02

Table 2.2507: Subgroup Analysis of Rate of RBC Transfusion by Hemoglobin Level at Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	< 8 g/dL		>= 8 g/dL	
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)
Total number of RBC Transfusion unit in RT phase				
N	27	6	39	33
Mean (SD)	11.0 (10.94)	10.3 (5.61)	8.6 (9.72)	8.5 (8.77)
Median	6.0	8.5	6.0	7.0
Q1, Q3	2.0, 16.0	6.0, 16.0	0.0, 12.0	2.0, 10.0
Min, Max	0.0, 38.0	5.0, 18.0	0.0, 38.0	0.0, 40.0
Duration of RBC Transfusion in RT phase (months)				
N	27	6	39	33
Mean (SD)	4.88 (1.398)	4.15 (2.303)	4.89 (1.440)	5.03 (1.362)
Median	5.55	5.44	5.52	5.55
Q1, Q3	4.67, 5.65	1.77, 5.78	5.29, 5.68	5.49, 5.59
Min, Max	0.92, 5.78	0.66, 5.78	0.95, 5.78	0.43, 5.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-hgb.pdf 24AUG2023:15:02

Table 2.2512: Subgroup Analysis of Rate of RBC Transfusion by Highest Dose of Ruxolitinib Received Since Randomization
Randomized Treatment Phase
ITT-Anemic Analysis Set on BAT Treatment Group

	< 20 mg BID (N=28)	>= 20 mg BID (N=6)	Not Taking Rux (N=5)
RBC Transfusion Rate in RT phase (units/month)			
N	28	6	5
Mean (SD)	2.2 (2.15)	1.0 (1.12)	2.1 (1.62)
Median	1.5	0.9	1.8
Q1, Q3	0.6, 2.7	0.0, 1.4	0.7, 3.1
Min, Max	0.0, 7.6	0.0, 3.0	0.5, 4.3

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-inc4.pdf 24AUG2023:15:01

Table 2.2512: Subgroup Analysis of Rate of RBC Transfusion by Highest Dose of Ruxolitinib Received Since Randomization
Randomized Treatment Phase
ITT-Anemic Analysis Set on BAT Treatment Group

	< 20 mg BID (N=28)	>= 20 mg BID (N=6)	Not Taking Rux (N=5)
Total number of RBC Transfusion unit in RT phase			
N	28	6	5
Mean (SD)	8.8 (8.56)	5.8 (6.34)	12.0 (9.41)
Median	7.5	5.0	10.0
Q1, Q3	3.5, 12.0	0.0, 8.0	4.0, 18.0
Min, Max	0.0, 40.0	0.0, 17.0	3.0, 25.0
Duration of RBC Transfusion in RT phase (months)			
N	28	6	5
Mean (SD)	4.72 (1.695)	5.08 (1.286)	5.65 (0.143)
Median	5.55	5.55	5.68
Q1, Q3	5.32, 5.55	5.49, 5.65	5.62, 5.75
Min, Max	0.43, 5.78	2.46, 5.78	5.42, 5.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-inc4.pdf 24AUG2023:15:01

Table 2.2509: Subgroup Analysis of Rate of RBC Transfusion by JAKV617F Mutation
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Positive		Negative	
	MMB (N=43)	BAT (N=27)	MMB (N=22)	BAT (N=9)
RBC Transfusion Rate in RT phase (units/month)				
N	43	27	22	9
Mean (SD)	2.0 (2.08)	1.8 (1.60)	2.3 (2.28)	2.2 (3.02)
Median	1.4	1.6	1.7	1.1
Q1, Q3	0.2, 3.3	0.5, 2.9	0.4, 3.3	0.0, 1.4
Min, Max	0.0, 8.2	0.0, 6.2	0.0, 6.8	0.0, 7.6
Negative Binomial Model				
Adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	1.40 (0.97, 2.01)	1.47 (0.98, 2.20)	1.91 (0.97, 3.74)	1.25 (0.40, 3.84)
Ratio of Rate for RBC Transfusion with 95% CI	0.95 (0.57, 1.59)		1.53 (0.47, 4.94)	
p-value	0.84		0.48	
Un-adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	1.97 (1.40, 2.77)	1.77 (1.15, 2.72)	2.29 (1.33, 3.92)	2.13 (0.87, 5.19)
Ratio of Rate for RBC Transfusion with 95% CI	1.11 (0.64, 1.92)		1.07 (0.38, 3.04)	
p-value	0.70		0.89	
Proportional Means Model - Supportive Analysis				
Stratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	0.93 (0.63, 1.37)		1.08 (0.45, 2.61)	
p-value	0.71		0.86	
Unstratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	1.10 (0.71, 1.72)		1.13 (0.42, 3.03)	
p-value	0.66		0.81	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-jak.pdf 24AUG2023:15:03

Table 2.2509: Subgroup Analysis of Rate of RBC Transfusion by JAKV617F Mutation
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Positive		Negative	
	MMB (N=43)	BAT (N=27)	MMB (N=22)	BAT (N=9)
Total number of RBC Transfusion unit in RT phase				
N	43	27	22	9
Mean (SD)	8.3 (9.07)	8.3 (6.58)	11.9 (12.25)	8.0 (12.44)
Median	6.0	7.0	8.5	5.0
Q1, Q3	1.0, 12.0	3.0, 13.0	2.0, 17.0	0.0, 8.0
Min, Max	0.0, 34.0	0.0, 25.0	0.0, 38.0	0.0, 40.0
Duration of RBC Transfusion in RT phase (months)				
N	43	27	22	9
Mean (SD)	4.63 (1.634)	5.10 (1.259)	5.35 (0.659)	4.07 (2.235)
Median	5.55	5.55	5.55	5.49
Q1, Q3	3.81, 5.68	5.49, 5.65	5.45, 5.62	2.46, 5.55
Min, Max	0.92, 5.78	1.61, 5.78	3.19, 5.78	0.43, 5.59

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-jak.pdf 24AUG2023:15:03

Table 2.2511: Subgroup Analysis of Rate of RBC Transfusion by Disease Type
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
RBC Transfusion Rate in RT phase (units/month)				
N	45	23	13	8
Mean (SD)	2.1 (2.22)	2.2 (2.05)	2.3 (2.20)	1.7 (1.84)
Median	1.7	1.6	2.2	1.4
Q1, Q3	0.3, 3.1	0.7, 2.9	0.2, 3.8	0.0, 3.1
Min, Max	0.0, 8.2	0.0, 7.6	0.0, 6.0	0.0, 4.5
Negative Binomial Model				
Adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	1.72 (1.18, 2.51)	1.60 (0.99, 2.60)	0.00 (0.00, -)	0.00 (0.00, -)
Ratio of Rate for RBC Transfusion with 95% CI	1.07 (0.61, 1.90)		1.29 (0.49, 3.40)	
p-value	0.80		0.61	
Un-adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	2.14 (1.52, 2.99)	2.07 (1.28, 3.34)	2.30 (1.16, 4.57)	1.80 (0.75, 4.31)
Ratio of Rate for RBC Transfusion with 95% CI	1.03 (0.57, 1.86)		1.28 (0.42, 3.90)	
p-value	0.92		0.66	
Proportional Means Model - Supportive Analysis				
Stratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	1.08 (0.70, 1.67)		1.02 (0.47, 2.21)	
p-value	0.74		0.96	
Unstratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	1.11 (0.69, 1.80)		0.95 (0.42, 2.16)	
p-value	0.67		0.91	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019

Table 2.2511: Subgroup Analysis of Rate of RBC Transfusion by Disease Type
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	Post-PV Myelofibrosis	
	MMB (N=8)	BAT (N=8)
RBC Transfusion Rate in RT phase (units/month)		
N	8	8
Mean (SD)	1.4 (1.33)	1.7 (2.04)
Median	1.0	1.1
Q1, Q3	0.6, 2.0	0.4, 2.4
Min, Max	0.0, 4.2	0.0, 6.2
Negative Binomial Model		
Adjusted for Strata		
Rate of RBC Transfusion with 95% CI(units/month)	0.89 (0.44, 1.81)	1.42 (0.71, 2.83)
Ratio of Rate for RBC Transfusion with 95% CI	0.63 (0.23, 1.70)	
p-value	0.36	
Un-adjusted for Strata		
Rate of RBC Transfusion with 95% CI(units/month)	1.41 (0.69, 2.87)	1.63 (0.79, 3.36)
Ratio of Rate for RBC Transfusion with 95% CI	0.87 (0.31, 2.39)	
p-value	0.78	
Proportional Means Model - Supportive Analysis		
Stratified		
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	0.64 (0.33, 1.26)	
p-value	0.20	
Unstratified		
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	0.99 (0.44, 2.21)	
p-value	0.98	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-mf.pdf 24AUG2023:15:02

Table 2.2511: Subgroup Analysis of Rate of RBC Transfusion by Disease Type
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)
Total number of RBC Transfusion unit in RT phase				
N	45	23	13	8
Mean (SD)	10.1 (11.09)	9.2 (8.64)	9.3 (9.62)	9.4 (10.18)
Median	7.0	6.0	6.0	8.0
Q1, Q3	1.0, 15.0	4.0, 14.0	1.0, 12.0	0.0, 17.0
Min, Max	0.0, 38.0	0.0, 40.0	0.0, 28.0	0.0, 25.0
Duration of RBC Transfusion in RT phase (months)				
N	45	23	13	8
Mean (SD)	4.87 (1.446)	4.94 (1.474)	4.71 (1.638)	4.56 (2.002)
Median	5.55	5.55	5.55	5.55
Q1, Q3	5.29, 5.62	5.42, 5.59	4.70, 5.72	3.89, 5.70
Min, Max	0.95, 5.78	0.66, 5.78	0.92, 5.78	0.43, 5.75

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-mf.pdf 24AUG2023:15:02

Table 2.2511: Subgroup Analysis of Rate of RBC Transfusion by Disease Type
Randomized Treatment Phase
ITT-Anemic Analysis Set

(Continued)	Post-PV Myelofibrosis MMB (N=8)	Post-PV Myelofibrosis BAT (N=8)
Total number of RBC Transfusion unit in RT phase		
N	8	8
Mean (SD)	7.0 (5.48)	6.8 (5.70)
Median	5.5	6.0
Q1, Q3	3.0, 11.5	2.0, 10.5
Min, Max	0.0, 16.0	0.0, 17.0
Duration of RBC Transfusion in RT phase (months)		
N	8	8
Mean (SD)	5.23 (0.756)	5.10 (1.348)
Median	5.55	5.55
Q1, Q3	4.90, 5.67	5.52, 5.60
Min, Max	3.81, 5.78	1.77, 5.72

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-mf.pdf 24AUG2023:15:02

Table 2.2503: Subgroup Analysis of Rate of RBC Transfusion by Race
Randomized Treatment Phase
ITT-Anemic Analysis Set

	White		All Other Races	
	MMB (N=54)	BAT (N=34)	MMB (N=5)	BAT (N=0)
RBC Transfusion Rate in RT phase (units/month)				
N	54	34	5	0
Mean (SD)	1.9 (2.15)	2.0 (2.07)	1.6 (1.53)	-
Median	1.0	1.4	1.1	-
Q1, Q3	0.2, 3.1	0.5, 2.9	0.7, 2.1	-
Min, Max	0.0, 8.2	0.0, 7.6	0.2, 4.0	-
Negative Binomial Model				
Adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	1.48 (1.04, 2.10)	1.46 (0.97, 2.21)	1.44 (0.66, 3.16)	-
Ratio of Rate for RBC Transfusion with 95% CI	1.01 (0.61, 1.67)		-	
p-value	0.97		-	
Un-adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	1.91 (1.38, 2.65)	1.98 (1.30, 3.00)	1.54 (0.66, 3.58)	-
Ratio of Rate for RBC Transfusion with 95% CI	0.97 (0.57, 1.64)		-	
p-value	0.90		-	
Proportional Means Model - Supportive Analysis				
Stratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	0.92 (0.62, 1.37)			
p-value	0.69			
Unstratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	0.99 (0.63, 1.54)			
p-value	0.96			

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-race.pdf 24AUG2023:15:01

Table 2.2503: Subgroup Analysis of Rate of RBC Transfusion by Race
Randomized Treatment Phase
ITT-Anemic Analysis Set

	White		All Other Races	
	MMB (N=54)	BAT (N=34)	MMB (N=5)	BAT (N=0)
Total number of RBC Transfusion unit in RT phase				
N	54	34	5	0
Mean (SD)	8.9 (10.22)	8.7 (8.65)	5.6 (5.59)	-
Median	6.0	6.0	4.0	-
Q1, Q3	1.0, 12.0	3.0, 13.0	2.0, 6.0	-
Min, Max	0.0, 38.0	0.0, 40.0	1.0, 15.0	-
Duration of RBC Transfusion in RT phase (months)				
N	54	34	5	0
Mean (SD)	4.96 (1.328)	4.79 (1.622)	4.33 (2.070)	-
Median	5.55	5.55	5.55	-
Q1, Q3	5.42, 5.68	5.32, 5.55	3.71, 5.65	-
Min, Max	0.92, 5.78	0.43, 5.78	0.95, 5.78	-

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-race.pdf 24AUG2023:15:01

Table 2.2510: Subgroup Analysis of Rate of RBC Transfusion by Duration of Ruxolitinib Received Prior to Randomization
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<12 Weeks		>= 12 Weeks	
	MMB (N=13)	BAT (N=8)	MMB (N=47)	BAT (N=24)
RBC Transfusion Rate in RT phase (units/month)				
N	13	8	47	24
Mean (SD)	2.1 (1.65)	3.6 (2.39)	2.1 (2.29)	1.6 (1.73)
Median	2.1	3.0	1.0	1.2
Q1, Q3	1.3, 2.9	2.1, 5.6	0.2, 3.3	0.5, 2.4
Min, Max	0.0, 6.1	0.0, 7.2	0.0, 8.2	0.0, 7.6
Negative Binomial Model				
Adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	1.30 (0.70, 2.41)	2.10 (1.03, 4.28)	1.54 (1.02, 2.34)	1.16 (0.71, 1.90)
Ratio of Rate for RBC Transfusion with 95% CI	0.62 (0.29, 1.33)		1.34 (0.74, 2.41)	
p-value	0.22		0.34	
Un-adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	2.02 (1.16, 3.53)	3.53 (1.77, 7.04)	2.09 (1.48, 2.95)	1.58 (0.96, 2.61)
Ratio of Rate for RBC Transfusion with 95% CI	0.57 (0.24, 1.39)		1.32 (0.72, 2.42)	
p-value	0.22		0.37	
Proportional Means Model - Supportive Analysis				
Stratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	0.60 (0.33, 1.07)		1.19 (0.80, 1.76)	
p-value	0.082		0.39	
Unstratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	0.59 (0.30, 1.16)		1.33 (0.83, 2.11)	
p-value	0.12		0.23	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-ruxDur.pdf 24AUG2023:15:01

Table 2.2510: Subgroup Analysis of Rate of RBC Transfusion by Duration of Ruxolitinib Received Prior to Randomization
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<12 Weeks		>= 12 Weeks	
	MMB (N=13)	BAT (N=8)	MMB (N=47)	BAT (N=24)
Total number of RBC Transfusion unit in RT phase				
N	13	8	47	24
Mean (SD)	9.3 (9.63)	14.5 (11.66)	9.5 (10.67)	7.3 (6.34)
Median	7.0	12.0	6.0	6.0
Q1, Q3	2.0, 13.0	9.0, 17.0	1.0, 13.0	3.0, 10.0
Min, Max	0.0, 34.0	0.0, 40.0	0.0, 38.0	0.0, 24.0
Duration of RBC Transfusion in RT phase (months)				
N	13	8	47	24
Mean (SD)	4.73 (1.769)	4.33 (1.797)	4.90 (1.378)	5.01 (1.550)
Median	5.55	5.49	5.55	5.55
Q1, Q3	5.29, 5.62	2.58, 5.55	4.70, 5.65	5.49, 5.62
Min, Max	0.92, 5.78	1.61, 5.78	0.95, 5.78	0.43, 5.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-ruxDur.pdf 24AUG2023:15:01

Table 2.2502: Subgroup Analysis of Rate of RBC Transfusion by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female	
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)
RBC Transfusion Rate in RT phase (units/month)				
N	52	18	14	21
Mean (SD)	2.1 (1.95)	2.2 (1.95)	2.3 (2.74)	1.8 (2.02)
Median	1.8	1.5	0.7	1.3
Q1, Q3	0.3, 3.2	0.7, 2.9	0.4, 4.7	0.4, 2.5
Min, Max	0.0, 6.8	0.0, 7.6	0.0, 8.2	0.0, 7.2
Negative Binomial Model				
Adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	1.67 (1.19, 2.36)	1.72 (1.02, 2.89)	1.00 (0.52, 1.94)	1.06 (0.65, 1.74)
Ratio of Rate for RBC Transfusion with 95% CI	0.97 (0.54, 1.74)		0.94 (0.45, 1.98)	
p-value	0.92		0.88	
Un-adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	2.05 (1.52, 2.75)	2.08 (1.24, 3.49)	2.19 (1.11, 4.35)	1.81 (1.04, 3.15)
Ratio of Rate for RBC Transfusion with 95% CI	0.99 (0.54, 1.79)		1.21 (0.50, 2.93)	
p-value	0.97		0.67	
Proportional Means Model - Supportive Analysis				
Stratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	1.06 (0.70, 1.60)		0.85 (0.42, 1.72)	
p-value	0.78		0.65	
Unstratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	1.10 (0.72, 1.69)		1.02 (0.48, 2.20)	
p-value	0.66		0.96	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-sex.pdf 24AUG2023:15:03

Table 2.2502: Subgroup Analysis of Rate of RBC Transfusion by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female	
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)
Total number of RBC Transfusion unit in RT phase				
N	52	18	14	21
Mean (SD)	9.8 (10.30)	8.4 (6.37)	8.8 (10.26)	9.0 (9.86)
Median	6.5	7.0	4.0	7.0
Q1, Q3	1.0, 14.0	4.0, 13.0	2.0, 13.0	2.0, 11.0
Min, Max	0.0, 38.0	0.0, 24.0	0.0, 32.0	0.0, 40.0
Duration of RBC Transfusion in RT phase (months)				
N	52	18	14	21
Mean (SD)	4.89 (1.455)	4.62 (1.916)	4.86 (1.289)	5.13 (1.116)
Median	5.55	5.55	5.52	5.55
Q1, Q3	4.99, 5.70	5.32, 5.68	4.24, 5.55	5.49, 5.55
Min, Max	0.92, 5.78	0.43, 5.78	1.58, 5.78	1.77, 5.75

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-sex.pdf 24AUG2023:15:03

Table 2.2505: Subgroup Analysis of Rate of RBC Transfusion by Spleen Volume at Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3	
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)
RBC Transfusion Rate in RT phase (units/month)				
N	28	24	38	15
Mean (SD)	1.5 (1.99)	1.9 (1.77)	2.6 (2.12)	2.2 (2.31)
Median	0.9	1.3	2.3	1.8
Q1, Q3	0.3, 1.9	0.8, 2.9	0.5, 4.0	0.4, 2.5
Min, Max	0.0, 8.2	0.0, 7.2	0.0, 6.6	0.0, 7.6
Negative Binomial Model				
Adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	1.18 (0.76, 1.83)	1.45 (0.93, 2.27)	1.87 (1.21, 2.87)	1.52 (0.82, 2.81)
Ratio of Rate for RBC Transfusion with 95% CI	0.81 (0.46, 1.45)		1.23 (0.59, 2.54)	
p-value	0.48		0.58	
Un-adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	1.43 (0.94, 2.15)	1.88 (1.21, 2.91)	2.56 (1.76, 3.71)	2.02 (1.09, 3.74)
Ratio of Rate for RBC Transfusion with 95% CI	0.76 (0.42, 1.38)		1.27 (0.62, 2.61)	
p-value	0.37		0.52	
Proportional Means Model - Supportive Analysis				
Stratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	0.71 (0.43, 1.18)		1.24 (0.75, 2.06)	
p-value	0.19		0.39	
Unstratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	0.72 (0.40, 1.27)		1.48 (0.86, 2.53)	
p-value	0.25		0.16	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-svb.pdf 24AUG2023:15:02

Table 2.2505: Subgroup Analysis of Rate of RBC Transfusion by Spleen Volume at Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3	
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)
Total number of RBC Transfusion unit in RT phase				
N	28	24	38	15
Mean (SD)	6.9 (8.43)	9.5 (9.08)	11.5 (11.08)	7.5 (7.08)
Median	5.0	7.5	10.0	5.0
Q1, Q3	1.5, 10.0	4.5, 13.0	1.0, 17.0	2.0, 13.0
Min, Max	0.0, 38.0	0.0, 40.0	0.0, 38.0	0.0, 25.0
Duration of RBC Transfusion in RT phase (months)				
N	28	24	38	15
Mean (SD)	5.28 (0.892)	5.20 (1.306)	4.59 (1.646)	4.41 (1.789)
Median	5.55	5.55	5.54	5.55
Q1, Q3	5.45, 5.68	5.49, 5.65	3.71, 5.62	2.46, 5.55
Min, Max	1.58, 5.78	0.43, 5.78	0.92, 5.78	0.66, 5.75

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-svb.pdf 24AUG2023:15:02

Table 2.2504: Subgroup Analysis of Rate of RBC Transfusion by Transfusion Dependence at Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Yes		No	
	MMB (N=52)	BAT (N=25)	MMB (N=14)	BAT (N=14)
RBC Transfusion Rate in RT phase (units/month)				
N	52	25	14	14
Mean (SD)	2.3 (2.26)	2.7 (2.08)	1.3 (1.17)	0.7 (0.91)
Median	1.6	1.8	1.5	0.4
Q1, Q3	0.4, 3.9	1.1, 3.2	0.0, 2.1	0.0, 1.6
Min, Max	0.0, 8.2	0.0, 7.6	0.0, 3.1	0.0, 2.4
Negative Binomial Model				
Adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	2.43 (1.82, 3.24)	2.61 (1.75, 3.89)	1.22 (0.58, 2.56)	0.69 (0.33, 1.46)
Ratio of Rate for RBC Transfusion with 95% CI	0.93 (0.57, 1.52)		1.77 (0.62, 5.06)	
p-value	0.78		0.29	
Un-adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	2.29 (1.73, 3.02)	2.62 (1.74, 3.93)	1.24 (0.59, 2.62)	0.74 (0.35, 1.56)
Ratio of Rate for RBC Transfusion with 95% CI	0.87 (0.53, 1.43)		1.68 (0.59, 4.85)	
p-value	0.59		0.33	
Proportional Means Model - Supportive Analysis				
Stratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	0.92 (0.63, 1.34)		1.64 (0.77, 3.48)	
p-value	0.66		0.20	
Unstratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	0.89 (0.60, 1.31)		1.63 (0.72, 3.68)	
p-value	0.55		0.24	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratification factor is total symptom score (< 18 vs. >=18) at baseline.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-tf.pdf 24AUG2023:15:02

Table 2.2504: Subgroup Analysis of Rate of RBC Transfusion by Transfusion Dependence at Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Yes		No	
	MMB (N=52)	BAT (N=25)	MMB (N=14)	BAT (N=14)
Total number of RBC Transfusion unit in RT phase				
N	52	25	14	14
Mean (SD)	10.8 (10.85)	11.6 (8.68)	4.9 (5.61)	3.6 (4.35)
Median	7.5	8.0	2.0	2.0
Q1, Q3	2.0, 16.0	6.0, 16.0	0.0, 10.0	0.0, 5.0
Min, Max	0.0, 38.0	0.0, 40.0	0.0, 17.0	0.0, 13.0
Duration of RBC Transfusion in RT phase (months)				
N	52	25	14	14
Mean (SD)	5.06 (1.192)	4.87 (1.691)	4.22 (1.947)	4.95 (1.275)
Median	5.55	5.55	5.49	5.55
Q1, Q3	5.44, 5.65	5.42, 5.65	3.19, 5.72	5.49, 5.59
Min, Max	0.92, 5.78	0.43, 5.78	0.95, 5.78	2.10, 5.72

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratification factor is total symptom score (< 18 vs. >=18) at baseline.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019

Table 2.2506: Subgroup Analysis of Rate of RBC Transfusion by TSS at Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	< 18		>= 18	
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)
RBC Transfusion Rate in RT phase (units/month)				
N	42	20	24	19
Mean (SD)	1.9 (2.03)	1.5 (1.47)	2.4 (2.27)	2.4 (2.34)
Median	1.0	1.1	2.0	1.8
Q1, Q3	0.3, 3.1	0.4, 2.7	0.5, 3.5	0.7, 3.2
Min, Max	0.0, 6.8	0.0, 5.0	0.0, 8.2	0.0, 7.6
Negative Binomial Model				
Adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	1.33 (0.86, 2.05)	1.12 (0.65, 1.95)	1.87 (1.23, 2.85)	1.85 (1.15, 2.97)
Ratio of Rate for RBC Transfusion with 95% CI	1.18 (0.64, 2.18)		1.01 (0.55, 1.86)	
p-value	0.60		0.98	
Un-adjusted for Strata				
Rate of RBC Transfusion with 95% CI(units/month)	1.90 (1.33, 2.73)	1.55 (0.91, 2.63)	2.39 (1.53, 3.71)	2.34 (1.42, 3.85)
Ratio of Rate for RBC Transfusion with 95% CI	1.23 (0.65, 2.32)		1.02 (0.52, 1.99)	
p-value	0.53		0.95	
Proportional Means Model - Supportive Analysis				
Stratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	1.05 (0.66, 1.67)		0.94 (0.56, 1.57)	
p-value	0.83		0.81	
Unstratified				
Ratio of Mean Cumulative Function of RBC Transfusion with 95% CI	1.22 (0.73, 2.02)		1.04 (0.60, 1.80)	
p-value	0.45		0.90	

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratification factor is transfusion dependence (Yes vs. No) at baseline.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell;
TSS = Total Symptom Score;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-tss.pdf 24AUG2023:15:02

Table 2.2506: Subgroup Analysis of Rate of RBC Transfusion by TSS at Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	< 18		>= 18	
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)
Total number of RBC Transfusion unit in RT phase				
N	42	20	24	19
Mean (SD)	9.4 (10.92)	7.7 (6.99)	9.9 (9.08)	9.9 (9.60)
Median	5.5	6.0	8.5	8.0
Q1, Q3	1.0, 13.0	2.5, 11.5	2.0, 14.5	4.0, 13.0
Min, Max	0.0, 38.0	0.0, 25.0	0.0, 32.0	0.0, 40.0
Duration of RBC Transfusion in RT phase (months)				
N	42	20	24	19
Mean (SD)	5.05 (1.253)	5.03 (1.477)	4.59 (1.641)	4.75 (1.627)
Median	5.55	5.55	5.52	5.55
Q1, Q3	5.45, 5.72	5.49, 5.70	3.91, 5.57	5.32, 5.55
Min, Max	0.95, 5.78	0.43, 5.78	0.92, 5.78	0.66, 5.78

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
Stratification factor is transfusion dependence (Yes vs. No) at baseline.
Proportional means model is Andersen-Gill model with robust sandwich variance estimate.
RBC = Red Blood Cell;
TSS = Total Symptom Score;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-rbc24.sas V.03.05 Output file: t-subgrp-rbc24-tss.pdf 24AUG2023:15:02

Table 2.4001: Subgroup Analysis of RBC Transfusion Dependent Response Rate at Week 24 and at Week 12 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years	
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)
RBC Transfusion Dependent Rate at Week 24				
Non-Dependent, n(%)	9 (37.5%)	3 (33.3%)	18 (42.9%)	8 (26.7%)
Transfusion Requiring, n(%)	1 (4.2%)	2 (22.2%)	4 (9.5%)	4 (13.3%)
Transfusion Independent, n(%)	8 (33.3%)	1 (11.1%)	14 (33.3%)	4 (13.3%)
Dependent, n(%)	15 (62.5%)	6 (66.7%)	24 (57.1%)	22 (73.3%)
95% Exact CI	0.4059, 0.8120	0.2993, 0.9251	0.4096, 0.7228	0.5411, 0.8772
Proportion Difference - Stratified CMH Method (95% CI)	0.08 (-0.29, 0.45)		-0.17 (-0.40, 0.07)	
Proportion Difference - Unstratified CMH Method (95% CI)	-0.04 (-0.43, 0.34)		-0.16 (-0.38, 0.06)	
Proportion Difference - Unstratified Exact Method (95% CI)	-0.04 (-0.42, 0.34)		-0.16 (-0.39, 0.08)	
>=4 units transfused in the last 8 weeks	5 (20.8%)	3 (33.3%)	9 (21.4%)	12 (40.0%)
Any Hgb assessment < 8g/dL in the last 8 weeks	6 (25.0%)	3 (33.3%)	13 (31.0%)	12 (40.0%)
Last Participation date < Day 162 in RT phase	8 (33.3%)	3 (33.3%)	10 (23.8%)	4 (13.3%)
Other	2 (8.3%)	1 (11.1%)	5 (11.9%)	7 (23.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-td.sas V.03.05 Output file: t-subgrp-rbctd24-age.pdf 24AUG2023:16:25

Table 2.4001: Subgroup Analysis of RBC Transfusion Dependent Response Rate at Week 24 and at Week 12 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years	
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)
RBC Transfusion Dependent Rate at Week 12				
Non-Dependent, n(%)	9 (37.5%)	2 (22.2%)	14 (33.3%)	10 (33.3%)
Transfusion Requiring, n(%)	3 (12.5%)	1 (11.1%)	5 (11.9%)	8 (26.7%)
Transfusion Independent, n(%)	6 (25.0%)	1 (11.1%)	9 (21.4%)	2 (6.7%)
Dependent, n(%)	15 (62.5%)	7 (77.8%)	28 (66.7%)	20 (66.7%)
95% Exact CI	0.4059, 0.8120	0.3999, 0.9719	0.5045, 0.8043	0.4719, 0.8271
Proportion Difference - Stratified CMH Method (95% CI)	-0.08 (-0.48, 0.31)		-0.04 (-0.27, 0.19)	
Proportion Difference - Unstratified CMH Method (95% CI)	-0.15 (-0.51, 0.21)		0.00 (-0.22, 0.22)	
Proportion Difference - Unstratified Exact Method (95% CI)	-0.15 (-0.52, 0.24)		0.00 (-0.23, 0.23)	
>=4 units transfused in the last 8 weeks	10 (41.7%)	1 (11.1%)	16 (38.1%)	12 (40.0%)
Any Hgb assessment < 8g/dL in the last 8 weeks	11 (45.8%)	2 (22.2%)	22 (52.4%)	14 (46.7%)
Last Participation date < Day 78 in RT phase	2 (8.3%)	3 (33.3%)	5 (11.9%)	3 (10.0%)
Other	4 (16.7%)	2 (22.2%)	9 (21.4%)	7 (23.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-td.sas V.03.05 Output file: t-subgrp-rbctd24-age.pdf 24AUG2023:16:25

Table 2.4008: Subgroup Analysis of RBC Transfusion Dependent Response Rate at Week 24 and at Week 12 by DIPSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk	
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)
RBC Transfusion Dependent Rate at Week 24				
Non-Dependent, n(%)	23 (46.9%)	10 (32.3%)	4 (23.5%)	1 (12.5%)
Transfusion Requiring, n(%)	5 (10.2%)	5 (16.1%)	0	1 (12.5%)
Transfusion Independent, n(%)	18 (36.7%)	5 (16.1%)	4 (23.5%)	0
Dependent, n(%)	26 (53.1%)	21 (67.7%)	13 (76.5%)	7 (87.5%)
95% Exact CI	0.3827, 0.6747	0.4863, 0.8332	0.5010, 0.9319	0.4735, 0.9968
Proportion Difference - Stratified CMH Method (95% CI)	-0.11 (-0.35, 0.13)		-0.07 (-0.42, 0.28)	
Proportion Difference - Unstratified CMH Method (95% CI)	-0.15 (-0.37, 0.07)		-0.11 (-0.46, 0.24)	
Proportion Difference - Unstratified Exact Method (95% CI)	-0.15 (-0.36, 0.08)		-0.11 (-0.50, 0.29)	
>=4 units transfused in the last 8 weeks	10 (20.4%)	11 (35.5%)	4 (23.5%)	4 (50.0%)
Any Hgb assessment < 8g/dL in the last 8 weeks	13 (26.5%)	9 (29.0%)	6 (35.3%)	6 (75.0%)
Last Participation date < Day 162 in RT phase	12 (24.5%)	6 (19.4%)	6 (35.3%)	1 (12.5%)
Other	3 (6.1%)	6 (19.4%)	4 (23.5%)	2 (25.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
DIPSS = Dynamic International Prognostic Scoring System.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-td.sas V.03.05 Output file: t-subgrp-rbctd24-dipss.pdf 24AUG2023:16:27

Table 2.4008: Subgroup Analysis of RBC Transfusion Dependent Response Rate at Week 24 and at Week 12 by DIPSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk	
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)
RBC Transfusion Dependent Rate at Week 12				
Non-Dependent, n(%)	18 (36.7%)	11 (35.5%)	5 (29.4%)	1 (12.5%)
Transfusion Requiring, n(%)	8 (16.3%)	8 (25.8%)	0	1 (12.5%)
Transfusion Independent, n(%)	10 (20.4%)	3 (9.7%)	5 (29.4%)	0
Dependent, n(%)	31 (63.3%)	20 (64.5%)	12 (70.6%)	7 (87.5%)
95% Exact CI	0.4829, 0.7658	0.4537, 0.8077	0.4404, 0.8969	0.4735, 0.9968
Proportion Difference - Stratified CMH Method (95% CI)	-0.04 (-0.27, 0.20)		-0.12 (-0.47, 0.23)	
Proportion Difference - Unstratified CMH Method (95% CI)	-0.01 (-0.23, 0.21)		-0.17 (-0.53, 0.19)	
Proportion Difference - Unstratified Exact Method (95% CI)	-0.01 (-0.23, 0.21)		-0.17 (-0.55, 0.24)	
>=4 units transfused in the last 8 weeks	18 (36.7%)	9 (29.0%)	8 (47.1%)	4 (50.0%)
Any Hgb assessment < 8g/dL in the last 8 weeks	25 (51.0%)	10 (32.3%)	8 (47.1%)	6 (75.0%)
Last Participation date < Day 78 in RT phase	4 (8.2%)	5 (16.1%)	3 (17.6%)	1 (12.5%)
Other	8 (16.3%)	7 (22.6%)	5 (29.4%)	2 (25.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
DIPSS = Dynamic International Prognostic Scoring System.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-td.sas V.03.05 Output file: t-subgrp-rbctd24-dipss.pdf 24AUG2023:16:27

Table 2.4007: Subgroup Analysis of RBC Transfusion Dependent Response Rate at Week 24 and at Week 12 by Hemoglobin Level at Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	< 8 g/dL		>= 8 g/dL	
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)
RBC Transfusion Dependent Rate at Week 24				
Non-Dependent, n(%)	9 (33.3%)	1 (16.7%)	18 (46.2%)	10 (30.3%)
Transfusion Requiring, n(%)	1 (3.7%)	1 (16.7%)	4 (10.3%)	5 (15.2%)
Transfusion Independent, n(%)	8 (29.6%)	0	14 (35.9%)	5 (15.2%)
Dependent, n(%)	18 (66.7%)	5 (83.3%)	21 (53.8%)	23 (69.7%)
95% Exact CI	0.4604, 0.8348	0.3588, 0.9958	0.3718, 0.6991	0.5129, 0.8441
Proportion Difference - Stratified CMH Method (95% CI)	-0.15 (-0.60, 0.30)		-0.12 (-0.36, 0.11)	
Proportion Difference - Unstratified CMH Method (95% CI)	-0.17 (-0.57, 0.24)		-0.16 (-0.38, 0.07)	
Proportion Difference - Unstratified Exact Method (95% CI)	-0.17 (-0.64, 0.29)		-0.16 (-0.38, 0.07)	
>=4 units transfused in the last 8 weeks	5 (18.5%)	2 (33.3%)	9 (23.1%)	13 (39.4%)
Any Hgb assessment < 8g/dL in the last 8 weeks	9 (33.3%)	3 (50.0%)	10 (25.6%)	12 (36.4%)
Last Participation date < Day 162 in RT phase	8 (29.6%)	2 (33.3%)	10 (25.6%)	5 (15.2%)
Other	4 (14.8%)	2 (33.3%)	3 (7.7%)	6 (18.2%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-td.sas V.03.05 Output file: t-subgrp-rbctd24-hgb.pdf 24AUG2023:16:26

Table 2.4007: Subgroup Analysis of RBC Transfusion Dependent Response Rate at Week 24 and at Week 12 by Hemoglobin Level at Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	< 8 g/dL		>= 8 g/dL	
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)
RBC Transfusion Dependent Rate at Week 12				
Non-Dependent, n(%)	6 (22.2%)	0	17 (43.6%)	12 (36.4%)
Transfusion Requiring, n(%)	3 (11.1%)	0	5 (12.8%)	9 (27.3%)
Transfusion Independent, n(%)	3 (11.1%)	0	12 (30.8%)	3 (9.1%)
Dependent, n(%)	21 (77.8%)	6 (100.0%)	22 (56.4%)	21 (63.6%)
95% Exact CI	0.5774, 0.9138	0.5407, 1.0000	0.3962, 0.7219	0.4512, 0.7960
Proportion Difference - Stratified CMH Method (95% CI)	-0.21 (-0.57, 0.15)		-0.06 (-0.30, 0.18)	
Proportion Difference - Unstratified CMH Method (95% CI)	-0.22 (-0.50, 0.06)		-0.07 (-0.30, 0.16)	
Proportion Difference - Unstratified Exact Method (95% CI)	-0.22 (-0.64, 0.23)		-0.07 (-0.30, 0.16)	
>=4 units transfused in the last 8 weeks	12 (44.4%)	2 (33.3%)	14 (35.9%)	11 (33.3%)
Any Hgb assessment < 8g/dL in the last 8 weeks	16 (59.3%)	3 (50.0%)	17 (43.6%)	13 (39.4%)
Last Participation date < Day 78 in RT phase	3 (11.1%)	2 (33.3%)	4 (10.3%)	4 (12.1%)
Other	10 (37.0%)	3 (50.0%)	3 (7.7%)	6 (18.2%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-td.sas V.03.05 Output file: t-subgrp-rbctd24-hgb.pdf 24AUG2023:16:26

Table 2.4012: Subgroup Analysis of RBC Transfusion Dependent Rate at Week 24 and 12 by Highest Dose of Ruxolitinib Received Since Randomization
Randomized Treatment Phase
ITT-Anemic Analysis Set on BAT Treatment Group

	< 20 mg BID (N=28)	>= 20 mg BID (N=6)	Not Taking Rux (N=5)
RBC Transfusion Dependent Rate at Week 24			
Not-Dependent, n(%)	9 (32.1%)	2 (33.3%)	0
Transfusion Requiring, n(%)	5 (17.9%)	1 (16.7%)	0
Transfusion Independent, n(%)	4 (14.3%)	1 (16.7%)	0
Dependent, n(%)	19 (67.9%)	4 (66.7%)	5 (100.0%)
95% Exact CI	0.4765, 0.8412	0.2228, 0.9567	0.4782, 1.0000
>=4 units transfused in the last 8 weeks	10 (35.7%)	2 (33.3%)	3 (60.0%)
Any Hgb assessment < 8g/dL in the last 8 weeks	9 (32.1%)	2 (33.3%)	4 (80.0%)
Last Participation date < Day 162 in RT phase	6 (21.4%)	1 (16.7%)	0
Other	3 (10.7%)	1 (16.7%)	4 (80.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-td-inc4.sas V.03.05 Output file: t-subgrp-rbctd24-inc4.pdf 24AUG2023:15:04

Table 2.4012: Subgroup Analysis of RBC Transfusion Dependent Rate at Week 24 and 12 by Highest Dose of Ruxolitinib Received Since Randomization
Randomized Treatment Phase
ITT-Anemic Analysis Set on BAT Treatment Group

	< 20 mg BID (N=28)	>= 20 mg BID (N=6)	Not Taking Rux (N=5)
RBC Transfusion Dependent Rate at Week 12			
Not-Dependent, n(%)	7 (25.0%)	3 (50.0%)	2 (40.0%)
Transfusion Requiring, n(%)	5 (17.9%)	2 (33.3%)	2 (40.0%)
Transfusion Independent, n(%)	2 (7.1%)	1 (16.7%)	0
Dependent, n(%)	21 (75.0%)	3 (50.0%)	3 (60.0%)
95% Exact CI	0.5513, 0.8931	0.1181, 0.8819	0.1466, 0.9473
>=4 units transfused in the last 8 weeks	10 (35.7%)	1 (16.7%)	2 (40.0%)
Any Hgb assessment < 8g/dL in the last 8 weeks	12 (42.9%)	2 (33.3%)	2 (40.0%)
Last Participation date < Day 78 in RT phase	5 (17.9%)	1 (16.7%)	0
Other	5 (17.9%)	2 (33.3%)	2 (40.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019

Table 2.4009: Subgroup Analysis of RBC Transfusion Dependent Response Rate at Week 24 and at Week 12 by JAKV617F Mutation
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Positive		Negative	
	MMB (N=43)	BAT (N=27)	MMB (N=22)	BAT (N=9)
RBC Transfusion Dependent Rate at Week 24				
Non-Dependent, n(%)	18 (41.9%)	6 (22.2%)	9 (40.9%)	4 (44.4%)
Transfusion Requiring, n(%)	4 (9.3%)	3 (11.1%)	1 (4.5%)	2 (22.2%)
Transfusion Independent, n(%)	14 (32.6%)	3 (11.1%)	8 (36.4%)	2 (22.2%)
Dependent, n(%)	25 (58.1%)	21 (77.8%)	13 (59.1%)	5 (55.6%)
95% Exact CI	0.4213, 0.7299	0.5774, 0.9138	0.3635, 0.7929	0.2120, 0.8630
Proportion Difference - Stratified CMH Method (95% CI)	-0.20 (-0.42, 0.02)		0.05 (-0.34, 0.45)	
Proportion Difference - Unstratified CMH Method (95% CI)	-0.20 (-0.42, 0.02)		0.04 (-0.37, 0.44)	
Proportion Difference - Unstratified Exact Method (95% CI)	-0.20 (-0.42, 0.05)		0.04 (-0.34, 0.42)	
>=4 units transfused in the last 8 weeks	7 (16.3%)	11 (40.7%)	6 (27.3%)	2 (22.2%)
Any Hgb assessment < 8g/dL in the last 8 weeks	8 (18.6%)	13 (48.1%)	10 (45.5%)	1 (11.1%)
Last Participation date < Day 162 in RT phase	15 (34.9%)	4 (14.8%)	3 (13.6%)	3 (33.3%)
Other	1 (2.3%)	7 (25.9%)	6 (27.3%)	1 (11.1%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-td.sas V.03.05 Output file: t-subgrp-rbctd24-jak.pdf 24AUG2023:16:27

Table 2.4009: Subgroup Analysis of RBC Transfusion Dependent Response Rate at Week 24 and at Week 12 by JAKV617F Mutation
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Positive		Negative	
	MMB (N=43)	BAT (N=27)	MMB (N=22)	BAT (N=9)
RBC Transfusion Dependent Rate at Week 12				
Non-Dependent, n(%)	15 (34.9%)	10 (37.0%)	7 (31.8%)	2 (22.2%)
Transfusion Requiring, n(%)	5 (11.6%)	7 (25.9%)	2 (9.1%)	2 (22.2%)
Transfusion Independent, n(%)	10 (23.3%)	3 (11.1%)	5 (22.7%)	0
Dependent, n(%)	28 (65.1%)	17 (63.0%)	15 (68.2%)	7 (77.8%)
95% Exact CI	0.4907, 0.7899	0.4237, 0.8060	0.4513, 0.8614	0.3999, 0.9719
Proportion Difference - Stratified CMH Method (95% CI)	-0.02 (-0.26, 0.22)		-0.07 (-0.46, 0.32)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.02 (-0.21, 0.26)		-0.10 (-0.46, 0.26)	
Proportion Difference - Unstratified Exact Method (95% CI)	0.02 (-0.21, 0.26)		-0.10 (-0.46, 0.29)	
>=4 units transfused in the last 8 weeks	15 (34.9%)	8 (29.6%)	11 (50.0%)	2 (22.2%)
Any Hgb assessment < 8g/dL in the last 8 weeks	19 (44.2%)	11 (40.7%)	14 (63.6%)	3 (33.3%)
Last Participation date < Day 78 in RT phase	7 (16.3%)	3 (11.1%)	0	3 (33.3%)
Other	8 (18.6%)	6 (22.2%)	5 (22.7%)	2 (22.2%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-td.sas V.03.05 Output file: t-subgrp-rbctd24-jak.pdf 24AUG2023:16:27

Table 2.4011: Subgroup Analysis of RBC Transfusion Dependent Response Rate at Week 24 and at Week 12 by Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis		Post-PV Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)	MMB (N=8)	BAT (N=8)
RBC Transfusion Dependent Rate at Week 24						
Non-Dependent, n(%)	18 (40.0%)	5 (21.7%)	5 (38.5%)	3 (37.5%)	4 (50.0%)	3 (37.5%)
Transfusion Requiring, n(%)	3 (6.7%)	3 (13.0%)	0	1 (12.5%)	2 (25.0%)	2 (25.0%)
Transfusion Independent, n(%)	15 (33.3%)	2 (8.7%)	5 (38.5%)	2 (25.0%)	2 (25.0%)	1 (12.5%)
Dependent, n(%)	27 (60.0%)	18 (78.3%)	8 (61.5%)	5 (62.5%)	4 (50.0%)	5 (62.5%)
95% Exact CI	0.4433, 0.7430	0.5630, 0.9254	0.3158, 0.8614	0.2449, 0.9148	0.1570, 0.8430	0.2449, 0.9148
Proportion Difference - Stratified CMH Method (95% CI)	-0.16 (-0.40, 0.09)		0.12 (-0.39, 0.63)		-0.10 (-0.73, 0.53)	
Proportion Difference - Unstratified CMH Method (95% CI)	-0.18 (-0.41, 0.05)		-0.01 (-0.46, 0.45)		-0.13 (-0.64, 0.39)	
Proportion Difference - Unstratified Exact Method (95% CI)	-0.18 (-0.41, 0.08)		-0.01 (-0.43, 0.43)		-0.13 (-0.60, 0.40)	
>=4 units transfused in the last 8 weeks	10 (22.2%)	10 (43.5%)	2 (15.4%)	3 (37.5%)	2 (25.0%)	2 (25.0%)
Any Hgb assessment < 8g/dL in the last 8 weeks	14 (31.1%)	9 (39.1%)	3 (23.1%)	3 (37.5%)	2 (25.0%)	3 (37.5%)
Last Participation date < Day 162 in RT phase	12 (26.7%)	4 (17.4%)	4 (30.8%)	2 (25.0%)	2 (25.0%)	1 (12.5%)
Other	6 (13.3%)	5 (21.7%)	1 (7.7%)	1 (12.5%)	0	2 (25.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019

Table 2.4011: Subgroup Analysis of RBC Transfusion Dependent Response Rate at Week 24 and at Week 12 by Disease Status
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis		Post-PV Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)	MMB (N=8)	BAT (N=8)
RBC Transfusion Dependent Rate at Week 12						
Non-Dependent, n(%)	15 (33.3%)	7 (30.4%)	3 (23.1%)	1 (12.5%)	5 (62.5%)	4 (50.0%)
Transfusion Requiring, n(%)	5 (11.1%)	6 (26.1%)	0	0	3 (37.5%)	3 (37.5%)
Transfusion Independent, n(%)	10 (22.2%)	1 (4.3%)	3 (23.1%)	1 (12.5%)	2 (25.0%)	1 (12.5%)
Dependent, n(%)	30 (66.7%)	16 (69.6%)	10 (76.9%)	7 (87.5%)	3 (37.5%)	4 (50.0%)
95% Exact CI	0.5105, 0.8000	0.4708, 0.8679	0.4619, 0.9496	0.4735, 0.9968	0.0852, 0.7551	0.1570, 0.8430
Proportion Difference - Stratified CMH Method (95% CI)	-0.02 (-0.28, 0.23)		-0.07 (-0.46, 0.32)		-0.24 (-0.87, 0.38)	
Proportion Difference - Unstratified CMH Method (95% CI)	-0.03 (-0.27, 0.21)		-0.11 (-0.47, 0.26)		-0.13 (-0.64, 0.39)	
Proportion Difference - Unstratified Exact Method (95% CI)	-0.03 (-0.27, 0.23)		-0.11 (-0.51, 0.33)		-0.13 (-0.60, 0.40)	
>=4 units transfused in the last 8 weeks	19 (42.2%)	7 (30.4%)	6 (46.2%)	5 (62.5%)	1 (12.5%)	1 (12.5%)
Any Hgb assessment < 8g/dL in the last 8 weeks	23 (51.1%)	9 (39.1%)	7 (53.8%)	4 (50.0%)	3 (37.5%)	3 (37.5%)
Last Participation date < Day 78 in RT phase	5 (11.1%)	3 (13.0%)	2 (15.4%)	2 (25.0%)	0	1 (12.5%)
Other	7 (15.6%)	7 (30.4%)	5 (38.5%)	1 (12.5%)	1 (12.5%)	1 (12.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019

Table 2.4003: Subgroup Analysis of RBC Transfusion Dependent Response Rate at Week 24 and at Week 12 by Race
Randomized Treatment Phase
ITT-Anemic Analysis Set

	White		All Other Races	
	MMB (N=54)	BAT (N=34)	MMB (N=5)	BAT (N=0)
RBC Transfusion Dependent Rate at Week 24				
Non-Dependent, n(%)	24 (44.4%)	9 (26.5%)	3 (60.0%)	0
Transfusion Requiring, n(%)	3 (5.6%)	5 (14.7%)	2 (40.0%)	0
Transfusion Independent, n(%)	21 (38.9%)	4 (11.8%)	1 (20.0%)	0
Dependent, n(%)	30 (55.6%)	25 (73.5%)	2 (40.0%)	0
95% Exact CI	0.4140, 0.6908	0.5564, 0.8712	0.0527, 0.8534	NA, NA
Proportion Difference - Stratified CMH Method (95% CI)	-0.16 (-0.37, 0.04)		NA	
Proportion Difference - Unstratified CMH Method (95% CI)	-0.18 (-0.38, 0.02)		NA	
Proportion Difference - Unstratified Exact Method (95% CI)	-0.18 (-0.38, 0.04)		NA	
>=4 units transfused in the last 8 weeks	12 (22.2%)	12 (35.3%)	0	0
Any Hgb assessment < 8g/dL in the last 8 weeks	16 (29.6%)	13 (38.2%)	0	0
Last Participation date < Day 162 in RT phase	13 (24.1%)	7 (20.6%)	2 (40.0%)	0
Other	5 (9.3%)	8 (23.5%)	0	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-td.sas V.03.05 Output file: t-subgrp-rbctd24-race.pdf 24AUG2023:16:26

Table 2.4003: Subgroup Analysis of RBC Transfusion Dependent Response Rate at Week 24 and at Week 12 by Race
Randomized Treatment Phase
ITT-Anemic Analysis Set

	White		All Other Races	
	MMB (N=54)	BAT (N=34)	MMB (N=5)	BAT (N=0)
RBC Transfusion Dependent Rate at Week 12				
Non-Dependent, n(%)	21 (38.9%)	12 (35.3%)	2 (40.0%)	0
Transfusion Requiring, n(%)	7 (13.0%)	9 (26.5%)	1 (20.0%)	0
Transfusion Independent, n(%)	14 (25.9%)	3 (8.8%)	1 (20.0%)	0
Dependent, n(%)	33 (61.1%)	22 (64.7%)	3 (60.0%)	0
95% Exact CI	0.4688, 0.7408	0.4649, 0.8025	0.1466, 0.9473	NA, NA
Proportion Difference - Stratified CMH Method (95% CI)	-0.06 (-0.26, 0.15)		NA	
Proportion Difference - Unstratified CMH Method (95% CI)	-0.04 (-0.25, 0.17)		NA	
Proportion Difference - Unstratified Exact Method (95% CI)	-0.04 (-0.25, 0.18)		NA	
>=4 units transfused in the last 8 weeks	19 (35.2%)	10 (29.4%)	1 (20.0%)	0
Any Hgb assessment < 8g/dL in the last 8 weeks	26 (48.1%)	12 (35.3%)	2 (40.0%)	0
Last Participation date < Day 78 in RT phase	5 (9.3%)	6 (17.6%)	1 (20.0%)	0
Other	12 (22.2%)	9 (26.5%)	0	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019

Table 2.4010: Subgroup Analysis of RBC Transfusion Dependent Rate at Week 24 and 12 by Duration of Ruxolitinib Received Prior to Randomization
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<12 weeks		>=12 weeks	
	MMB (N=13)	BAT (N=8)	MMB (N=47)	BAT (N=24)
RBC Transfusion Dependent Rate at Week 24				
Non-Dependent, n(%)	4 (30.8%)	0	21 (44.7%)	9 (37.5%)
Transfusion Requiring, n(%)	1 (7.7%)	0	3 (6.4%)	5 (20.8%)
Transfusion Independent, n(%)	3 (23.1%)	0	18 (38.3%)	4 (16.7%)
Dependent, n(%)	9 (69.2%)	8 (100.0%)	26 (55.3%)	15 (62.5%)
95% Exact CI	0.3857, 0.9091	0.6306, 1.0000	0.4012, 0.6983	0.4059, 0.8120
Proportion Difference - Stratified CMH Method (95% CI)	-0.31 (-0.66, 0.04)		-0.06 (-0.31, 0.19)	
Proportion Difference - Unstratified CMH Method (95% CI)	-0.31 (-0.62, 0.01)		-0.07 (-0.32, 0.17)	
Proportion Difference - Unstratified Exact Method (95% CI)	-0.31 (-0.68, 0.14)		-0.07 (-0.30, 0.18)	
>=4 units transfused in the last 8 weeks	3 (23.1%)	5 (62.5%)	9 (19.1%)	8 (33.3%)
Any Hgb assessment < 8g/dL in the last 8 weeks	5 (38.5%)	4 (50.0%)	14 (29.8%)	8 (33.3%)
Last Participation date < Day 162 in RT phase	4 (30.8%)	3 (37.5%)	12 (25.5%)	3 (12.5%)
Other	3 (23.1%)	4 (50.0%)	4 (8.5%)	2 (8.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019

Table 2.4010: Subgroup Analysis of RBC Transfusion Dependent Rate at Week 24 and 12 by Duration of Ruxolitinib Received Prior to Randomization
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<12 weeks		>=12 weeks	
	MMB (N=13)	BAT (N=8)	MMB (N=47)	BAT (N=24)
RBC Transfusion Dependent Rate at Week 12				
Non-Dependent, n(%)	3 (23.1%)	0	17 (36.2%)	8 (33.3%)
Transfusion Requiring, n(%)	0	0	6 (12.8%)	5 (20.8%)
Transfusion Independent, n(%)	3 (23.1%)	0	11 (23.4%)	3 (12.5%)
Dependent, n(%)	10 (76.9%)	8 (100.0%)	30 (63.8%)	16 (66.7%)
95% Exact CI	0.4619, 0.9496	0.6306, 1.0000	0.4852, 0.7733	0.4468, 0.8437
Proportion Difference - Stratified CMH Method (95% CI)	-0.23 (-0.57, 0.11)		-0.06 (-0.31, 0.20)	
Proportion Difference - Unstratified CMH Method (95% CI)	-0.23 (-0.53, 0.07)		-0.03 (-0.27, 0.21)	
Proportion Difference - Unstratified Exact Method (95% CI)	-0.23 (-0.62, 0.21)		-0.03 (-0.26, 0.22)	
>=4 units transfused in the last 8 weeks	7 (53.8%)	4 (50.0%)	17 (36.2%)	7 (29.2%)
Any Hgb assessment < 8g/dL in the last 8 weeks	8 (61.5%)	3 (37.5%)	24 (51.1%)	11 (45.8%)
Last Participation date < Day 78 in RT phase	2 (15.4%)	2 (25.0%)	5 (10.6%)	3 (12.5%)
Other	2 (15.4%)	4 (50.0%)	11 (23.4%)	4 (16.7%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019

Table 2.4002: Subgroup Analysis of RBC Transfusion Dependent Response Rate at Week 24 and at Week 12 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female	
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)
RBC Transfusion Dependent Rate at Week 24				
Non-Dependent, n(%)	20 (38.5%)	4 (22.2%)	7 (50.0%)	7 (33.3%)
Transfusion Requiring, n(%)	5 (9.6%)	3 (16.7%)	0	3 (14.3%)
Transfusion Independent, n(%)	15 (28.8%)	1 (5.6%)	7 (50.0%)	4 (19.0%)
Dependent, n(%)	32 (61.5%)	14 (77.8%)	7 (50.0%)	14 (66.7%)
95% Exact CI	0.4702, 0.7470	0.5236, 0.9359	0.2304, 0.7696	0.4303, 0.8541
Proportion Difference - Stratified CMH Method (95% CI)	-0.15 (-0.41, 0.12)		-0.11 (-0.46, 0.24)	
Proportion Difference - Unstratified CMH Method (95% CI)	-0.16 (-0.40, 0.08)		-0.17 (-0.51, 0.18)	
Proportion Difference - Unstratified Exact Method (95% CI)	-0.16 (-0.42, 0.11)		-0.17 (-0.49, 0.18)	
>=4 units transfused in the last 8 weeks	11 (21.2%)	7 (38.9%)	3 (21.4%)	8 (38.1%)
Any Hgb assessment < 8g/dL in the last 8 weeks	16 (30.8%)	7 (38.9%)	3 (21.4%)	8 (38.1%)
Last Participation date < Day 162 in RT phase	14 (26.9%)	4 (22.2%)	4 (28.6%)	3 (14.3%)
Other	6 (11.5%)	3 (16.7%)	1 (7.1%)	5 (23.8%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-td.sas V.03.05 Output file: t-subgrp-rbctd24-sex.pdf 24AUG2023:16:25

Table 2.4002: Subgroup Analysis of RBC Transfusion Dependent Response Rate at Week 24 and at Week 12 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female	
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)
RBC Transfusion Dependent Rate at Week 12				
Non-Dependent, n(%)	16 (30.8%)	5 (27.8%)	7 (50.0%)	7 (33.3%)
Transfusion Requiring, n(%)	5 (9.6%)	5 (27.8%)	3 (21.4%)	4 (19.0%)
Transfusion Independent, n(%)	11 (21.2%)	0	4 (28.6%)	3 (14.3%)
Dependent, n(%)	36 (69.2%)	13 (72.2%)	7 (50.0%)	14 (66.7%)
95% Exact CI	0.5490, 0.8128	0.4652, 0.9031	0.2304, 0.7696	0.4303, 0.8541
Proportion Difference - Stratified CMH Method (95% CI)	-0.03 (-0.31, 0.24)		-0.17 (-0.50, 0.16)	
Proportion Difference - Unstratified CMH Method (95% CI)	-0.03 (-0.28, 0.22)		-0.17 (-0.51, 0.18)	
Proportion Difference - Unstratified Exact Method (95% CI)	-0.03 (-0.30, 0.24)		-0.17 (-0.49, 0.18)	
>=4 units transfused in the last 8 weeks	21 (40.4%)	6 (33.3%)	5 (35.7%)	7 (33.3%)
Any Hgb assessment < 8g/dL in the last 8 weeks	27 (51.9%)	6 (33.3%)	6 (42.9%)	10 (47.6%)
Last Participation date < Day 78 in RT phase	6 (11.5%)	4 (22.2%)	1 (7.1%)	2 (9.5%)
Other	10 (19.2%)	3 (16.7%)	3 (21.4%)	6 (28.6%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-td.sas V.03.05 Output file: t-subgrp-rbctd24-sex.pdf 24AUG2023:16:25

Table 2.4005: Subgroup Analysis of RBC Transfusion Dependent Response Rate at Week 24 and at Week 12 by Spleen Volume at Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3	
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)
RBC Transfusion Dependent Rate at Week 24				
Non-Dependent, n(%)	14 (50.0%)	8 (33.3%)	13 (34.2%)	3 (20.0%)
Transfusion Requiring, n(%)	1 (3.6%)	5 (20.8%)	4 (10.5%)	1 (6.7%)
Transfusion Independent, n(%)	13 (46.4%)	3 (12.5%)	9 (23.7%)	2 (13.3%)
Dependent, n(%)	14 (50.0%)	16 (66.7%)	25 (65.8%)	12 (80.0%)
95% Exact CI	0.3065, 0.6935	0.4468, 0.8437	0.4865, 0.8037	0.5191, 0.9567
Proportion Difference - Stratified CMH Method (95% CI)	-0.18 (-0.46, 0.11)		-0.14 (-0.46, 0.17)	
Proportion Difference - Unstratified CMH Method (95% CI)	-0.17 (-0.44, 0.10)		-0.14 (-0.41, 0.12)	
Proportion Difference - Unstratified Exact Method (95% CI)	-0.17 (-0.43, 0.11)		-0.14 (-0.43, 0.15)	
>=4 units transfused in the last 8 weeks	4 (14.3%)	10 (41.7%)	10 (26.3%)	5 (33.3%)
Any Hgb assessment < 8g/dL in the last 8 weeks	8 (28.6%)	12 (50.0%)	11 (28.9%)	3 (20.0%)
Last Participation date < Day 162 in RT phase	5 (17.9%)	2 (8.3%)	13 (34.2%)	5 (33.3%)
Other	2 (7.1%)	5 (20.8%)	5 (13.2%)	3 (20.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019

Table 2.4005: Subgroup Analysis of RBC Transfusion Dependent Response Rate at Week 24 and at Week 12 by Spleen Volume at Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3	
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)
RBC Transfusion Dependent Rate at Week 12				
Non-Dependent, n(%)	14 (50.0%)	9 (37.5%)	9 (23.7%)	3 (20.0%)
Transfusion Requiring, n(%)	6 (21.4%)	7 (29.2%)	2 (5.3%)	2 (13.3%)
Transfusion Independent, n(%)	8 (28.6%)	2 (8.3%)	7 (18.4%)	1 (6.7%)
Dependent, n(%)	14 (50.0%)	15 (62.5%)	29 (76.3%)	12 (80.0%)
95% Exact CI	0.3065, 0.6935	0.4059, 0.8120	0.5976, 0.8856	0.5191, 0.9567
Proportion Difference - Stratified CMH Method (95% CI)	-0.14 (-0.42, 0.14)		-0.05 (-0.36, 0.27)	
Proportion Difference - Unstratified CMH Method (95% CI)	-0.13 (-0.40, 0.15)		-0.04 (-0.29, 0.22)	
Proportion Difference - Unstratified Exact Method (95% CI)	-0.13 (-0.39, 0.15)		-0.04 (-0.33, 0.25)	
>=4 units transfused in the last 8 weeks	8 (28.6%)	8 (33.3%)	18 (47.4%)	5 (33.3%)
Any Hgb assessment < 8g/dL in the last 8 weeks	12 (42.9%)	10 (41.7%)	21 (55.3%)	6 (40.0%)
Last Participation date < Day 78 in RT phase	1 (3.6%)	2 (8.3%)	6 (15.8%)	4 (26.7%)
Other	4 (14.3%)	6 (25.0%)	9 (23.7%)	3 (20.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019

Table 2.4004: Subgroup Analysis of RBC Transfusion Dependent Response Rate at Week 24 and at Week 12 by Transfusion Dependence at Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Yes		No	
	MMB (N=52)	BAT (N=25)	MMB (N=14)	BAT (N=14)
RBC Transfusion Dependent Rate at Week 24				
Non-Dependent, n(%)	22 (42.3%)	6 (24.0%)	5 (35.7%)	5 (35.7%)
Transfusion Requiring, n(%)	5 (9.6%)	5 (20.0%)	0	1 (7.1%)
Transfusion Independent, n(%)	17 (32.7%)	1 (4.0%)	5 (35.7%)	4 (28.6%)
Dependent, n(%)	30 (57.7%)	19 (76.0%)	9 (64.3%)	9 (64.3%)
95% Exact CI	0.4320, 0.7127	0.5487, 0.9064	0.3514, 0.8724	0.3514, 0.8724
Proportion Difference - Stratified CMH Method (95% CI)	-0.16 (-0.38, 0.06)		0.01 (-0.36, 0.38)	
Proportion Difference - Unstratified CMH Method (95% CI)	-0.18 (-0.40, 0.04)		0.00 (-0.37, 0.37)	
Proportion Difference - Unstratified Exact Method (95% CI)	-0.18 (-0.41, 0.05)		0.00 (-0.39, 0.39)	
>=4 units transfused in the last 8 weeks	11 (21.2%)	12 (48.0%)	3 (21.4%)	3 (21.4%)
Any Hgb assessment < 8g/dL in the last 8 weeks	17 (32.7%)	11 (44.0%)	2 (14.3%)	4 (28.6%)
Last Participation date < Day 162 in RT phase	12 (23.1%)	4 (16.0%)	6 (42.9%)	3 (21.4%)
Other	7 (13.5%)	7 (28.0%)	0	1 (7.1%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Stratification factor is total symptom score (< 18 vs. >=18) at baseline.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-td.sas V.03.05 Output file: t-subgrp-rbctd24-tf.pdf 24AUG2023:16:26

Table 2.4004: Subgroup Analysis of RBC Transfusion Dependent Response Rate at Week 24 and at Week 12 by Transfusion Dependence at Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Yes		No	
	MMB (N=52)	BAT (N=25)	MMB (N=14)	BAT (N=14)
RBC Transfusion Dependent Rate at Week 12				
Non-Dependent, n(%)	16 (30.8%)	5 (20.0%)	7 (50.0%)	7 (50.0%)
Transfusion Requiring, n(%)	6 (11.5%)	5 (20.0%)	2 (14.3%)	4 (28.6%)
Transfusion Independent, n(%)	10 (19.2%)	0	5 (35.7%)	3 (21.4%)
Dependent, n(%)	36 (69.2%)	20 (80.0%)	7 (50.0%)	7 (50.0%)
95% Exact CI	0.5490, 0.8128	0.5930, 0.9317	0.2304, 0.7696	0.2304, 0.7696
Proportion Difference - Stratified CMH Method (95% CI)	-0.09 (-0.30, 0.13)		0.01 (-0.39, 0.41)	
Proportion Difference - Unstratified CMH Method (95% CI)	-0.11 (-0.31, 0.10)		0.00 (-0.38, 0.38)	
Proportion Difference - Unstratified Exact Method (95% CI)	-0.11 (-0.34, 0.13)		0.00 (-0.39, 0.39)	
>=4 units transfused in the last 8 weeks	22 (42.3%)	11 (44.0%)	4 (28.6%)	2 (14.3%)
Any Hgb assessment < 8g/dL in the last 8 weeks	30 (57.7%)	13 (52.0%)	3 (21.4%)	3 (21.4%)
Last Participation date < Day 78 in RT phase	4 (7.7%)	4 (16.0%)	3 (21.4%)	2 (14.3%)
Other	13 (25.0%)	8 (32.0%)	0	1 (7.1%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Stratification factor is total symptom score (< 18 vs. >=18) at baseline.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-td.sas V.03.05 Output file: t-subgrp-rbctd24-tf.pdf 24AUG2023:16:26

Table 2.4006: Subgroup Analysis of RBC Transfusion Dependent Response Rate at Week 24 and at Week 12 by TSS at Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18	
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)
RBC Transfusion Dependent Rate at Week 24				
Non-Dependent, n(%)	21 (50.0%)	7 (35.0%)	6 (25.0%)	4 (21.1%)
Transfusion Requiring, n(%)	3 (7.1%)	5 (25.0%)	2 (8.3%)	1 (5.3%)
Transfusion Independent, n(%)	18 (42.9%)	2 (10.0%)	4 (16.7%)	3 (15.8%)
Dependent, n(%)	21 (50.0%)	13 (65.0%)	18 (75.0%)	15 (78.9%)
95% Exact CI	0.3419, 0.6581	0.4078, 0.8461	0.5329, 0.9023	0.5443, 0.9395
Proportion Difference - Stratified CMH Method (95% CI)	-0.16 (-0.43, 0.12)		-0.05 (-0.31, 0.21)	
Proportion Difference - Unstratified CMH Method (95% CI)	-0.15 (-0.41, 0.11)		-0.04 (-0.30, 0.22)	
Proportion Difference - Unstratified Exact Method (95% CI)	-0.15 (-0.41, 0.12)		-0.04 (-0.33, 0.25)	
>=4 units transfused in the last 8 weeks	6 (14.3%)	6 (30.0%)	8 (33.3%)	9 (47.4%)
Any Hgb assessment < 8g/dL in the last 8 weeks	12 (28.6%)	8 (40.0%)	7 (29.2%)	7 (36.8%)
Last Participation date < Day 162 in RT phase	9 (21.4%)	3 (15.0%)	9 (37.5%)	4 (21.1%)
Other	6 (14.3%)	6 (30.0%)	1 (4.2%)	2 (10.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Stratification factor is transfusion dependence (Yes vs. No) at baseline.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;
TSS = Total Symptom Score;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-td.sas V.03.05 Output file: t-subgrp-rbctd24-tss.pdf 24AUG2023:16:26

Table 2.4006: Subgroup Analysis of RBC Transfusion Dependent Response Rate at Week 24 and at Week 12 by TSS at Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18	
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)
RBC Transfusion Dependent Rate at Week 12				
Non-Dependent, n(%)	17 (40.5%)	7 (35.0%)	6 (25.0%)	5 (26.3%)
Transfusion Requiring, n(%)	7 (16.7%)	6 (30.0%)	1 (4.2%)	3 (15.8%)
Transfusion Independent, n(%)	10 (23.8%)	1 (5.0%)	5 (20.8%)	2 (10.5%)
Dependent, n(%)	25 (59.5%)	13 (65.0%)	18 (75.0%)	14 (73.7%)
95% Exact CI	0.4328, 0.7437	0.4078, 0.8461	0.5329, 0.9023	0.4880, 0.9085
Proportion Difference - Stratified CMH Method (95% CI)	-0.08 (-0.35, 0.19)		-0.03 (-0.30, 0.24)	
Proportion Difference - Unstratified CMH Method (95% CI)	-0.05 (-0.32, 0.21)		0.01 (-0.26, 0.29)	
Proportion Difference - Unstratified Exact Method (95% CI)	-0.05 (-0.32, 0.21)		0.01 (-0.28, 0.30)	
>=4 units transfused in the last 8 weeks	15 (35.7%)	6 (30.0%)	11 (45.8%)	7 (36.8%)
Any Hgb assessment < 8g/dL in the last 8 weeks	22 (52.4%)	8 (40.0%)	11 (45.8%)	8 (42.1%)
Last Participation date < Day 78 in RT phase	3 (7.1%)	2 (10.0%)	4 (16.7%)	4 (21.1%)
Other	9 (21.4%)	6 (30.0%)	4 (16.7%)	3 (15.8%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Stratification factor is transfusion dependence (Yes vs. No) at baseline.
Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;
TSS = Total Symptom Score;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-td.sas V.03.05 Output file: t-subgrp-rbctd24-tss.pdf 24AUG2023:16:26

Table 2.3301: Subgroup Analysis of RBC Transfusion Independent Response Rate at Week 24 and Week 12 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years	
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)
RBC Transfusion Independent Rate at Week 24				
Responder, n(%)	8 (33.3%)	1 (11.1%)	14 (33.3%)	4 (13.3%)
95% Exact CI	0.1563, 0.5532	0.0028, 0.4825	0.1957, 0.4955	0.0376, 0.3072
Proportion Difference - Stratified CMH Method(95% CI)	0.19(-0.18, 0.55)		0.22(0.02, 0.41)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.22(-0.09, 0.54)		0.20(0.01, 0.39)	
Proportion Difference - Unstratified Exact Method(95% CI)	0.22(-0.16, 0.60)		0.20(-0.04, 0.42)	
Non-Responder, n(%)	16 (66.7%)	8 (88.9%)	28 (66.7%)	26 (86.7%)
Transfusion(except bleeding) in the last 12 weeks	8 (33.3%)	5 (55.6%)	18 (42.9%)	20 (66.7%)
Any Hgb assessment < 8g/dL in the last 12 weeks	7 (29.2%)	3 (33.3%)	14 (33.3%)	15 (50.0%)
Last Participation date < Day 162 in RT phase	8 (33.3%)	3 (33.3%)	10 (23.8%)	4 (13.3%)
Other	2 (8.3%)	1 (11.1%)	7 (16.7%)	2 (6.7%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-age.pdf 24AUG2023:16:28

Table 2.3301: Subgroup Analysis of RBC Transfusion Independent Response Rate at Week 24 and Week 12 by Age
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<65 Years		>=65 Years	
	MMB (N=24)	BAT (N=9)	MMB (N=42)	BAT (N=30)
RBC Transfusion Independent Rate at Week 12				
Responder, n(%)	6 (25.0%)	1 (11.1%)	9 (21.4%)	2 (6.7%)
95% Exact CI	0.0977, 0.4671	0.0028, 0.4825	0.1030, 0.3681	0.0082, 0.2207
Proportion Difference - Stratified CMH Method(95% CI)	0.11(-0.24, 0.46)		0.18(-0.00, 0.35)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.14(-0.17, 0.44)		0.15(-0.01, 0.31)	
Proportion Difference - Unstratified Exact Method(95% CI)	0.14(-0.25, 0.50)		0.15(-0.09, 0.37)	
Non-Responder, n(%)	18 (75.0%)	8 (88.9%)	33 (78.6%)	28 (93.3%)
Transfusion(except bleeding) in the last 12 weeks	16 (66.7%)	5 (55.6%)	26 (61.9%)	23 (76.7%)
Any Hgb assessment < 8g/dL in the last 12 weeks	13 (54.2%)	4 (44.4%)	23 (54.8%)	16 (53.3%)
Last Participation date < Day 78 in RT phase	2 (8.3%)	3 (33.3%)	5 (11.9%)	3 (10.0%)
Other	7 (29.2%)	2 (22.2%)	13 (31.0%)	3 (10.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-age.pdf 24AUG2023:16:28

Table 2.3308: Subgroup Analysis of RBC Transfusion Independent Response Rate at Week 24 and Week 12 by DIPSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk	
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)
RBC Transfusion Independent Rate at Week 24				
Responder, n(%)	18 (36.7%)	5 (16.1%)	4 (23.5%)	0
95% Exact CI	0.2342, 0.5171	0.0545, 0.3373	0.0681, 0.4990	0.0000, 0.3694
Proportion Difference - Stratified CMH Method(95% CI)	0.23(0.04, 0.43)		0.22(-0.13, 0.57)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.21(0.01, 0.40)		0.24(-0.04, 0.51)	
Proportion Difference - Unstratified Exact Method(95% CI)	0.21(-0.02, 0.42)		0.24(-0.17, 0.60)	
Non-Responder, n(%)	31 (63.3%)	26 (83.9%)	13 (76.5%)	8 (100.0%)
Transfusion(except bleeding) in the last 12 weeks	19 (38.8%)	18 (58.1%)	7 (41.2%)	7 (87.5%)
Any Hgb assessment < 8g/dL in the last 12 weeks	15 (30.6%)	12 (38.7%)	6 (35.3%)	6 (75.0%)
Last Participation date < Day 162 in RT phase	12 (24.5%)	6 (19.4%)	6 (35.3%)	1 (12.5%)
Other	5 (10.2%)	2 (6.5%)	4 (23.5%)	1 (12.5%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
DIPSS = Dynamic International Prognostic Scoring System.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-dipss.pdf 24AUG2023:16:32

Table 2.3308: Subgroup Analysis of RBC Transfusion Independent Response Rate at Week 24 and Week 12 by DIPSS
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Intermediate Risk		High Risk	
	MMB (N=49)	BAT (N=31)	MMB (N=17)	BAT (N=8)
RBC Transfusion Independent Rate at Week 12				
Responder, n(%)	10 (20.4%)	3 (9.7%)	5 (29.4%)	0
95% Exact CI	0.1024, 0.3434	0.0204, 0.2575	0.1031, 0.5596	0.0000, 0.3694
Proportion Difference - Stratified CMH Method(95% CI)	0.15(-0.02, 0.33)		0.27(-0.07, 0.62)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.11(-0.05, 0.27)		0.29(0.01, 0.58)	
Proportion Difference - Unstratified Exact Method(95% CI)	0.11(-0.12, 0.32)		0.29(-0.11, 0.65)	
Non-Responder, n(%)	39 (79.6%)	28 (90.3%)	12 (70.6%)	8 (100.0%)
Transfusion(except bleeding) in the last 12 weeks	33 (67.3%)	21 (67.7%)	9 (52.9%)	7 (87.5%)
Any Hgb assessment < 8g/dL in the last 12 weeks	28 (57.1%)	14 (45.2%)	8 (47.1%)	6 (75.0%)
Last Participation date < Day 78 in RT phase	4 (8.2%)	5 (16.1%)	3 (17.6%)	1 (12.5%)
Other	15 (30.6%)	3 (9.7%)	5 (29.4%)	2 (25.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
DIPSS = Dynamic International Prognostic Scoring System.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-dipss.pdf 24AUG2023:16:32

Table 2.3307: Subgroup Analysis of RBC Transfusion Independent Response Rate at Week 24 and Week 12 by Hemoglobin Level at Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	< 8 g/dL		>= 8 g/dL	
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)
RBC Transfusion Independent Rate at Week 24				
Responder, n(%)	8 (29.6%)	0	14 (35.9%)	5 (15.2%)
95% Exact CI	0.1375, 0.5018	0.0000, 0.4593	0.2120, 0.5282	0.0511, 0.3190
Proportion Difference - Stratified CMH Method(95% CI)	0.28(-0.09, 0.65)		0.20(-0.00, 0.40)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.30(0.01, 0.58)		0.21(0.01, 0.41)	
Proportion Difference - Unstratified Exact Method(95% CI)	0.30(-0.16, 0.72)		0.21(-0.03, 0.42)	
Non-Responder, n(%)	19 (70.4%)	6 (100.0%)	25 (64.1%)	28 (84.8%)
Transfusion(except bleeding) in the last 12 weeks	11 (40.7%)	4 (66.7%)	15 (38.5%)	21 (63.6%)
Any Hgb assessment < 8g/dL in the last 12 weeks	11 (40.7%)	3 (50.0%)	10 (25.6%)	15 (45.5%)
Last Participation date < Day 162 in RT phase	8 (29.6%)	2 (33.3%)	10 (25.6%)	5 (15.2%)
Other	4 (14.8%)	1 (16.7%)	5 (12.8%)	2 (6.1%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-hgb.pdf 24AUG2023:16:31

Table 2.3307: Subgroup Analysis of RBC Transfusion Independent Response Rate at Week 24 and Week 12 by Hemoglobin Level at Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	< 8 g/dL		>= 8 g/dL	
	MMB (N=27)	BAT (N=6)	MMB (N=39)	BAT (N=33)
RBC Transfusion Independent Rate at Week 12				
Responder, n(%)	3 (11.1%)	0	12 (30.8%)	3 (9.1%)
95% Exact CI	0.0235, 0.2916	0.0000, 0.4593	0.1702, 0.4757	0.0192, 0.2433
Proportion Difference - Stratified CMH Method(95% CI)	0.11(-0.24, 0.46)		0.23(0.03, 0.42)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.11(-0.15, 0.37)		0.22(0.04, 0.40)	
Proportion Difference - Unstratified Exact Method(95% CI)	0.11(-0.34, 0.54)		0.22(-0.02, 0.43)	
Non-Responder, n(%)	24 (88.9%)	6 (100.0%)	27 (69.2%)	30 (90.9%)
Transfusion(except bleeding) in the last 12 weeks	19 (70.4%)	4 (66.7%)	23 (59.0%)	24 (72.7%)
Any Hgb assessment < 8g/dL in the last 12 weeks	19 (70.4%)	4 (66.7%)	17 (43.6%)	16 (48.5%)
Last Participation date < Day 78 in RT phase	3 (11.1%)	2 (33.3%)	4 (10.3%)	4 (12.1%)
Other	16 (59.3%)	2 (33.3%)	4 (10.3%)	3 (9.1%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-hgb.pdf 24AUG2023:16:31

Table 2.3312: Subgroup Analysis of RBC Transfusion Independent Rate at Week 24 and 12 by Highest Dose of Ruxolitinib Received Since Randomization
Randomized Treatment Phase
ITT-Anemic Analysis Set on BAT Treatment Group

	< 20 mg BID (N=28)	>= 20 mg BID (N=6)	Not Taking Rux (N=5)
RBC Transfusion Independent Rate at Week 24			
Dependent, n(%)	4 (14.3%)	1 (16.7%)	0
95% Exact CI	0.0403, 0.3267	0.0042, 0.6412	0.0000, 0.5218
Not-Dependent, n(%)	24 (85.7%)	5 (83.3%)	5 (100.0%)
Transfusion(except bleeding) in the last 12 weeks	17 (60.7%)	4 (66.7%)	4 (80.0%)
Any Hgb assessment < 8g/dL in the last 12 weeks	12 (42.9%)	2 (33.3%)	4 (80.0%)
Last Participation date < Day 162 in RT phase	6 (21.4%)	1 (16.7%)	0
Other	0	0	3 (60.0%)
RBC Transfusion Independent Rate at Week 12			
Dependent, n(%)	2 (7.1%)	1 (16.7%)	0
95% Exact CI	0.0088, 0.2350	0.0042, 0.6412	0.0000, 0.5218
Not-Dependent, n(%)	26 (92.9%)	5 (83.3%)	5 (100.0%)
Transfusion(except bleeding) in the last 12 weeks	19 (67.9%)	4 (66.7%)	5 (100.0%)
Any Hgb assessment < 8g/dL in the last 12 weeks	13 (46.4%)	3 (50.0%)	4 (80.0%)
Last Participation date < Day 78 in RT phase	5 (17.9%)	1 (16.7%)	0
Other	2 (7.1%)	1 (16.7%)	2 (40.0%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-ti-inc4.sas V.03.05 Output file: t-subgrp-rbcti24-inc4.pdf 24AUG2023:15:03

Table 2.3309: Subgroup Analysis of RBC Transfusion Independent Response Rate at Week 24 and Week 12 by JAKV617F Mutation
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Positive		Negative	
	MMB (N=43)	BAT (N=27)	MMB (N=22)	BAT (N=9)
RBC Transfusion Independent Rate at Week 24				
Responder, n(%)	14 (32.6%)	3 (11.1%)	8 (36.4%)	2 (22.2%)
95% Exact CI	0.1908, 0.4854	0.0235, 0.2916	0.1720, 0.5934	0.0281, 0.6001
Proportion Difference - Stratified CMH Method(95% CI)	0.23(0.04, 0.42)		0.15(-0.19, 0.49)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.21(0.02, 0.41)		0.14(-0.22, 0.51)	
Proportion Difference - Unstratified Exact Method(95% CI)	0.21(-0.03, 0.44)		0.14(-0.25, 0.50)	
Non-Responder, n(%)	29 (67.4%)	24 (88.9%)	14 (63.6%)	7 (77.8%)
Transfusion(except bleeding) in the last 12 weeks	14 (32.6%)	18 (66.7%)	11 (50.0%)	4 (44.4%)
Any Hgb assessment < 8g/dL in the last 12 weeks	10 (23.3%)	15 (55.6%)	10 (45.5%)	1 (11.1%)
Last Participation date < Day 162 in RT phase	15 (34.9%)	4 (14.8%)	3 (13.6%)	3 (33.3%)
Other	2 (4.7%)	3 (11.1%)	7 (31.8%)	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-jak.pdf 24AUG2023:16:33

Table 2.3309: Subgroup Analysis of RBC Transfusion Independent Response Rate at Week 24 and Week 12 by JAKV617F Mutation
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Positive		Negative	
	MMB (N=43)	BAT (N=27)	MMB (N=22)	BAT (N=9)
RBC Transfusion Independent Rate at Week 12				
Responder, n(%)	10 (23.3%)	3 (11.1%)	5 (22.7%)	0
95% Exact CI	0.1176, 0.3863	0.0235, 0.2916	0.0782, 0.4537	0.0000, 0.3363
Proportion Difference - Stratified CMH Method(95% CI)	0.17(-0.03, 0.36)		0.24(-0.05, 0.53)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.12(-0.06, 0.30)		0.23(-0.01, 0.46)	
Proportion Difference - Unstratified Exact Method(95% CI)	0.12(-0.12, 0.35)		0.23(-0.16, 0.60)	
Non-Responder, n(%)	33 (76.7%)	24 (88.9%)	17 (77.3%)	9 (100.0%)
Transfusion(except bleeding) in the last 12 weeks	25 (58.1%)	20 (74.1%)	16 (72.7%)	5 (55.6%)
Any Hgb assessment < 8g/dL in the last 12 weeks	20 (46.5%)	14 (51.9%)	16 (72.7%)	4 (44.4%)
Last Participation date < Day 78 in RT phase	7 (16.3%)	3 (11.1%)	0	3 (33.3%)
Other	9 (20.9%)	4 (14.8%)	11 (50.0%)	1 (11.1%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-jak.pdf 24AUG2023:16:33

Table 2.3311: Subgroup Analysis of RBC Transfusion Independent Response Rate at Week 24 and at Week 12 by Disease Type
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis		Post-PV Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)	MMB (N=8)	BAT (N=8)
RBC Transfusion Independent Rate at Week 24						
Responder, n(%)	15 (33.3%)	2 (8.7%)	5 (38.5%)	2 (25.0%)	2 (25.0%)	1 (12.5%)
95% Exact CI	0.2000, 0.4895	0.0107, 0.2804	0.1386, 0.6842	0.0319, 0.6509	0.0319, 0.6509	0.0032, 0.5265
Proportion Difference - Stratified CMH Method(95% CI)	0.24(0.03, 0.44)		0.06(-0.38, 0.50)		0.24(-0.31, 0.80)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.25(0.06, 0.44)		0.13(-0.30, 0.57)		0.13(-0.31, 0.56)	
Proportion Difference - Unstratified Exact Method(95% CI)	0.25(-0.01, 0.47)		0.13(-0.31, 0.53)		0.13(-0.40, 0.60)	
Non-Responder, n(%)	30 (66.7%)	21 (91.3%)	8 (61.5%)	6 (75.0%)	6 (75.0%)	7 (87.5%)
Transfusion(except bleeding) in the last 12 weeks	18 (40.0%)	16 (69.6%)	4 (30.8%)	4 (50.0%)	4 (50.0%)	5 (62.5%)
Any Hgb assessment < 8g/dL in the last 12 weeks	15 (33.3%)	11 (47.8%)	3 (23.1%)	3 (37.5%)	3 (37.5%)	4 (50.0%)
Last Participation date < Day 162 in RT phase	12 (26.7%)	4 (17.4%)	4 (30.8%)	2 (25.0%)	2 (25.0%)	1 (12.5%)
Other	8 (17.8%)	3 (13.0%)	1 (7.7%)	0	0	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-mf.pdf 24AUG2023:16:34

Table 2.3311: Subgroup Analysis of RBC Transfusion Independent Response Rate at Week 24 and at Week 12 by Disease Type
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Primary Myelofibrosis		Post-ET Myelofibrosis		Post-PV Myelofibrosis	
	MMB (N=45)	BAT (N=23)	MMB (N=13)	BAT (N=8)	MMB (N=8)	BAT (N=8)
RBC Transfusion Independent Rate at Week 12						
Responder, n(%)	10 (22.2%)	1 (4.3%)	3 (23.1%)	1 (12.5%)	2 (25.0%)	1 (12.5%)
95% Exact CI	0.1120, 0.3709	0.0011, 0.2195	0.0504, 0.5381	0.0032, 0.5265	0.0319, 0.6509	0.0032, 0.5265
Proportion Difference - Stratified CMH Method(95% CI)	0.19(0.01, 0.38)		0.07(-0.32, 0.46)		0.24(-0.31, 0.80)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.18(0.02, 0.34)		0.11(-0.26, 0.47)		0.13(-0.31, 0.56)	
Proportion Difference - Unstratified Exact Method(95% CI)	0.18(-0.08, 0.41)		0.11(-0.33, 0.51)		0.13(-0.40, 0.60)	
Non-Responder, n(%)	35 (77.8%)	22 (95.7%)	10 (76.9%)	7 (87.5%)	6 (75.0%)	7 (87.5%)
Transfusion(except bleeding) in the last 12 weeks	29 (64.4%)	17 (73.9%)	7 (53.8%)	5 (62.5%)	6 (75.0%)	6 (75.0%)
Any Hgb assessment < 8g/dL in the last 12 weeks	26 (57.8%)	13 (56.5%)	7 (53.8%)	4 (50.0%)	3 (37.5%)	3 (37.5%)
Last Participation date < Day 78 in RT phase	5 (11.1%)	3 (13.0%)	2 (15.4%)	2 (25.0%)	0	1 (12.5%)
Other	14 (31.1%)	5 (21.7%)	5 (38.5%)	0	1 (12.5%)	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-mf.pdf 24AUG2023:16:34

Table 2.3303: Subgroup Analysis of RBC Transfusion Independent Response Rate at Week 24 and Week 12 by Race
Randomized Treatment Phase
ITT-Anemic Analysis Set

	White		All Other Races	
	MMB (N=54)	BAT (N=34)	MMB (N=5)	BAT (N=0)
RBC Transfusion Independent Rate at Week 24				
Responder, n(%)	21 (38.9%)	4 (11.8%)	1 (20.0%)	0
95% Exact CI	0.2592, 0.5312	0.0330, 0.2745	0.0051, 0.7164	NA, NA
Proportion Difference - Stratified CMH Method(95% CI)	0.28(0.11, 0.45)		NA	
Proportion Difference - Unstratified CMH Method (95% CI)	0.27(0.10, 0.45)		NA	
Proportion Difference - Unstratified Exact Method(95% CI)	0.27(0.06, 0.47)		NA	
Non-Responder, n(%)	33 (61.1%)	30 (88.2%)	4 (80.0%)	0
Transfusion(except bleeding) in the last 12 weeks	20 (37.0%)	21 (61.8%)	2 (40.0%)	0
Any Hgb assessment < 8g/dL in the last 12 weeks	16 (29.6%)	15 (44.1%)	1 (20.0%)	0
Last Participation date < Day 162 in RT phase	13 (24.1%)	7 (20.6%)	2 (40.0%)	0
Other	8 (14.8%)	3 (8.8%)	0	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-race.pdf 24AUG2023:16:29

Table 2.3303: Subgroup Analysis of RBC Transfusion Independent Response Rate at Week 24 and Week 12 by Race
Randomized Treatment Phase
ITT-Anemic Analysis Set

	White		All Other Races	
	MMB (N=54)	BAT (N=34)	MMB (N=5)	BAT (N=0)
RBC Transfusion Independent Rate at Week 12				
Responder, n(%)	14 (25.9%)	3 (8.8%)	1 (20.0%)	0
95% Exact CI	0.1496, 0.3965	0.0186, 0.2368	0.0051, 0.7164	NA, NA
Proportion Difference - Stratified CMH Method(95% CI)	0.20(0.03, 0.36)		NA	
Proportion Difference - Unstratified CMH Method (95% CI)	0.17(0.01, 0.33)		NA	
Proportion Difference - Unstratified Exact Method(95% CI)	0.17(-0.04, 0.38)		NA	
Non-Responder, n(%)	40 (74.1%)	31 (91.2%)	4 (80.0%)	0
Transfusion(except bleeding) in the last 12 weeks	33 (61.1%)	24 (70.6%)	3 (60.0%)	0
Any Hgb assessment < 8g/dL in the last 12 weeks	28 (51.9%)	16 (47.1%)	2 (40.0%)	0
Last Participation date < Day 78 in RT phase	5 (9.3%)	6 (17.6%)	1 (20.0%)	0
Other	14 (25.9%)	5 (14.7%)	1 (20.0%)	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-race.pdf 24AUG2023:16:29

Table 2.3310: Subgroup Analysis of RBC Transfusion Independent Rate at Week 24 and 12 by Duration of Ruxolitinib Received Prior to Randomization
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<12 weeks		>=12 weeks	
	MMB (N=13)	BAT (N=8)	MMB (N=47)	BAT (N=24)
RBC Transfusion Independent Rate at Week 24				
Responder, n(%)	3 (23.1%)	0	18 (38.3%)	4 (16.7%)
95% Exact CI	0.0504, 0.5381	0.0000, 0.3694	0.2451, 0.5362	0.0474, 0.3738
Proportion Difference - Stratified CMH Method(95% CI)	0.23(-0.11, 0.57)		0.24(0.04, 0.45)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.23(-0.07, 0.53)		0.22(0.01, 0.43)	
Proportion Difference - Unstratified Exact Method(95% CI)	0.23(-0.21, 0.62)		0.22(-0.04, 0.44)	
Non-Responder, n(%)	10 (76.9%)	8 (100.0%)	29 (61.7%)	20 (83.3%)
Transfusion(except bleeding) in the last 12 weeks	6 (46.2%)	5 (62.5%)	17 (36.2%)	16 (66.7%)
Any Hgb assessment < 8g/dL in the last 12 weeks	5 (38.5%)	4 (50.0%)	15 (31.9%)	11 (45.8%)
Last Participation date < Day 162 in RT phase	4 (30.8%)	3 (37.5%)	12 (25.5%)	3 (12.5%)
Other	2 (15.4%)	2 (25.0%)	7 (14.9%)	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-ruxDur.pdf 24AUG2023:16:27

Table 2.3310: Subgroup Analysis of RBC Transfusion Independent Rate at Week 24 and 12 by Duration of Ruxolitinib Received Prior to Randomization
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<12 weeks		>=12 weeks	
	MMB (N=13)	BAT (N=8)	MMB (N=47)	BAT (N=24)
RBC Transfusion Independent Rate at Week 12				
Responder, n(%)	3 (23.1%)	0	11 (23.4%)	3 (12.5%)
95% Exact CI	0.0504, 0.5381	0.0000, 0.3694	0.1230, 0.3803	0.0266, 0.3236
Proportion Difference - Stratified CMH Method(95% CI)	0.23(-0.11, 0.57)		0.15(-0.04, 0.35)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.23(-0.07, 0.53)		0.11(-0.08, 0.30)	
Proportion Difference - Unstratified Exact Method(95% CI)	0.23(-0.21, 0.62)		0.11(-0.14, 0.34)	
Non-Responder, n(%)	10 (76.9%)	8 (100.0%)	36 (76.6%)	21 (87.5%)
Transfusion(except bleeding) in the last 12 weeks	8 (61.5%)	5 (62.5%)	29 (61.7%)	17 (70.8%)
Any Hgb assessment < 8g/dL in the last 12 weeks	8 (61.5%)	4 (50.0%)	26 (55.3%)	13 (54.2%)
Last Participation date < Day 78 in RT phase	2 (15.4%)	2 (25.0%)	5 (10.6%)	3 (12.5%)
Other	2 (15.4%)	3 (37.5%)	17 (36.2%)	2 (8.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019

Table 2.3302: Subgroup Analysis of RBC Transfusion Independent Response Rate at Week 24 and Week 12 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female	
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)
RBC Transfusion Independent Rate at Week 24				
Responder, n(%)	15 (28.8%)	1 (5.6%)	7 (50.0%)	4 (19.0%)
95% Exact CI	0.1713, 0.4308	0.0014, 0.2729	0.2304, 0.7696	0.0545, 0.4191
Proportion Difference - Stratified CMH Method(95% CI)	0.22(0.01, 0.43)		0.31(0.02, 0.61)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.23(0.05, 0.41)		0.31(-0.01, 0.63)	
Proportion Difference - Unstratified Exact Method(95% CI)	0.23(-0.03, 0.49)		0.31(-0.04, 0.61)	
Non-Responder, n(%)	37 (71.2%)	17 (94.4%)	7 (50.0%)	17 (81.0%)
Transfusion(except bleeding) in the last 12 weeks	23 (44.2%)	12 (66.7%)	3 (21.4%)	13 (61.9%)
Any Hgb assessment < 8g/dL in the last 12 weeks	18 (34.6%)	7 (38.9%)	3 (21.4%)	11 (52.4%)
Last Participation date < Day 162 in RT phase	14 (26.9%)	4 (22.2%)	4 (28.6%)	3 (14.3%)
Other	8 (15.4%)	2 (11.1%)	1 (7.1%)	1 (4.8%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-sex.pdf 24AUG2023:16:29

Table 2.3302: Subgroup Analysis of RBC Transfusion Independent Response Rate at Week 24 and Week 12 by Gender
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Male		Female	
	MMB (N=52)	BAT (N=18)	MMB (N=14)	BAT (N=21)
RBC Transfusion Independent Rate at Week 12				
Responder, n(%)	11 (21.2%)	0	4 (28.6%)	3 (14.3%)
95% Exact CI	0.1106, 0.3470	0.0000, 0.1853	0.0839, 0.5810	0.0305, 0.3634
Proportion Difference - Stratified CMH Method(95% CI)	0.21(0.02, 0.41)		0.21(-0.08, 0.49)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.21(0.08, 0.35)		0.14(-0.15, 0.44)	
Proportion Difference - Unstratified Exact Method(95% CI)	0.21(-0.05, 0.47)		0.14(-0.20, 0.47)	
Non-Responder, n(%)	41 (78.8%)	18 (100.0%)	10 (71.4%)	18 (85.7%)
Transfusion(except bleeding) in the last 12 weeks	34 (65.4%)	13 (72.2%)	8 (57.1%)	15 (71.4%)
Any Hgb assessment < 8g/dL in the last 12 weeks	29 (55.8%)	9 (50.0%)	7 (50.0%)	11 (52.4%)
Last Participation date < Day 78 in RT phase	6 (11.5%)	4 (22.2%)	1 (7.1%)	2 (9.5%)
Other	17 (32.7%)	2 (11.1%)	3 (21.4%)	3 (14.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-sex.pdf 24AUG2023:16:29

Table 2.3305: Subgroup Analysis of RBC Transfusion Independent Response Rate at Week 24 and Week 12 by Spleen Volume at Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3	
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)
RBC Transfusion Independent Rate at Week 24				
Responder, n(%)	13 (46.4%)	3 (12.5%)	9 (23.7%)	2 (13.3%)
95% Exact CI	0.2751, 0.6613	0.0266, 0.3236	0.1144, 0.4024	0.0166, 0.4046
Proportion Difference - Stratified CMH Method(95% CI)	0.37(0.13, 0.61)		0.09(-0.21, 0.40)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.34(0.10, 0.57)		0.10(-0.13, 0.34)	
Proportion Difference - Unstratified Exact Method(95% CI)	0.34(0.06, 0.58)		0.10(-0.19, 0.39)	
Non-Responder, n(%)	15 (53.6%)	21 (87.5%)	29 (76.3%)	13 (86.7%)
Transfusion(except bleeding) in the last 12 weeks	10 (35.7%)	19 (79.2%)	16 (42.1%)	6 (40.0%)
Any Hgb assessment < 8g/dL in the last 12 weeks	9 (32.1%)	13 (54.2%)	12 (31.6%)	5 (33.3%)
Last Participation date < Day 162 in RT phase	5 (17.9%)	2 (8.3%)	13 (34.2%)	5 (33.3%)
Other	4 (14.3%)	2 (8.3%)	5 (13.2%)	1 (6.7%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-svb.pdf 24AUG2023:16:30

Table 2.3305: Subgroup Analysis of RBC Transfusion Independent Response Rate at Week 24 and Week 12 by Spleen Volume at Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	< Median 2329.91 cm^3		>= Median 2329.91 cm^3	
	MMB (N=28)	BAT (N=24)	MMB (N=38)	BAT (N=15)
RBC Transfusion Independent Rate at Week 12				
Responder, n(%)	8 (28.6%)	2 (8.3%)	7 (18.4%)	1 (6.7%)
95% Exact CI	0.1322, 0.4867	0.0103, 0.2700	0.0774, 0.3433	0.0017, 0.3195
Proportion Difference - Stratified CMH Method(95% CI)	0.21(-0.03, 0.45)		0.14(-0.14, 0.42)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.20(-0.01, 0.41)		0.12(-0.08, 0.32)	
Proportion Difference - Unstratified Exact Method(95% CI)	0.20(-0.07, 0.46)		0.12(-0.18, 0.40)	
Non-Responder, n(%)	20 (71.4%)	22 (91.7%)	31 (81.6%)	14 (93.3%)
Transfusion(except bleeding) in the last 12 weeks	18 (64.3%)	19 (79.2%)	24 (63.2%)	9 (60.0%)
Any Hgb assessment < 8g/dL in the last 12 weeks	13 (46.4%)	13 (54.2%)	23 (60.5%)	7 (46.7%)
Last Participation date < Day 78 in RT phase	1 (3.6%)	2 (8.3%)	6 (15.8%)	4 (26.7%)
Other	7 (25.0%)	4 (16.7%)	13 (34.2%)	1 (6.7%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-svb.pdf 24AUG2023:16:30

Table 2.3304: Subgroup Analysis of RBC Transfusion Independent Response Rate at Week 24 and Week 12 by Transfusion Dependence at Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Yes		No	
	MMB (N=52)	BAT (N=25)	MMB (N=14)	BAT (N=14)
RBC Transfusion Independent Rate at Week 24				
Responder, n(%)	17 (32.7%)	1 (4.0%)	5 (35.7%)	4 (28.6%)
95% Exact CI	0.2033, 0.4711	0.0010, 0.2035	0.1276, 0.6486	0.0839, 0.5810
Proportion Difference - Stratified CMH Method(95% CI)	0.27(0.11, 0.44)		0.05(-0.31, 0.42)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.29(0.13, 0.45)		0.07(-0.29, 0.43)	
Proportion Difference - Unstratified Exact Method(95% CI)	0.29(0.05, 0.50)		0.07(-0.32, 0.45)	
Non-Responder, n(%)	35 (67.3%)	24 (96.0%)	9 (64.3%)	10 (71.4%)
Transfusion(except bleeding) in the last 12 weeks	23 (44.2%)	19 (76.0%)	3 (21.4%)	6 (42.9%)
Any Hgb assessment < 8g/dL in the last 12 weeks	19 (36.5%)	13 (52.0%)	2 (14.3%)	5 (35.7%)
Last Participation date < Day 162 in RT phase	12 (23.1%)	4 (16.0%)	6 (42.9%)	3 (21.4%)
Other	9 (17.3%)	3 (12.0%)	0	0

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Stratification factor is total symptom score (< 18 vs. >=18) at baseline.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-tf.pdf 24AUG2023:16:30

Table 2.3304: Subgroup Analysis of RBC Transfusion Independent Response Rate at Week 24 and Week 12 by Transfusion Dependence at Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	Yes		No	
	MMB (N=52)	BAT (N=25)	MMB (N=14)	BAT (N=14)
RBC Transfusion Independent Rate at Week 12				
Responder, n(%)	10 (19.2%)	0	5 (35.7%)	3 (21.4%)
95% Exact CI	0.0963, 0.3253	0.0000, 0.1372	0.1276, 0.6486	0.0466, 0.5080
Proportion Difference - Stratified CMH Method(95% CI)	0.19(0.05, 0.33)		0.14(-0.22, 0.51)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.19(0.07, 0.31)		0.14(-0.21, 0.49)	
Proportion Difference - Unstratified Exact Method(95% CI)	0.19(-0.05, 0.42)		0.14(-0.26, 0.51)	
Non-Responder, n(%)	42 (80.8%)	25 (100.0%)	9 (64.3%)	11 (78.6%)
Transfusion(except bleeding) in the last 12 weeks	36 (69.2%)	21 (84.0%)	6 (42.9%)	7 (50.0%)
Any Hgb assessment < 8g/dL in the last 12 weeks	33 (63.5%)	17 (68.0%)	3 (21.4%)	3 (21.4%)
Last Participation date < Day 78 in RT phase	4 (7.7%)	4 (16.0%)	3 (21.4%)	2 (14.3%)
Other	20 (38.5%)	4 (16.0%)	0	1 (7.1%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Stratification factor is total symptom score (< 18 vs. >=18) at baseline.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-tf.pdf 24AUG2023:16:30

Table 2.3306: Subgroup Analysis of RBC Transfusion Independent Response Rate at Week 24 and Week 12 by TSS at Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18	
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)
RBC Transfusion Independent Rate at Week 24				
Responder, n(%)	18 (42.9%)	2 (10.0%)	4 (16.7%)	3 (15.8%)
95% Exact CI	0.2772, 0.5904	0.0123, 0.3170	0.0474, 0.3738	0.0338, 0.3958
Proportion Difference - Stratified CMH Method(95% CI)	0.36(0.16, 0.56)		0.02(-0.23, 0.26)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.33(0.12, 0.54)		0.01(-0.23, 0.24)	
Proportion Difference - Unstratified Exact Method(95% CI)	0.33(0.06, 0.56)		0.01(-0.28, 0.30)	
Non-Responder, n(%)	24 (57.1%)	18 (90.0%)	20 (83.3%)	16 (84.2%)
Transfusion(except bleeding) in the last 12 weeks	15 (35.7%)	13 (65.0%)	11 (45.8%)	12 (63.2%)
Any Hgb assessment < 8g/dL in the last 12 weeks	12 (28.6%)	9 (45.0%)	9 (37.5%)	9 (47.4%)
Last Participation date < Day 162 in RT phase	9 (21.4%)	3 (15.0%)	9 (37.5%)	4 (21.1%)
Other	7 (16.7%)	2 (10.0%)	2 (8.3%)	1 (5.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Stratification factor is transfusion dependence (Yes vs. No) at baseline.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;
TSS = Total Symptom Score;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-subgrp-ti.sas V.03.05 Output file: t-subgrp-rbcti24-tss.pdf 24AUG2023:16:31

Table 2.3306: Subgroup Analysis of RBC Transfusion Independent Response Rate at Week 24 and Week 12 by TSS at Baseline
Randomized Treatment Phase
ITT-Anemic Analysis Set

	<18		>=18	
	MMB (N=42)	BAT (N=20)	MMB (N=24)	BAT (N=19)
RBC Transfusion Independent Rate at Week 12				
Responder, n(%)	10 (23.8%)	1 (5.0%)	5 (20.8%)	2 (10.5%)
95% Exact CI	0.1205, 0.3945	0.0013, 0.2487	0.0713, 0.4215	0.0130, 0.3314
Proportion Difference - Stratified CMH Method(95% CI)	0.22(0.03, 0.40)		0.13(-0.11, 0.36)	
Proportion Difference - Unstratified CMH Method (95% CI)	0.19(0.01, 0.36)		0.10(-0.12, 0.33)	
Proportion Difference - Unstratified Exact Method(95% CI)	0.19(-0.08, 0.44)		0.10(-0.20, 0.39)	
Non-Responder, n(%)	32 (76.2%)	19 (95.0%)	19 (79.2%)	17 (89.5%)
Transfusion(except bleeding) in the last 12 weeks	27 (64.3%)	15 (75.0%)	15 (62.5%)	13 (68.4%)
Any Hgb assessment < 8g/dL in the last 12 weeks	23 (54.8%)	11 (55.0%)	13 (54.2%)	9 (47.4%)
Last Participation date < Day 78 in RT phase	3 (7.1%)	2 (10.0%)	4 (16.7%)	4 (21.1%)
Other	13 (31.0%)	4 (20.0%)	7 (29.2%)	1 (5.3%)

ITT-Anemic Analysis includes subjects in the Intent-to-Treat Population with Baseline Hemoglobin < 10 g/dL.
95% Exact CI is based on Clopper-Pearson method without stratification.
Stratification factor is transfusion dependence (Yes vs. No) at baseline.
CMH = Cochran-Mantel-Haenszel;
RBC = Red Blood Cell;
TSS = Total Symptom Score;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders	4 (33.3%)	4 (66.7%)	8 (44.4%)	22 (73.3%)
Grade 1	3 (25.0%)	1 (16.7%)	4 (22.2%)	9 (30.0%)
Grade 2	1 (8.3%)	2 (33.3%)	3 (16.7%)	11 (36.7%)
Grade 3	0	1 (16.7%)	1 (5.6%)	2 (6.7%)
Grade 4	0	0	0	0
Diarrhoea (excl infective)	3 (25.0%)	3 (50.0%)	6 (33.3%)	13 (43.3%)
Grade 1	3 (25.0%)	0	3 (16.7%)	6 (20.0%)
Grade 2	0	2 (33.3%)	2 (11.1%)	6 (20.0%)
Grade 3	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Diarrhoea	3 (25.0%)	3 (50.0%)	6 (33.3%)	13 (43.3%)
Grade 1	3 (25.0%)	0	3 (16.7%)	6 (20.0%)
Grade 2	0	2 (33.3%)	2 (11.1%)	6 (20.0%)
Grade 3	0	1 (16.7%)	1 (5.6%)	1 (3.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-et.pdf 24AUG2023:15:01

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders	15 (48.4%)	17 (70.8%)	32 (58.2%)	47 (71.2%)
Grade 1	5 (16.1%)	8 (33.3%)	13 (23.6%)	19 (28.8%)
Grade 2	7 (22.6%)	4 (16.7%)	11 (20.0%)	17 (25.8%)
Grade 3	3 (9.7%)	4 (16.7%)	7 (12.7%)	10 (15.2%)
Grade 4	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Diarrhoea (excl infective)	10 (32.3%)	4 (16.7%)	14 (25.5%)	22 (33.3%)
Grade 1	7 (22.6%)	2 (8.3%)	9 (16.4%)	15 (22.7%)
Grade 2	2 (6.5%)	1 (4.2%)	3 (5.5%)	4 (6.1%)
Grade 3	1 (3.2%)	1 (4.2%)	2 (3.6%)	3 (4.5%)
Diarrhoea	10 (32.3%)	4 (16.7%)	14 (25.5%)	22 (33.3%)
Grade 1	7 (22.6%)	2 (8.3%)	9 (16.4%)	15 (22.7%)
Grade 2	2 (6.5%)	1 (4.2%)	3 (5.5%)	4 (6.1%)
Grade 3	1 (3.2%)	1 (4.2%)	2 (3.6%)	3 (4.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal and abdominal pains (excl oral and throat)	0	1 (16.7%)	1 (5.6%)	9 (30.0%)
Grade 1	0	1 (16.7%)	1 (5.6%)	6 (20.0%)
Grade 2	0	0	0	2 (6.7%)
Grade 3	0	0	0	1 (3.3%)
Abdominal pain	0	1 (16.7%)	1 (5.6%)	8 (26.7%)
Grade 1	0	1 (16.7%)	1 (5.6%)	5 (16.7%)
Grade 2	0	0	0	2 (6.7%)
Grade 3	0	0	0	1 (3.3%)
Abdominal pain upper	0	0	0	1 (3.3%)
Grade 1	0	0	0	1 (3.3%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal and abdominal pains (excl oral and throat)	4 (12.9%)	5 (20.8%)	9 (16.4%)	16 (24.2%)
Grade 1	1 (3.2%)	3 (12.5%)	4 (7.3%)	6 (9.1%)
Grade 2	2 (6.5%)	2 (8.3%)	4 (7.3%)	8 (12.1%)
Grade 3	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Abdominal pain	3 (9.7%)	2 (8.3%)	5 (9.1%)	7 (10.6%)
Grade 1	0	0	0	1 (1.5%)
Grade 2	2 (6.5%)	2 (8.3%)	4 (7.3%)	5 (7.6%)
Grade 3	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Abdominal pain upper	1 (3.2%)	3 (12.5%)	4 (7.3%)	8 (12.1%)
Grade 1	1 (3.2%)	3 (12.5%)	4 (7.3%)	4 (6.1%)
Grade 2	0	0	0	3 (4.5%)
Grade 3	0	0	0	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal and abdominal pains (excl oral and throat) (cont)				
Abdominal pain lower	0	0	0	0
Grade 1	0	0	0	0
Nausea and vomiting symptoms	2 (16.7%)	2 (33.3%)	4 (22.2%)	8 (26.7%)
Grade 1	2 (16.7%)	1 (16.7%)	3 (16.7%)	6 (20.0%)
Grade 2	0	1 (16.7%)	1 (5.6%)	2 (6.7%)
Grade 3	0	0	0	0
Nausea	2 (16.7%)	2 (33.3%)	4 (22.2%)	8 (26.7%)
Grade 1	2 (16.7%)	1 (16.7%)	3 (16.7%)	6 (20.0%)
Grade 2	0	1 (16.7%)	1 (5.6%)	2 (6.7%)
Vomiting	1 (8.3%)	1 (16.7%)	2 (11.1%)	4 (13.3%)
Grade 1	1 (8.3%)	1 (16.7%)	2 (11.1%)	4 (13.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal and abdominal pains (excl oral and throat) (cont)				
Abdominal pain lower	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)
Nausea and vomiting symptoms	3 (9.7%)	4 (16.7%)	7 (12.7%)	14 (21.2%)
Grade 1	3 (9.7%)	1 (4.2%)	4 (7.3%)	11 (16.7%)
Grade 2	0	2 (8.3%)	2 (3.6%)	2 (3.0%)
Grade 3	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Nausea	3 (9.7%)	3 (12.5%)	6 (10.9%)	13 (19.7%)
Grade 1	3 (9.7%)	1 (4.2%)	4 (7.3%)	11 (16.7%)
Grade 2	0	2 (8.3%)	2 (3.6%)	2 (3.0%)
Vomiting	1 (3.2%)	2 (8.3%)	3 (5.5%)	3 (4.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Nausea and vomiting symptoms (cont)				
Vomiting (cont)				
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Gastrointestinal atonic and hypomotility disorders NEC	1 (8.3%)	0	1 (5.6%)	6 (20.0%)
Grade 1	1 (8.3%)	0	1 (5.6%)	4 (13.3%)
Grade 2	0	0	0	2 (6.7%)
Constipation	1 (8.3%)	0	1 (5.6%)	2 (6.7%)
Grade 1	1 (8.3%)	0	1 (5.6%)	2 (6.7%)
Gastrooesophageal reflux disease	0	0	0	4 (13.3%)
Grade 1	0	0	0	2 (6.7%)
Grade 2	0	0	0	2 (6.7%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Nausea and vomiting symptoms (cont)				
Vomiting (cont)				
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 3	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Gastrointestinal atonic and hypomotility disorders NEC	3 (9.7%)	1 (4.2%)	4 (7.3%)	9 (13.6%)
Grade 1	2 (6.5%)	1 (4.2%)	3 (5.5%)	8 (12.1%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Constipation	2 (6.5%)	1 (4.2%)	3 (5.5%)	8 (12.1%)
Grade 1	2 (6.5%)	1 (4.2%)	3 (5.5%)	8 (12.1%)
Gastrooesophageal reflux disease	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	0	0	0	0
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal atonic and hypomotility disorders NEC (cont)				
Impaired gastric emptying	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Dyspeptic signs and symptoms	0	0	0	2 (6.7%)
Grade 1	0	0	0	0
Grade 2	0	0	0	2 (6.7%)
Dyspepsia	0	0	0	2 (6.7%)
Grade 1	0	0	0	0
Grade 2	0	0	0	2 (6.7%)
Epigastric discomfort	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal atonic and hypomotility disorders NEC (cont)				
Impaired gastric emptying	0	0	0	0
Grade 1	0	0	0	0
Dyspeptic signs and symptoms	1 (3.2%)	1 (4.2%)	2 (3.6%)	7 (10.6%)
Grade 1	1 (3.2%)	1 (4.2%)	2 (3.6%)	5 (7.6%)
Grade 2	0	0	0	2 (3.0%)
Dyspepsia	1 (3.2%)	1 (4.2%)	2 (3.6%)	6 (9.1%)
Grade 1	1 (3.2%)	1 (4.2%)	2 (3.6%)	4 (6.1%)
Grade 2	0	0	0	2 (3.0%)
Epigastric discomfort	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Non-site specific gastrointestinal haemorrhages	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Melaena	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Gastrointestinal haemorrhage	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Haematemesis	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Non-site specific gastrointestinal haemorrhages	2 (6.5%)	3 (12.5%)	5 (9.1%)	6 (9.1%)
Grade 1	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	1 (4.2%)	2 (3.6%)	1 (1.5%)
Grade 3	1 (3.2%)	1 (4.2%)	2 (3.6%)	4 (6.1%)
Melaena	1 (3.2%)	2 (8.3%)	3 (5.5%)	4 (6.1%)
Grade 1	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Grade 3	0	0	0	1 (1.5%)
Gastrointestinal haemorrhage	2 (6.5%)	1 (4.2%)	3 (5.5%)	3 (4.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 3	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Haematemesis	1 (3.2%)	0	1 (1.8%)	2 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-et.pdf 24AUG2023:15:01

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Non-site specific gastrointestinal haemorrhages (cont)				
Haematemesis (cont)				
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Upper gastrointestinal haemorrhage	0	0	0	0
Grade 3	0	0	0	0
Peritoneal and retroperitoneal disorders	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Ascites	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Non-site specific gastrointestinal haemorrhages (cont)				
Haematemesis (cont)				
Grade 2	1 (3.2%)	0	1 (1.8%)	0
Grade 3	0	0	0	2 (3.0%)
Upper gastrointestinal haemorrhage	0	0	0	2 (3.0%)
Grade 3	0	0	0	2 (3.0%)
Peritoneal and retroperitoneal disorders	1 (3.2%)	2 (8.3%)	3 (5.5%)	5 (7.6%)
Grade 1	0	0	0	2 (3.0%)
Grade 2	1 (3.2%)	2 (8.3%)	3 (5.5%)	3 (4.5%)
Ascites	1 (3.2%)	2 (8.3%)	3 (5.5%)	5 (7.6%)
Grade 1	0	0	0	2 (3.0%)
Grade 2	1 (3.2%)	2 (8.3%)	3 (5.5%)	3 (4.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Flatulence, bloating and distension	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 1	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 2	0	0	0	0
Abdominal distension	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 1	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 2	0	0	0	0
Flatulence	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Gastrointestinal signs and symptoms NEC	0	0	0	0
Grade 1	0	0	0	0
Abdominal discomfort	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Flatulence, bloating and distension	1 (3.2%)	0	1 (1.8%)	3 (4.5%)
Grade 1	0	0	0	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Abdominal distension	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	0	0	0	0
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Flatulence	0	0	0	2 (3.0%)
Grade 1	0	0	0	1 (1.5%)
Grade 2	0	0	0	1 (1.5%)
Gastrointestinal signs and symptoms NEC	0	3 (12.5%)	3 (5.5%)	4 (6.1%)
Grade 1	0	3 (12.5%)	3 (5.5%)	4 (6.1%)
Abdominal discomfort	0	2 (8.3%)	2 (3.6%)	3 (4.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal signs and symptoms NEC (cont)				
Abdominal discomfort (cont)				
Grade 1	0	0	0	0
Dysphagia	0	0	0	0
Grade 1	0	0	0	0
Stomatitis and ulceration	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 1	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 2	0	0	0	0
Mouth ulceration	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 1	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

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Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal signs and symptoms NEC (cont)				
Abdominal discomfort (cont)				
Grade 1	0	2 (8.3%)	2 (3.6%)	3 (4.5%)
Dysphagia	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 1	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Stomatitis and ulceration	2 (6.5%)	0	2 (3.6%)	3 (4.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Mouth ulceration	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Grade 1	0	0	0	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Stomatitis and ulceration (cont)				
Palatal ulcer	0	0	0	0
Grade 1	0	0	0	0
Dental and periodontal infections and inflammations	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	0	0	0	0
Grade 2	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Dental caries	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	0	0	0	0
Grade 2	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Intestinal haemorrhages	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Stomatitis and ulceration (cont)				
Palatal ulcer	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Dental and periodontal infections and inflammations	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Grade 1	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Dental caries	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Grade 1	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Intestinal haemorrhages	1 (3.2%)	1 (4.2%)	2 (3.6%)	3 (4.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Grade 3	0	1 (4.2%)	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Intestinal haemorrhages (cont)				
Rectal haemorrhage	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Anal haemorrhage	0	0	0	0
Grade 1	0	0	0	0
Oral dryness and saliva altered	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 1	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 2	0	0	0	0
Dry mouth	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 1	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Intestinal haemorrhages (cont)				
Rectal haemorrhage	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 3	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Anal haemorrhage	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)
Oral dryness and saliva altered	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Dry mouth	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal spastic and hypermotility disorders	0	0	0	1 (3.3%)
Grade 1	0	0	0	1 (3.3%)
Defaecation urgency	0	0	0	1 (3.3%)
Grade 1	0	0	0	1 (3.3%)
Frequent bowel movements	0	0	0	0
Grade 1	0	0	0	0
Haemorrhoids and gastrointestinal varices (excl oesophageal)	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Haemorrhoidal haemorrhage	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

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Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal spastic and hypermotility disorders	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)
Defaecation urgency	0	0	0	0
Grade 1	0	0	0	0
Frequent bowel movements	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)
Haemorrhoids and gastrointestinal varices (excl oesophageal)	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Haemorrhoidal haemorrhage	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
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Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Haemorrhoids and gastrointestinal varices (excl oesophageal) (cont)				
Haemorrhoidal haemorrhage (cont)				
Grade 1	0	0	0	0
Haemorrhoids	0	0	0	0
Grade 2	0	0	0	0
Abdominal wall conditions NEC	0	0	0	0
Grade 3	0	0	0	0
Abdominal wall haematoma	0	0	0	0
Grade 3	0	0	0	0
Anal and rectal disorders NEC	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

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Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
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Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Haemorrhoids and gastrointestinal varices (excl oesophageal) (cont)				
Haemorrhoidal haemorrhage (cont)				
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Haemorrhoids	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Abdominal wall conditions NEC	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 3	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Abdominal wall haematoma	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 3	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Anal and rectal disorders NEC	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Anal and rectal disorders NEC (cont)				
Anal fissure	0	0	0	0
Grade 2	0	0	0	0
Anal and rectal signs and symptoms	0	0	0	0
Grade 1	0	0	0	0
Anorectal discomfort	0	0	0	0
Grade 1	0	0	0	0
Dental pain and sensation disorders	0	0	0	0
Grade 2	0	0	0	0
Toothache	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Anal and rectal disorders NEC (cont)				
Anal fissure	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Anal and rectal signs and symptoms	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)
Anorectal discomfort	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)
Dental pain and sensation disorders	0	0	0	1 (1.5%)
Grade 2	0	0	0	1 (1.5%)
Toothache	0	0	0	1 (1.5%)
Grade 2	0	0	0	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Diaphragmatic hernias	0	0	0	0
Grade 2	0	0	0	0
Hiatus hernia	0	0	0	0
Grade 2	0	0	0	0
Gastric and oesophageal haemorrhages	0	0	0	0
Grade 2	0	0	0	0
Oesophageal haemorrhage	0	0	0	0
Grade 2	0	0	0	0
Gastric ulcers and perforation	0	0	0	0
Grade 3	0	0	0	0
Gastric ulcer	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Diaphragmatic hernias	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Hiatus hernia	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Gastric and oesophageal haemorrhages	0	0	0	1 (1.5%)
Grade 2	0	0	0	1 (1.5%)
Oesophageal haemorrhage	0	0	0	1 (1.5%)
Grade 2	0	0	0	1 (1.5%)
Gastric ulcers and perforation	0	0	0	1 (1.5%)
Grade 3	0	0	0	1 (1.5%)
Gastric ulcer	0	0	0	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastric ulcers and perforation (cont)				
Gastric ulcer (cont)				
Grade 3	0	0	0	0
Gastritis (excl infective)	0	0	0	0
Grade 1	0	0	0	0
Gastritis	0	0	0	0
Grade 1	0	0	0	0
Gastrointestinal mucosal dystrophies and secretion disorders	0	0	0	0
Grade 1	0	0	0	0
Gastrointestinal melanosis	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastric ulcers and perforation (cont)				
Gastric ulcer (cont)				
Grade 3	0	0	0	1 (1.5%)
Gastritis (excl infective)	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)
Gastritis	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)
Gastrointestinal mucosal dystrophies and secretion disorders	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)
Gastrointestinal melanosis	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal vascular occlusion and infarction	0	0	0	0
Grade 4	0	0	0	0
Visceral venous thrombosis	0	0	0	0
Grade 4	0	0	0	0
Oesophageal varices	0	0	0	0
Grade 2	0	0	0	0
Varices oesophageal	0	0	0	0
Grade 2	0	0	0	0
Oral soft tissue haemorrhages	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal vascular occlusion and infarction	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 4	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Visceral venous thrombosis	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 4	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Oesophageal varices	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Varices oesophageal	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Oral soft tissue haemorrhages	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Oral soft tissue haemorrhages (cont)				
Mouth haemorrhage	0	0	0	0
Grade 2	0	0	0	0
Oral soft tissue pain and paraesthesia	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 1	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Oral pain	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 1	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Umbilical hernias	0	0	0	0
Grade 1	0	0	0	0
Umbilical hernia	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Oral soft tissue haemorrhages (cont)				
Mouth haemorrhage	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Oral soft tissue pain and paraesthesia	0	0	0	0
Grade 1	0	0	0	0
Oral pain	0	0	0	0
Grade 1	0	0	0	0
Umbilical hernias	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Umbilical hernia	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions	4 (33.3%)	4 (66.7%)	8 (44.4%)	18 (60.0%)
Grade 1	2 (16.7%)	1 (16.7%)	3 (16.7%)	7 (23.3%)
Grade 2	1 (8.3%)	2 (33.3%)	3 (16.7%)	7 (23.3%)
Grade 3	0	1 (16.7%)	1 (5.6%)	3 (10.0%)
Grade 5	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Asthenic conditions	1 (8.3%)	3 (50.0%)	4 (22.2%)	12 (40.0%)
Grade 1	1 (8.3%)	0	1 (5.6%)	3 (10.0%)
Grade 2	0	2 (33.3%)	2 (11.1%)	7 (23.3%)
Grade 3	0	1 (16.7%)	1 (5.6%)	2 (6.7%)
Asthenia	1 (8.3%)	2 (33.3%)	3 (16.7%)	9 (30.0%)
Grade 1	1 (8.3%)	0	1 (5.6%)	2 (6.7%)
Grade 2	0	1 (16.7%)	1 (5.6%)	5 (16.7%)
Grade 3	0	1 (16.7%)	1 (5.6%)	2 (6.7%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions	21 (67.7%)	15 (62.5%)	36 (65.5%)	46 (69.7%)
Grade 1	7 (22.6%)	5 (20.8%)	12 (21.8%)	12 (18.2%)
Grade 2	10 (32.3%)	7 (29.2%)	17 (30.9%)	21 (31.8%)
Grade 3	4 (12.9%)	3 (12.5%)	7 (12.7%)	13 (19.7%)
Grade 5	0	0	0	0
Asthenic conditions	9 (29.0%)	10 (41.7%)	19 (34.5%)	29 (43.9%)
Grade 1	3 (9.7%)	3 (12.5%)	6 (10.9%)	9 (13.6%)
Grade 2	4 (12.9%)	5 (20.8%)	9 (16.4%)	13 (19.7%)
Grade 3	2 (6.5%)	2 (8.3%)	4 (7.3%)	7 (10.6%)
Asthenia	5 (16.1%)	7 (29.2%)	12 (21.8%)	16 (24.2%)
Grade 1	2 (6.5%)	1 (4.2%)	3 (5.5%)	4 (6.1%)
Grade 2	2 (6.5%)	4 (16.7%)	6 (10.9%)	6 (9.1%)
Grade 3	1 (3.2%)	2 (8.3%)	3 (5.5%)	6 (9.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Asthenic conditions (cont)				
Fatigue	0	2 (33.3%)	2 (11.1%)	4 (13.3%)
Grade 1	0	0	0	1 (3.3%)
Grade 2	0	1 (16.7%)	1 (5.6%)	2 (6.7%)
Grade 3	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Febrile disorders	2 (16.7%)	2 (33.3%)	4 (22.2%)	7 (23.3%)
Grade 1	1 (8.3%)	1 (16.7%)	2 (11.1%)	4 (13.3%)
Grade 2	1 (8.3%)	1 (16.7%)	2 (11.1%)	2 (6.7%)
Grade 3	0	0	0	1 (3.3%)
Pyrexia	2 (16.7%)	2 (33.3%)	4 (22.2%)	7 (23.3%)
Grade 1	1 (8.3%)	1 (16.7%)	2 (11.1%)	4 (13.3%)
Grade 2	1 (8.3%)	1 (16.7%)	2 (11.1%)	2 (6.7%)
Grade 3	0	0	0	1 (3.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-et.pdf 24AUG2023:15:01

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Asthenic conditions (cont)				
Fatigue	4 (12.9%)	3 (12.5%)	7 (12.7%)	14 (21.2%)
Grade 1	1 (3.2%)	2 (8.3%)	3 (5.5%)	6 (9.1%)
Grade 2	2 (6.5%)	1 (4.2%)	3 (5.5%)	7 (10.6%)
Grade 3	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Febrile disorders	9 (29.0%)	7 (29.2%)	16 (29.1%)	19 (28.8%)
Grade 1	6 (19.4%)	5 (20.8%)	11 (20.0%)	12 (18.2%)
Grade 2	2 (6.5%)	2 (8.3%)	4 (7.3%)	5 (7.6%)
Grade 3	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Pyrexia	9 (29.0%)	7 (29.2%)	16 (29.1%)	19 (28.8%)
Grade 1	6 (19.4%)	5 (20.8%)	11 (20.0%)	12 (18.2%)
Grade 2	2 (6.5%)	2 (8.3%)	4 (7.3%)	5 (7.6%)
Grade 3	1 (3.2%)	0	1 (1.8%)	2 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-et.pdf 24AUG2023:15:01

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Oedema NEC	1 (8.3%)	0	1 (5.6%)	5 (16.7%)
Grade 1	0	0	0	2 (6.7%)
Grade 2	1 (8.3%)	0	1 (5.6%)	3 (10.0%)
Grade 3	0	0	0	0
Oedema peripheral	0	0	0	4 (13.3%)
Grade 1	0	0	0	2 (6.7%)
Grade 2	0	0	0	2 (6.7%)
Grade 3	0	0	0	0
Generalised oedema	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Oedema	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Oedema NEC	9 (29.0%)	3 (12.5%)	12 (21.8%)	16 (24.2%)
Grade 1	3 (9.7%)	1 (4.2%)	4 (7.3%)	6 (9.1%)
Grade 2	5 (16.1%)	1 (4.2%)	6 (10.9%)	8 (12.1%)
Grade 3	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Oedema peripheral	8 (25.8%)	3 (12.5%)	11 (20.0%)	15 (22.7%)
Grade 1	2 (6.5%)	1 (4.2%)	3 (5.5%)	5 (7.6%)
Grade 2	5 (16.1%)	1 (4.2%)	6 (10.9%)	8 (12.1%)
Grade 3	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Generalised oedema	0	0	0	0
Grade 2	0	0	0	0
Oedema	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Feelings and sensations NEC	1 (8.3%)	0	1 (5.6%)	3 (10.0%)
Grade 1	1 (8.3%)	0	1 (5.6%)	2 (6.7%)
Grade 2	0	0	0	1 (3.3%)
Early satiety	0	0	0	1 (3.3%)
Grade 1	0	0	0	0
Grade 2	0	0	0	1 (3.3%)
Chills	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	0	0	0	0
Feeling hot	0	0	0	1 (3.3%)
Grade 1	0	0	0	1 (3.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Feelings and sensations NEC	2 (6.5%)	2 (8.3%)	4 (7.3%)	5 (7.6%)
Grade 1	1 (3.2%)	1 (4.2%)	2 (3.6%)	3 (4.5%)
Grade 2	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Early satiety	1 (3.2%)	1 (4.2%)	2 (3.6%)	3 (4.5%)
Grade 1	1 (3.2%)	1 (4.2%)	2 (3.6%)	3 (4.5%)
Grade 2	0	0	0	0
Chills	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Grade 1	0	0	0	0
Grade 2	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Feeling hot	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-et.pdf 24AUG2023:15:01

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Pain and discomfort NEC	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	0	0	0	0
Chest pain	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	0	0	0	0
Chest discomfort	0	0	0	0
Grade 1	0	0	0	0
Facial pain	0	0	0	0
Grade 1	0	0	0	0
Non-cardiac chest pain	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Pain and discomfort NEC	2 (6.5%)	0	2 (3.6%)	5 (7.6%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	4 (6.1%)
Chest pain	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Grade 1	0	0	0	0
Grade 2	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Chest discomfort	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Facial pain	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Non-cardiac chest pain	0	0	0	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Pain and discomfort NEC (cont)				
Non-cardiac chest pain (cont)				
Grade 2	0	0	0	0
Pain	0	0	0	0
Grade 2	0	0	0	0
General signs and symptoms NEC	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Grade 5	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Disease progression	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 3	0	0	0	0
Grade 5	1 (8.3%)	0	1 (5.6%)	1 (3.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Pain and discomfort NEC (cont)				
Non-cardiac chest pain (cont)				
Grade 2	0	0	0	1 (1.5%)
Pain	0	0	0	1 (1.5%)
Grade 2	0	0	0	1 (1.5%)
General signs and symptoms NEC	1 (3.2%)	0	1 (1.8%)	3 (4.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 3	0	0	0	2 (3.0%)
Grade 5	0	0	0	0
Disease progression	0	0	0	1 (1.5%)
Grade 3	0	0	0	1 (1.5%)
Grade 5	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
General signs and symptoms NEC (cont)				
General physical health deterioration	0	0	0	0
Grade 3	0	0	0	0
Peripheral swelling	0	0	0	0
Grade 1	0	0	0	0
Gait disturbances	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	0	0	0	0
Gait disturbance	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
General signs and symptoms NEC (cont)				
General physical health deterioration	0	0	0	1 (1.5%)
Grade 3	0	0	0	1 (1.5%)
Peripheral swelling	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Gait disturbances	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Grade 1	1 (3.2%)	0	1 (1.8%)	0
Grade 2	0	0	0	2 (3.0%)
Gait disturbance	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Grade 1	1 (3.2%)	0	1 (1.8%)	0
Grade 2	0	0	0	2 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Inflammations	0	0	0	0
Grade 2	0	0	0	0
Inflammation	0	0	0	0
Grade 2	0	0	0	0
Injection site reactions	0	0	0	0
Grade 1	0	0	0	0
Injection site pain	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Inflammations	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Inflammation	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Injection site reactions	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)
Injection site pain	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations	7 (58.3%)	4 (66.7%)	11 (61.1%)	20 (66.7%)
Grade 1	0	2 (33.3%)	2 (11.1%)	5 (16.7%)
Grade 2	3 (25.0%)	2 (33.3%)	5 (27.8%)	5 (16.7%)
Grade 3	3 (25.0%)	0	3 (16.7%)	7 (23.3%)
Grade 4	0	0	0	1 (3.3%)
Grade 5	1 (8.3%)	0	1 (5.6%)	2 (6.7%)
Lower respiratory tract and lung infections	3 (25.0%)	2 (33.3%)	5 (27.8%)	7 (23.3%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	1 (8.3%)	2 (33.3%)	3 (16.7%)	3 (10.0%)
Grade 3	1 (8.3%)	0	1 (5.6%)	2 (6.7%)
Grade 4	0	0	0	1 (3.3%)
Grade 5	0	0	0	0
Pneumonia	2 (16.7%)	0	2 (11.1%)	4 (13.3%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations	20 (64.5%)	14 (58.3%)	34 (61.8%)	44 (66.7%)
Grade 1	3 (9.7%)	4 (16.7%)	7 (12.7%)	5 (7.6%)
Grade 2	9 (29.0%)	6 (25.0%)	15 (27.3%)	25 (37.9%)
Grade 3	3 (9.7%)	2 (8.3%)	5 (9.1%)	7 (10.6%)
Grade 4	3 (9.7%)	0	3 (5.5%)	3 (4.5%)
Grade 5	2 (6.5%)	2 (8.3%)	4 (7.3%)	4 (6.1%)
Lower respiratory tract and lung infections	11 (35.5%)	5 (20.8%)	16 (29.1%)	21 (31.8%)
Grade 1	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Grade 2	5 (16.1%)	1 (4.2%)	6 (10.9%)	11 (16.7%)
Grade 3	4 (12.9%)	2 (8.3%)	6 (10.9%)	6 (9.1%)
Grade 4	0	0	0	0
Grade 5	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Pneumonia	5 (16.1%)	3 (12.5%)	8 (14.5%)	9 (13.6%)
Grade 1	0	0	0	0
Grade 2	1 (3.2%)	1 (4.2%)	2 (3.6%)	3 (4.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-et.pdf 24AUG2023:15:01

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Lower respiratory tract and lung infections (cont)				
Pneumonia (cont)				
Grade 3	1 (8.3%)	0	1 (5.6%)	2 (6.7%)
Grade 4	0	0	0	1 (3.3%)
Grade 5	0	0	0	0
Bronchitis	1 (8.3%)	2 (33.3%)	3 (16.7%)	3 (10.0%)
Grade 1	0	0	0	0
Grade 2	1 (8.3%)	2 (33.3%)	3 (16.7%)	3 (10.0%)
Lung infection	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Atypical pneumonia	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Lower respiratory tract and lung infections (cont)				
Pneumonia (cont)				
Grade 3	3 (9.7%)	1 (4.2%)	4 (7.3%)	4 (6.1%)
Grade 4	0	0	0	0
Grade 5	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Bronchitis	5 (16.1%)	1 (4.2%)	6 (10.9%)	8 (12.1%)
Grade 1	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 2	5 (16.1%)	0	5 (9.1%)	7 (10.6%)
Lung infection	1 (3.2%)	2 (8.3%)	3 (5.5%)	5 (7.6%)
Grade 2	0	1 (4.2%)	1 (1.8%)	3 (4.5%)
Grade 3	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Atypical pneumonia	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-et.pdf 24AUG2023:15:01

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Lower respiratory tract and lung infections (cont)				
Atypical pneumonia (cont)				
Grade 1	0	0	0	0
Lower respiratory tract infection	0	0	0	0
Grade 2	0	0	0	0
Upper respiratory tract infections	3 (25.0%)	3 (50.0%)	6 (33.3%)	9 (30.0%)
Grade 1	1 (8.3%)	2 (33.3%)	3 (16.7%)	5 (16.7%)
Grade 2	2 (16.7%)	1 (16.7%)	3 (16.7%)	3 (10.0%)
Grade 3	0	0	0	0
Grade 4	0	0	0	1 (3.3%)
Upper respiratory tract infection	1 (8.3%)	2 (33.3%)	3 (16.7%)	6 (20.0%)
Grade 1	0	2 (33.3%)	2 (11.1%)	4 (13.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Lower respiratory tract and lung infections (cont)				
Atypical pneumonia (cont)				
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Lower respiratory tract infection	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Upper respiratory tract infections	9 (29.0%)	4 (16.7%)	13 (23.6%)	19 (28.8%)
Grade 1	2 (6.5%)	3 (12.5%)	5 (9.1%)	6 (9.1%)
Grade 2	6 (19.4%)	1 (4.2%)	7 (12.7%)	12 (18.2%)
Grade 3	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 4	0	0	0	0
Upper respiratory tract infection	7 (22.6%)	3 (12.5%)	10 (18.2%)	13 (19.7%)
Grade 1	2 (6.5%)	2 (8.3%)	4 (7.3%)	4 (6.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Upper respiratory tract infections (cont)				
Upper respiratory tract infection (cont)				
Grade 2	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 3	0	0	0	0
Grade 4	0	0	0	1 (3.3%)
Nasopharyngitis	1 (8.3%)	1 (16.7%)	2 (11.1%)	3 (10.0%)
Grade 1	1 (8.3%)	1 (16.7%)	2 (11.1%)	3 (10.0%)
Grade 2	0	0	0	0
Sinusitis	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Tracheitis	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 2	0	1 (16.7%)	1 (5.6%)	1 (3.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Upper respiratory tract infections (cont)				
Upper respiratory tract infection (cont)				
Grade 2	4 (12.9%)	1 (4.2%)	5 (9.1%)	8 (12.1%)
Grade 3	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 4	0	0	0	0
Nasopharyngitis	2 (6.5%)	1 (4.2%)	3 (5.5%)	4 (6.1%)
Grade 1	1 (3.2%)	1 (4.2%)	2 (3.6%)	3 (4.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Sinusitis	2 (6.5%)	0	2 (3.6%)	4 (6.1%)
Grade 2	2 (6.5%)	0	2 (3.6%)	4 (6.1%)
Tracheitis	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Urinary tract infections	2 (16.7%)	1 (16.7%)	3 (16.7%)	4 (13.3%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 3	1 (8.3%)	0	1 (5.6%)	2 (6.7%)
Urinary tract infection	1 (8.3%)	1 (16.7%)	2 (11.1%)	3 (10.0%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 3	0	0	0	1 (3.3%)
Cystitis	0	0	0	0
Grade 2	0	0	0	0
Kidney infection	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 3	1 (8.3%)	0	1 (5.6%)	1 (3.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Urinary tract infections	6 (19.4%)	5 (20.8%)	11 (20.0%)	14 (21.2%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	3 (9.7%)	5 (20.8%)	8 (14.5%)	11 (16.7%)
Grade 3	2 (6.5%)	0	2 (3.6%)	2 (3.0%)
Urinary tract infection	5 (16.1%)	5 (20.8%)	10 (18.2%)	12 (18.2%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	2 (6.5%)	5 (20.8%)	7 (12.7%)	9 (13.6%)
Grade 3	2 (6.5%)	0	2 (3.6%)	2 (3.0%)
Cystitis	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Grade 2	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Kidney infection	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Herpes viral infections	0	0	0	1 (3.3%)
Grade 1	0	0	0	1 (3.3%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Oral herpes	0	0	0	1 (3.3%)
Grade 1	0	0	0	1 (3.3%)
Grade 2	0	0	0	0
Herpes zoster	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Herpes simplex	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Herpes viral infections	4 (12.9%)	2 (8.3%)	6 (10.9%)	9 (13.6%)
Grade 1	2 (6.5%)	0	2 (3.6%)	3 (4.5%)
Grade 2	2 (6.5%)	2 (8.3%)	4 (7.3%)	5 (7.6%)
Grade 3	0	0	0	1 (1.5%)
Oral herpes	1 (3.2%)	1 (4.2%)	2 (3.6%)	4 (6.1%)
Grade 1	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Grade 2	0	1 (4.2%)	1 (1.8%)	2 (3.0%)
Herpes zoster	2 (6.5%)	1 (4.2%)	3 (5.5%)	4 (6.1%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	1 (4.2%)	2 (3.6%)	3 (4.5%)
Herpes simplex	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Grade 2	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-et.pdf 24AUG2023:15:01

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Herpes viral infections (cont)				
Ophthalmic herpes zoster	0	0	0	0
Grade 3	0	0	0	0
Bacterial infections NEC	0	0	0	2 (6.7%)
Grade 2	0	0	0	0
Grade 3	0	0	0	1 (3.3%)
Grade 5	0	0	0	1 (3.3%)
Cellulitis	0	0	0	0
Grade 3	0	0	0	0
Urinary tract infection bacterial	0	0	0	0
Grade 2	0	0	0	0
Bacterial rhinitis	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Herpes viral infections (cont)				
Ophthalmic herpes zoster	0	0	0	1 (1.5%)
Grade 3	0	0	0	1 (1.5%)
Bacterial infections NEC	5 (16.1%)	0	5 (9.1%)	7 (10.6%)
Grade 2	2 (6.5%)	0	2 (3.6%)	3 (4.5%)
Grade 3	3 (9.7%)	0	3 (5.5%)	4 (6.1%)
Grade 5	0	0	0	0
Cellulitis	2 (6.5%)	0	2 (3.6%)	3 (4.5%)
Grade 3	2 (6.5%)	0	2 (3.6%)	3 (4.5%)
Urinary tract infection bacterial	2 (6.5%)	0	2 (3.6%)	2 (3.0%)
Grade 2	2 (6.5%)	0	2 (3.6%)	2 (3.0%)
Bacterial rhinitis	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Bacterial infections NEC (cont)				
Bacterial rhinitis (cont)				
Grade 2	0	0	0	0
Bacterial sepsis	0	0	0	1 (3.3%)
Grade 5	0	0	0	1 (3.3%)
Citrobacter infection	0	0	0	0
Grade 3	0	0	0	0
Peritonitis bacterial	0	0	0	1 (3.3%)
Grade 3	0	0	0	1 (3.3%)
Propionibacterium infection	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Bacterial infections NEC (cont)				
Bacterial rhinitis (cont)				
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Bacterial sepsis	0	0	0	0
Grade 5	0	0	0	0
Citrobacter infection	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 3	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Peritonitis bacterial	0	0	0	0
Grade 3	0	0	0	0
Propionibacterium infection	0	0	0	1 (1.5%)
Grade 2	0	0	0	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Sepsis, bacteraemia, viraemia and fungaemia NEC	1 (8.3%)	0	1 (5.6%)	3 (10.0%)
Grade 3	0	0	0	1 (3.3%)
Grade 4	0	0	0	1 (3.3%)
Grade 5	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Sepsis	0	0	0	2 (6.7%)
Grade 3	0	0	0	1 (3.3%)
Grade 4	0	0	0	1 (3.3%)
Grade 5	0	0	0	0
Bacteraemia	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 5	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Urosepsis	0	0	0	0
Grade 4	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Sepsis, bacteraemia, viraemia and fungaemia NEC	4 (12.9%)	1 (4.2%)	5 (9.1%)	5 (7.6%)
Grade 3	0	0	0	0
Grade 4	3 (9.7%)	0	3 (5.5%)	3 (4.5%)
Grade 5	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Sepsis	4 (12.9%)	1 (4.2%)	5 (9.1%)	5 (7.6%)
Grade 3	0	0	0	0
Grade 4	3 (9.7%)	0	3 (5.5%)	3 (4.5%)
Grade 5	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Bacteraemia	0	0	0	0
Grade 5	0	0	0	0
Urosepsis	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 4	0	1 (4.2%)	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Infections NEC	2 (16.7%)	0	2 (11.1%)	2 (6.7%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Respiratory tract infection	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	0	0	0	0
Infection	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Localised infection	0	0	0	0
Grade 2	0	0	0	0
Wound infection	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Infections NEC	1 (3.2%)	2 (8.3%)	3 (5.5%)	4 (6.1%)
Grade 1	0	0	0	1 (1.5%)
Grade 2	1 (3.2%)	2 (8.3%)	3 (5.5%)	3 (4.5%)
Respiratory tract infection	0	1 (4.2%)	1 (1.8%)	2 (3.0%)
Grade 1	0	0	0	1 (1.5%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Infection	0	0	0	0
Grade 2	0	0	0	0
Localised infection	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Wound infection	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-et.pdf 24AUG2023:15:01

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Candida infections	0	0	0	2 (6.7%)
Grade 1	0	0	0	2 (6.7%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Oral candidiasis	0	0	0	1 (3.3%)
Grade 1	0	0	0	1 (3.3%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Oropharyngeal candidiasis	0	0	0	1 (3.3%)
Grade 1	0	0	0	1 (3.3%)
Abdominal and gastrointestinal infections	1 (8.3%)	0	1 (5.6%)	2 (6.7%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 3	0	0	0	1 (3.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Candida infections	0	1 (4.2%)	1 (1.8%)	2 (3.0%)
Grade 1	0	0	0	0
Grade 2	0	0	0	1 (1.5%)
Grade 3	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Oral candidiasis	0	1 (4.2%)	1 (1.8%)	2 (3.0%)
Grade 1	0	0	0	0
Grade 2	0	0	0	1 (1.5%)
Grade 3	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Oropharyngeal candidiasis	0	0	0	0
Grade 1	0	0	0	0
Abdominal and gastrointestinal infections	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Abdominal and gastrointestinal infections (cont)				
Gastroenteritis	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Diverticulitis	0	0	0	1 (3.3%)
Grade 3	0	0	0	1 (3.3%)
Ear infections	0	0	0	0
Grade 2	0	0	0	0
Ear infection	0	0	0	0
Grade 2	0	0	0	0
Otitis media	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Abdominal and gastrointestinal infections (cont)				
Gastroenteritis	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Diverticulitis	0	0	0	0
Grade 3	0	0	0	0
Ear infections	3 (9.7%)	0	3 (5.5%)	3 (4.5%)
Grade 2	3 (9.7%)	0	3 (5.5%)	3 (4.5%)
Ear infection	2 (6.5%)	0	2 (3.6%)	2 (3.0%)
Grade 2	2 (6.5%)	0	2 (3.6%)	2 (3.0%)
Otitis media	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Fungal infections NEC	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Oral fungal infection	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Fungal skin infection	0	0	0	0
Grade 1	0	0	0	0
Dental and oral soft tissue infections	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Dental fistula	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	1 (8.3%)	0	1 (5.6%)	1 (3.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Fungal infections NEC	2 (6.5%)	1 (4.2%)	3 (5.5%)	3 (4.5%)
Grade 1	2 (6.5%)	0	2 (3.6%)	2 (3.0%)
Grade 3	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Oral fungal infection	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 3	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Fungal skin infection	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Dental and oral soft tissue infections	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Dental fistula	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-et.pdf 24AUG2023:15:01

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Dental and oral soft tissue infections (cont)				
Tooth abscess	0	0	0	0
Grade 2	0	0	0	0
Escherichia infections	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Escherichia bacteraemia	0	0	0	0
Grade 3	0	0	0	0
Escherichia infection	0	0	0	0
Grade 1	0	0	0	0
Escherichia urinary tract infection	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Dental and oral soft tissue infections (cont)				
Tooth abscess	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Escherichia infections	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Grade 2	1 (3.2%)	0	1 (1.8%)	0
Grade 3	0	1 (4.2%)	1 (1.8%)	2 (3.0%)
Escherichia bacteraemia	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 3	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Escherichia infection	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Escherichia urinary tract infection	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Escherichia infections (cont)				
Escherichia urinary tract infection (cont)				
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Eye and eyelid infections	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Conjunctivitis	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Influenza viral infections	0	0	0	1 (3.3%)
Grade 1	0	0	0	1 (3.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Escherichia infections (cont)				
Escherichia urinary tract infection (cont)				
Grade 2	1 (3.2%)	0	1 (1.8%)	0
Grade 3	0	0	0	1 (1.5%)
Eye and eyelid infections	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	0	0	0	1 (1.5%)
Conjunctivitis	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	0	0	0	1 (1.5%)
Influenza viral infections	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Influenza viral infections (cont)				
(cont)				
Grade 2	0	0	0	0
Influenza	0	0	0	1 (3.3%)
Grade 1	0	0	0	1 (3.3%)
Grade 2	0	0	0	0
Skin structures and soft tissue infections	0	0	0	2 (6.7%)
Grade 1	0	0	0	1 (3.3%)
Grade 2	0	0	0	1 (3.3%)
Folliculitis	0	0	0	1 (3.3%)
Grade 1	0	0	0	1 (3.3%)
Skin infection	0	0	0	1 (3.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Influenza viral infections (cont)				
(cont)				
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Influenza	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 1	0	0	0	0
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Skin structures and soft tissue infections	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Folliculitis	0	0	0	0
Grade 1	0	0	0	0
Skin infection	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

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Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Skin structures and soft tissue infections (cont)				
Skin infection (cont)				
Grade 2	0	0	0	1 (3.3%)
Viral infections NEC	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	0	0	0	0
Grade 3	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Pneumonia viral	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 3	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Viral rash	0	0	0	0
Grade 1	0	0	0	0
Clostridia infections	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Skin structures and soft tissue infections (cont)				
Skin infection (cont)				
Grade 2	0	0	0	0
Viral infections NEC	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 1	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 3	0	0	0	0
Pneumonia viral	0	0	0	0
Grade 3	0	0	0	0
Viral rash	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 1	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Clostridia infections	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Clostridia infections (cont)				
(cont)				
Grade 3	0	0	0	0
Clostridium difficile infection	0	0	0	0
Grade 3	0	0	0	0
Enterococcal infections	0	0	0	0
Grade 2	0	0	0	0
Urinary tract infection enterococcal	0	0	0	0
Grade 2	0	0	0	0
Muscle and soft tissue infections	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Clostridia infections (cont)				
(cont)				
Grade 3	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Clostridium difficile infection	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 3	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Enterococcal infections	0	0	0	1 (1.5%)
Grade 2	0	0	0	1 (1.5%)
Urinary tract infection enterococcal	0	0	0	1 (1.5%)
Grade 2	0	0	0	1 (1.5%)
Muscle and soft tissue infections	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 3	0	1 (4.2%)	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Muscle and soft tissue infections (cont)				
Soft tissue infection	0	0	0	0
Grade 3	0	0	0	0
Staphylococcal infections	0	0	0	0
Grade 2	0	0	0	0
Staphylococcal infection	0	0	0	0
Grade 2	0	0	0	0
Streptococcal infections	0	0	0	0
Grade 2	0	0	0	0
Erysipelas	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Muscle and soft tissue infections (cont)				
Soft tissue infection	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 3	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Staphylococcal infections	0	0	0	1 (1.5%)
Grade 2	0	0	0	1 (1.5%)
Staphylococcal infection	0	0	0	1 (1.5%)
Grade 2	0	0	0	1 (1.5%)
Streptococcal infections	0	0	0	1 (1.5%)
Grade 2	0	0	0	1 (1.5%)
Erysipelas	0	0	0	1 (1.5%)
Grade 2	0	0	0	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Vascular infections	0	0	0	0
Grade 2	0	0	0	0
Haematoma infection	0	0	0	0
Grade 2	0	0	0	0
Nervous system disorders	5 (41.7%)	3 (50.0%)	8 (44.4%)	17 (56.7%)
Grade 1	3 (25.0%)	2 (33.3%)	5 (27.8%)	11 (36.7%)
Grade 2	1 (8.3%)	0	1 (5.6%)	3 (10.0%)
Grade 3	0	1 (16.7%)	1 (5.6%)	2 (6.7%)
Grade 4	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Neurological signs and symptoms NEC	2 (16.7%)	0	2 (11.1%)	5 (16.7%)
Grade 1	2 (16.7%)	0	2 (11.1%)	3 (10.0%)
Grade 2	0	0	0	1 (3.3%)
Grade 3	0	0	0	1 (3.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Vascular infections	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Haematoma infection	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Nervous system disorders	13 (41.9%)	14 (58.3%)	27 (49.1%)	40 (60.6%)
Grade 1	6 (19.4%)	8 (33.3%)	14 (25.5%)	22 (33.3%)
Grade 2	3 (9.7%)	5 (20.8%)	8 (14.5%)	12 (18.2%)
Grade 3	3 (9.7%)	1 (4.2%)	4 (7.3%)	5 (7.6%)
Grade 4	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Neurological signs and symptoms NEC	5 (16.1%)	3 (12.5%)	8 (14.5%)	16 (24.2%)
Grade 1	3 (9.7%)	3 (12.5%)	6 (10.9%)	12 (18.2%)
Grade 2	1 (3.2%)	0	1 (1.8%)	3 (4.5%)
Grade 3	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Neurological signs and symptoms NEC (cont)				
Dizziness	2 (16.7%)	0	2 (11.1%)	5 (16.7%)
Grade 1	2 (16.7%)	0	2 (11.1%)	4 (13.3%)
Grade 2	0	0	0	1 (3.3%)
Grade 3	0	0	0	0
Presyncope	0	0	0	1 (3.3%)
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	1 (3.3%)
Dizziness exertional	0	0	0	0
Grade 1	0	0	0	0
Dizziness postural	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Neurological signs and symptoms NEC (cont)				
Dizziness	4 (12.9%)	3 (12.5%)	7 (12.7%)	12 (18.2%)
Grade 1	3 (9.7%)	3 (12.5%)	6 (10.9%)	10 (15.2%)
Grade 2	0	0	0	1 (1.5%)
Grade 3	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Presyncope	1 (3.2%)	0	1 (1.8%)	3 (4.5%)
Grade 1	0	0	0	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Grade 3	0	0	0	0
Dizziness exertional	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)
Dizziness postural	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Peripheral neuropathies NEC	1 (8.3%)	1 (16.7%)	2 (11.1%)	5 (16.7%)
Grade 1	0	1 (16.7%)	1 (5.6%)	3 (10.0%)
Grade 2	1 (8.3%)	0	1 (5.6%)	2 (6.7%)
Grade 3	0	0	0	0
Peripheral sensory neuropathy	1 (8.3%)	1 (16.7%)	2 (11.1%)	4 (13.3%)
Grade 1	0	1 (16.7%)	1 (5.6%)	2 (6.7%)
Grade 2	1 (8.3%)	0	1 (5.6%)	2 (6.7%)
Grade 3	0	0	0	0
Neuropathy peripheral	0	0	0	0
Grade 2	0	0	0	0
Peripheral motor neuropathy	0	0	0	1 (3.3%)
Grade 1	0	0	0	1 (3.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Peripheral neuropathies NEC	4 (12.9%)	6 (25.0%)	10 (18.2%)	13 (19.7%)
Grade 1	2 (6.5%)	4 (16.7%)	6 (10.9%)	9 (13.6%)
Grade 2	2 (6.5%)	1 (4.2%)	3 (5.5%)	3 (4.5%)
Grade 3	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Peripheral sensory neuropathy	3 (9.7%)	5 (20.8%)	8 (14.5%)	11 (16.7%)
Grade 1	2 (6.5%)	4 (16.7%)	6 (10.9%)	9 (13.6%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 3	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Neuropathy peripheral	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Peripheral motor neuropathy	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-et.pdf 24AUG2023:15:01

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Peripheral neuropathies NEC (cont)				
Peripheral sensorimotor neuropathy	0	0	0	0
Grade 2	0	0	0	0
Headaches NEC	0	3 (50.0%)	3 (16.7%)	4 (13.3%)
Grade 1	0	2 (33.3%)	2 (11.1%)	3 (10.0%)
Grade 2	0	0	0	0
Grade 3	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Headache	0	3 (50.0%)	3 (16.7%)	4 (13.3%)
Grade 1	0	2 (33.3%)	2 (11.1%)	3 (10.0%)
Grade 2	0	0	0	0
Grade 3	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Paraesthesias and dysaesthesias	1 (8.3%)	0	1 (5.6%)	2 (6.7%)
Grade 1	1 (8.3%)	0	1 (5.6%)	2 (6.7%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Peripheral neuropathies NEC (cont)				
Peripheral sensorimotor neuropathy	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Headaches NEC	0	3 (12.5%)	3 (5.5%)	10 (15.2%)
Grade 1	0	1 (4.2%)	1 (1.8%)	6 (9.1%)
Grade 2	0	2 (8.3%)	2 (3.6%)	4 (6.1%)
Grade 3	0	0	0	0
Headache	0	3 (12.5%)	3 (5.5%)	10 (15.2%)
Grade 1	0	1 (4.2%)	1 (1.8%)	6 (9.1%)
Grade 2	0	2 (8.3%)	2 (3.6%)	4 (6.1%)
Grade 3	0	0	0	0
Paraesthesias and dysaesthesias	1 (3.2%)	3 (12.5%)	4 (7.3%)	6 (9.1%)
Grade 1	1 (3.2%)	3 (12.5%)	4 (7.3%)	5 (7.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Paraesthesias and dysaesthesias (cont)				
(cont)				
Grade 2	0	0	0	0
Paraesthesia	1 (8.3%)	0	1 (5.6%)	2 (6.7%)
Grade 1	1 (8.3%)	0	1 (5.6%)	2 (6.7%)
Grade 2	0	0	0	0
Hypoaesthesia	0	0	0	0
Grade 1	0	0	0	0
Disturbances in consciousness NEC	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Somnolence	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Paraesthesias and dysaesthesias (cont)				
(cont)				
Grade 2	0	0	0	1 (1.5%)
Paraesthesia	0	3 (12.5%)	3 (5.5%)	6 (9.1%)
Grade 1	0	3 (12.5%)	3 (5.5%)	5 (7.6%)
Grade 2	0	0	0	1 (1.5%)
Hypoaesthesia	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Disturbances in consciousness NEC	2 (6.5%)	2 (8.3%)	4 (7.3%)	6 (9.1%)
Grade 1	0	2 (8.3%)	2 (3.6%)	3 (4.5%)
Grade 3	2 (6.5%)	0	2 (3.6%)	3 (4.5%)
Somnolence	0	2 (8.3%)	2 (3.6%)	3 (4.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Disturbances in consciousness NEC (cont)				
Somnolence (cont)				
Grade 1	0	0	0	0
Syncope	0	0	0	0
Grade 3	0	0	0	0
Loss of consciousness	0	0	0	0
Grade 3	0	0	0	0
Sensory abnormalities NEC	1 (8.3%)	0	1 (5.6%)	3 (10.0%)
Grade 1	1 (8.3%)	0	1 (5.6%)	2 (6.7%)
Grade 2	0	0	0	1 (3.3%)
Restless legs syndrome	0	0	0	2 (6.7%)
Grade 1	0	0	0	1 (3.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Disturbances in consciousness NEC (cont)				
Somnolence (cont)				
Grade 1	0	2 (8.3%)	2 (3.6%)	3 (4.5%)
Syncope	2 (6.5%)	0	2 (3.6%)	3 (4.5%)
Grade 3	2 (6.5%)	0	2 (3.6%)	3 (4.5%)
Loss of consciousness	0	0	0	1 (1.5%)
Grade 3	0	0	0	1 (1.5%)
Sensory abnormalities NEC	1 (3.2%)	1 (4.2%)	2 (3.6%)	3 (4.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Restless legs syndrome	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Sensory abnormalities NEC (cont)				
Restless legs syndrome (cont)				
Grade 2	0	0	0	1 (3.3%)
Allodynia	0	0	0	0
Grade 2	0	0	0	0
Hypogeusia	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Neuralgia	0	0	0	0
Grade 1	0	0	0	0
Post herpetic neuralgia	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Sensory abnormalities NEC (cont)				
Restless legs syndrome (cont)				
Grade 2	0	0	0	0
Allodynia	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Hypogeusia	0	0	0	0
Grade 1	0	0	0	0
Neuralgia	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)
Post herpetic neuralgia	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Sensory abnormalities NEC (cont)				
Taste disorder	0	0	0	0
Grade 1	0	0	0	0
Mental impairment (excl dementia and memory loss)	0	0	0	0
Grade 1	0	0	0	0
Disturbance in attention	0	0	0	0
Grade 1	0	0	0	0
Cognitive disorder	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Sensory abnormalities NEC (cont)				
Taste disorder	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)
Mental impairment (excl dementia and memory loss)	2 (6.5%)	1 (4.2%)	3 (5.5%)	4 (6.1%)
Grade 1	2 (6.5%)	1 (4.2%)	3 (5.5%)	4 (6.1%)
Disturbance in attention	1 (3.2%)	1 (4.2%)	2 (3.6%)	3 (4.5%)
Grade 1	1 (3.2%)	1 (4.2%)	2 (3.6%)	3 (4.5%)
Cognitive disorder	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Central nervous system haemorrhages and cerebrovascular accidents	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	0	0	0	0
Grade 4	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Cerebrovascular accident	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	0	0	0	0
Grade 4	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Cerebral infarction	0	0	0	0
Grade 1	0	0	0	0
Subarachnoid haemorrhage	0	0	0	0
Grade 4	0	0	0	0
Tremor (excl congenital)	0	0	0	2 (6.7%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Central nervous system haemorrhages and cerebrovascular accidents	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Grade 1	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 4	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Cerebrovascular accident	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 4	0	0	0	0
Cerebral infarction	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 1	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Subarachnoid haemorrhage	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 4	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Tremor (excl congenital)	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Tremor (excl congenital) (cont)				
(cont)				
Grade 1	0	0	0	2 (6.7%)
Grade 2	0	0	0	0
Tremor	0	0	0	2 (6.7%)
Grade 1	0	0	0	2 (6.7%)
Grade 2	0	0	0	0
Coordination and balance disturbances	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Balance disorder	0	0	0	0
Grade 1	0	0	0	0
Coordination abnormal	1 (8.3%)	0	1 (5.6%)	1 (3.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Tremor (excl congenital) (cont)				
(cont)				
Grade 1	0	0	0	0
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Tremor	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	0	0	0	0
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Coordination and balance disturbances	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)
Balance disorder	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)
Coordination abnormal	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Coordination and balance disturbances (cont)				
Coordination abnormal (cont)				
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Memory loss (excl dementia)	0	0	0	1 (3.3%)
Grade 1	0	0	0	1 (3.3%)
Amnesia	0	0	0	0
Grade 1	0	0	0	0
Memory impairment	0	0	0	1 (3.3%)
Grade 1	0	0	0	1 (3.3%)
Central nervous system aneurysms and dissections	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Coordination and balance disturbances (cont)				
Coordination abnormal (cont)				
Grade 1	0	0	0	0
Memory loss (excl dementia)	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Amnesia	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Memory impairment	0	0	0	0
Grade 1	0	0	0	0
Central nervous system aneurysms and dissections	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 3	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Central nervous system aneurysms and dissections (cont)				
Carotid artery aneurysm	0	0	0	0
Grade 3	0	0	0	0
Cervical spinal cord and nerve root disorders	0	0	0	0
Grade 1	0	0	0	0
Cervical radiculopathy	0	0	0	0
Grade 1	0	0	0	0
Dementia (excl Alzheimer's type)	0	0	0	0
Grade 1	0	0	0	0
Dementia	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Central nervous system aneurysms and dissections (cont)				
Carotid artery aneurysm	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 3	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Cervical spinal cord and nerve root disorders	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)
Cervical radiculopathy	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)
Dementia (excl Alzheimer's type)	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 1	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Dementia	0	1 (4.2%)	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Dementia (excl Alzheimer's type) (cont)				
Dementia (cont)				
Grade 1	0	0	0	0
Hypoglossal nerve disorders	0	0	0	0
Grade 2	0	0	0	0
Tongue paralysis	0	0	0	0
Grade 2	0	0	0	0
Lumbar spinal cord and nerve root disorders	0	0	0	0
Grade 2	0	0	0	0
Sciatica	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Dementia (excl Alzheimer's type) (cont)				
Dementia (cont)				
Grade 1	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Hypoglossal nerve disorders	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Tongue paralysis	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Lumbar spinal cord and nerve root disorders	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Sciatica	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Mononeuropathies	0	0	0	1 (3.3%)
Grade 1	0	0	0	1 (3.3%)
Nerve compression	0	0	0	1 (3.3%)
Grade 1	0	0	0	1 (3.3%)
Nervous system cysts and polyps	0	0	0	0
Grade 1	0	0	0	0
Arachnoid cyst	0	0	0	0
Grade 1	0	0	0	0
Neurologic visual problems NEC	0	0	0	0
Grade 2	0	0	0	0
Visual field defect	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Mononeuropathies	0	0	0	0
Grade 1	0	0	0	0
Nerve compression	0	0	0	0
Grade 1	0	0	0	0
Nervous system cysts and polyps	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 1	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Arachnoid cyst	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 1	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Neurologic visual problems NEC	0	0	0	1 (1.5%)
Grade 2	0	0	0	1 (1.5%)
Visual field defect	0	0	0	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Neurologic visual problems NEC (cont)				
Visual field defect (cont)				
Grade 2	0	0	0	0
Neuromuscular disorders NEC	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Muscle contractions involuntary	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Olfactory nerve disorders	0	0	0	0
Grade 1	0	0	0	0
Parosmia	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Neurologic visual problems NEC (cont)				
Visual field defect (cont)				
Grade 2	0	0	0	1 (1.5%)
Neuromuscular disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Muscle contractions involuntary	0	0	0	0
Grade 1	0	0	0	0
Olfactory nerve disorders	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)
Parosmia	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Speech and language abnormalities	0	0	0	1 (3.3%)
Grade 1	0	0	0	1 (3.3%)
Speech disorder	0	0	0	1 (3.3%)
Grade 1	0	0	0	1 (3.3%)
Blood and lymphatic system disorders	4 (33.3%)	2 (33.3%)	6 (33.3%)	12 (40.0%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	0	1 (16.7%)	1 (5.6%)	3 (10.0%)
Grade 3	1 (8.3%)	1 (16.7%)	2 (11.1%)	4 (13.3%)
Grade 4	2 (16.7%)	0	2 (11.1%)	4 (13.3%)
Anaemias NEC	2 (16.7%)	1 (16.7%)	3 (16.7%)	6 (20.0%)
Grade 2	0	0	0	0
Grade 3	2 (16.7%)	1 (16.7%)	3 (16.7%)	6 (20.0%)
Grade 4	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Speech and language abnormalities	0	0	0	0
Grade 1	0	0	0	0
Speech disorder	0	0	0	0
Grade 1	0	0	0	0
Blood and lymphatic system disorders	13 (41.9%)	18 (75.0%)	31 (56.4%)	42 (63.6%)
Grade 1	1 (3.2%)	1 (4.2%)	2 (3.6%)	3 (4.5%)
Grade 2	1 (3.2%)	4 (16.7%)	5 (9.1%)	6 (9.1%)
Grade 3	9 (29.0%)	9 (37.5%)	18 (32.7%)	25 (37.9%)
Grade 4	2 (6.5%)	4 (16.7%)	6 (10.9%)	8 (12.1%)
Anaemias NEC	8 (25.8%)	8 (33.3%)	16 (29.1%)	23 (34.8%)
Grade 2	0	1 (4.2%)	1 (1.8%)	2 (3.0%)
Grade 3	8 (25.8%)	7 (29.2%)	15 (27.3%)	20 (30.3%)
Grade 4	0	0	0	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Anaemias NEC (cont)				
Anaemia	2 (16.7%)	1 (16.7%)	3 (16.7%)	6 (20.0%)
Grade 2	0	0	0	0
Grade 3	2 (16.7%)	1 (16.7%)	3 (16.7%)	6 (20.0%)
Grade 4	0	0	0	0
Thrombocytopenias	2 (16.7%)	1 (16.7%)	3 (16.7%)	7 (23.3%)
Grade 1	0	0	0	0
Grade 2	0	1 (16.7%)	1 (5.6%)	3 (10.0%)
Grade 3	0	0	0	0
Grade 4	2 (16.7%)	0	2 (11.1%)	4 (13.3%)
Thrombocytopenia	2 (16.7%)	1 (16.7%)	3 (16.7%)	7 (23.3%)
Grade 1	0	0	0	0
Grade 2	0	1 (16.7%)	1 (5.6%)	3 (10.0%)
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Anaemias NEC (cont)				
Anaemia	8 (25.8%)	8 (33.3%)	16 (29.1%)	23 (34.8%)
Grade 2	0	1 (4.2%)	1 (1.8%)	2 (3.0%)
Grade 3	8 (25.8%)	7 (29.2%)	15 (27.3%)	20 (30.3%)
Grade 4	0	0	0	1 (1.5%)
Thrombocytopenias	4 (12.9%)	7 (29.2%)	11 (20.0%)	16 (24.2%)
Grade 1	0	0	0	1 (1.5%)
Grade 2	2 (6.5%)	2 (8.3%)	4 (7.3%)	5 (7.6%)
Grade 3	2 (6.5%)	2 (8.3%)	4 (7.3%)	6 (9.1%)
Grade 4	0	3 (12.5%)	3 (5.5%)	4 (6.1%)
Thrombocytopenia	4 (12.9%)	7 (29.2%)	11 (20.0%)	16 (24.2%)
Grade 1	0	0	0	1 (1.5%)
Grade 2	2 (6.5%)	2 (8.3%)	4 (7.3%)	5 (7.6%)
Grade 3	2 (6.5%)	2 (8.3%)	4 (7.3%)	6 (9.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Thrombocytopenias (cont)				
Thrombocytopenia (cont)				
Grade 4	2 (16.7%)	0	2 (11.1%)	4 (13.3%)
Neutropenias	0	0	0	2 (6.7%)
Grade 1	0	0	0	1 (3.3%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Grade 4	0	0	0	1 (3.3%)
Neutropenia	0	0	0	2 (6.7%)
Grade 1	0	0	0	1 (3.3%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Grade 4	0	0	0	1 (3.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Thrombocytopenias (cont)				
Thrombocytopenia (cont)				
Grade 4	0	3 (12.5%)	3 (5.5%)	4 (6.1%)
Neutropenias	2 (6.5%)	2 (8.3%)	4 (7.3%)	8 (12.1%)
Grade 1	0	0	0	0
Grade 2	0	0	0	1 (1.5%)
Grade 3	0	2 (8.3%)	2 (3.6%)	3 (4.5%)
Grade 4	2 (6.5%)	0	2 (3.6%)	4 (6.1%)
Neutropenia	2 (6.5%)	2 (8.3%)	4 (7.3%)	8 (12.1%)
Grade 1	0	0	0	0
Grade 2	0	0	0	1 (1.5%)
Grade 3	0	2 (8.3%)	2 (3.6%)	3 (4.5%)
Grade 4	2 (6.5%)	0	2 (3.6%)	4 (6.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Spleen disorders	0	0	0	1 (3.3%)
Grade 2	0	0	0	0
Grade 3	0	0	0	1 (3.3%)
Grade 4	0	0	0	0
Splenic infarction	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Splenomegaly	0	0	0	1 (3.3%)
Grade 2	0	0	0	0
Grade 3	0	0	0	1 (3.3%)
Leukocytoses NEC	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Spleen disorders	0	4 (16.7%)	4 (7.3%)	5 (7.6%)
Grade 2	0	2 (8.3%)	2 (3.6%)	3 (4.5%)
Grade 3	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 4	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Splenic infarction	0	3 (12.5%)	3 (5.5%)	4 (6.1%)
Grade 2	0	1 (4.2%)	1 (1.8%)	2 (3.0%)
Grade 3	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 4	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Splenomegaly	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 3	0	0	0	0
Leukocytoses NEC	3 (9.7%)	0	3 (5.5%)	4 (6.1%)
Grade 1	2 (6.5%)	0	2 (3.6%)	3 (4.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-et.pdf 24AUG2023:15:01

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Leukocytoses NEC (cont)				
(cont)				
Grade 2	0	0	0	0
Leukocytosis	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	0	0	0	0
Neutrophilia	0	0	0	0
Grade 1	0	0	0	0
Leukopenias NEC	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Leukopenia	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Leukocytoses NEC (cont)				
(cont)				
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Leukocytosis	3 (9.7%)	0	3 (5.5%)	3 (4.5%)
Grade 1	2 (6.5%)	0	2 (3.6%)	2 (3.0%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Neutrophilia	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)
Leukopenias NEC	1 (3.2%)	1 (4.2%)	2 (3.6%)	3 (4.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 3	0	1 (4.2%)	1 (1.8%)	2 (3.0%)
Leukopenia	1 (3.2%)	1 (4.2%)	2 (3.6%)	3 (4.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Leukopenias NEC (cont)				
Leukopenia (cont)				
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Bleeding tendencies	0	0	0	0
Grade 1	0	0	0	0
Increased tendency to bruise	0	0	0	0
Grade 1	0	0	0	0
Anaemias haemolytic NEC	0	0	0	0
Grade 3	0	0	0	0
Haemolytic anaemia	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Leukopenias NEC (cont)				
Leukopenia (cont)				
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 3	0	1 (4.2%)	1 (1.8%)	2 (3.0%)
Bleeding tendencies	0	1 (4.2%)	1 (1.8%)	2 (3.0%)
Grade 1	0	1 (4.2%)	1 (1.8%)	2 (3.0%)
Increased tendency to bruise	0	1 (4.2%)	1 (1.8%)	2 (3.0%)
Grade 1	0	1 (4.2%)	1 (1.8%)	2 (3.0%)
Anaemias haemolytic NEC	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 3	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Haemolytic anaemia	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 3	0	1 (4.2%)	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-et.pdf 24AUG2023:15:01

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Coagulopathies	0	0	0	0
Grade 1	0	0	0	0
Hyperfibrinogenaemia	0	0	0	0
Grade 1	0	0	0	0
Lymphatic system disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Lymphadenopathy	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Coagulopathies	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)
Hyperfibrinogenaemia	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)
Lymphatic system disorders NEC	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)
Lymphadenopathy	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders	5 (41.7%)	3 (50.0%)	8 (44.4%)	16 (53.3%)
Grade 1	4 (33.3%)	1 (16.7%)	5 (27.8%)	9 (30.0%)
Grade 2	0	1 (16.7%)	1 (5.6%)	3 (10.0%)
Grade 3	1 (8.3%)	1 (16.7%)	2 (11.1%)	2 (6.7%)
Grade 4	0	0	0	1 (3.3%)
Grade 5	0	0	0	1 (3.3%)
Coughing and associated symptoms	2 (16.7%)	3 (50.0%)	5 (27.8%)	9 (30.0%)
Grade 1	2 (16.7%)	1 (16.7%)	3 (16.7%)	7 (23.3%)
Grade 2	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 3	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Cough	2 (16.7%)	3 (50.0%)	5 (27.8%)	8 (26.7%)
Grade 1	2 (16.7%)	1 (16.7%)	3 (16.7%)	6 (20.0%)
Grade 2	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 3	0	1 (16.7%)	1 (5.6%)	1 (3.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders	19 (61.3%)	12 (50.0%)	31 (56.4%)	38 (57.6%)
Grade 1	4 (12.9%)	3 (12.5%)	7 (12.7%)	8 (12.1%)
Grade 2	6 (19.4%)	4 (16.7%)	10 (18.2%)	13 (19.7%)
Grade 3	5 (16.1%)	4 (16.7%)	9 (16.4%)	11 (16.7%)
Grade 4	2 (6.5%)	1 (4.2%)	3 (5.5%)	3 (4.5%)
Grade 5	2 (6.5%)	0	2 (3.6%)	3 (4.5%)
Coughing and associated symptoms	11 (35.5%)	3 (12.5%)	14 (25.5%)	18 (27.3%)
Grade 1	3 (9.7%)	1 (4.2%)	4 (7.3%)	6 (9.1%)
Grade 2	6 (19.4%)	2 (8.3%)	8 (14.5%)	10 (15.2%)
Grade 3	2 (6.5%)	0	2 (3.6%)	2 (3.0%)
Cough	11 (35.5%)	3 (12.5%)	14 (25.5%)	17 (25.8%)
Grade 1	3 (9.7%)	1 (4.2%)	4 (7.3%)	6 (9.1%)
Grade 2	6 (19.4%)	2 (8.3%)	8 (14.5%)	9 (13.6%)
Grade 3	2 (6.5%)	0	2 (3.6%)	2 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Coughing and associated symptoms (cont)				
Haemoptysis	0	0	0	1 (3.3%)
Grade 1	0	0	0	1 (3.3%)
Grade 2	0	0	0	0
Productive cough	0	0	0	1 (3.3%)
Grade 1	0	0	0	1 (3.3%)
Sputum discoloured	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 2	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Breathing abnormalities	0	2 (33.3%)	2 (11.1%)	3 (10.0%)
Grade 1	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 2	0	1 (16.7%)	1 (5.6%)	2 (6.7%)
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Coughing and associated symptoms (cont)				
Haemoptysis	0	0	0	1 (1.5%)
Grade 1	0	0	0	0
Grade 2	0	0	0	1 (1.5%)
Productive cough	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 1	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Sputum discoloured	0	0	0	0
Grade 2	0	0	0	0
Breathing abnormalities	7 (22.6%)	5 (20.8%)	12 (21.8%)	17 (25.8%)
Grade 1	3 (9.7%)	2 (8.3%)	5 (9.1%)	7 (10.6%)
Grade 2	2 (6.5%)	2 (8.3%)	4 (7.3%)	5 (7.6%)
Grade 3	0	1 (4.2%)	1 (1.8%)	3 (4.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Breathing abnormalities (cont) (cont)				
Grade 4	0	0	0	0
Grade 5	0	0	0	0
Dyspnoea	0	2 (33.3%)	2 (11.1%)	3 (10.0%)
Grade 1	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 2	0	1 (16.7%)	1 (5.6%)	2 (6.7%)
Grade 3	0	0	0	0
Dyspnoea exertional	0	0	0	0
Grade 1	0	0	0	0
Respiratory distress	0	0	0	0
Grade 4	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Breathing abnormalities (cont) (cont)				
Grade 4	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 5	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Dyspnoea	4 (12.9%)	4 (16.7%)	8 (14.5%)	14 (21.2%)
Grade 1	2 (6.5%)	2 (8.3%)	4 (7.3%)	6 (9.1%)
Grade 2	2 (6.5%)	2 (8.3%)	4 (7.3%)	6 (9.1%)
Grade 3	0	0	0	2 (3.0%)
Dyspnoea exertional	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Grade 1	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Respiratory distress	2 (6.5%)	0	2 (3.6%)	2 (3.0%)
Grade 4	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Breathing abnormalities (cont)				
Respiratory distress (cont)				
Grade 5	0	0	0	0
Sleep apnoea syndrome	0	0	0	0
Grade 3	0	0	0	0
Nasal disorders NEC	1 (8.3%)	0	1 (5.6%)	3 (10.0%)
Grade 1	1 (8.3%)	0	1 (5.6%)	2 (6.7%)
Grade 2	0	0	0	1 (3.3%)
Epistaxis	0	0	0	2 (6.7%)
Grade 1	0	0	0	1 (3.3%)
Grade 2	0	0	0	1 (3.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Breathing abnormalities (cont)				
Respiratory distress (cont)				
Grade 5	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Sleep apnoea syndrome	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 3	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Nasal disorders NEC	1 (3.2%)	2 (8.3%)	3 (5.5%)	7 (10.6%)
Grade 1	1 (3.2%)	1 (4.2%)	2 (3.6%)	5 (7.6%)
Grade 2	0	1 (4.2%)	1 (1.8%)	2 (3.0%)
Epistaxis	1 (3.2%)	2 (8.3%)	3 (5.5%)	7 (10.6%)
Grade 1	1 (3.2%)	1 (4.2%)	2 (3.6%)	5 (7.6%)
Grade 2	0	1 (4.2%)	1 (1.8%)	2 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Nasal disorders NEC (cont)				
Nasal septum ulceration	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Upper respiratory tract signs and symptoms	2 (16.7%)	1 (16.7%)	3 (16.7%)	4 (13.3%)
Grade 1	2 (16.7%)	1 (16.7%)	3 (16.7%)	4 (13.3%)
Oropharyngeal pain	1 (8.3%)	0	1 (5.6%)	2 (6.7%)
Grade 1	1 (8.3%)	0	1 (5.6%)	2 (6.7%)
Rhinorrhoea	1 (8.3%)	1 (16.7%)	2 (11.1%)	2 (6.7%)
Grade 1	1 (8.3%)	1 (16.7%)	2 (11.1%)	2 (6.7%)
Dysphonia	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Nasal disorders NEC (cont)				
Nasal septum ulceration	0	0	0	0
Grade 1	0	0	0	0
Upper respiratory tract signs and symptoms	2 (6.5%)	0	2 (3.6%)	4 (6.1%)
Grade 1	2 (6.5%)	0	2 (3.6%)	4 (6.1%)
Oropharyngeal pain	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Rhinorrhoea	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)
Dysphonia	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Upper respiratory tract signs and symptoms (cont)				
Upper-airway cough syndrome	0	0	0	0
Grade 1	0	0	0	0
Lower respiratory tract inflammatory and immunologic conditions	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Grade 5	0	0	0	0
Pneumonitis	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Upper respiratory tract signs and symptoms (cont)				
Upper-airway cough syndrome	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Lower respiratory tract inflammatory and immunologic conditions	5 (16.1%)	1 (4.2%)	6 (10.9%)	6 (9.1%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 3	2 (6.5%)	1 (4.2%)	3 (5.5%)	3 (4.5%)
Grade 4	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 5	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Pneumonitis	3 (9.7%)	1 (4.2%)	4 (7.3%)	4 (6.1%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 3	2 (6.5%)	1 (4.2%)	3 (5.5%)	3 (4.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Lower respiratory tract inflammatory and immunologic conditions (cont)				
Pneumonia aspiration	0	0	0	0
Grade 4	0	0	0	0
Grade 5	0	0	0	0
Pulmonary oedemas	0	0	0	1 (3.3%)
Grade 3	0	0	0	0
Grade 4	0	0	0	1 (3.3%)
Pulmonary oedema	0	0	0	0
Grade 3	0	0	0	0
Acute respiratory distress syndrome	0	0	0	1 (3.3%)
Grade 4	0	0	0	1 (3.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Lower respiratory tract inflammatory and immunologic conditions (cont)				
Pneumonia aspiration	2 (6.5%)	0	2 (3.6%)	2 (3.0%)
Grade 4	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 5	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Pulmonary oedemas	0	3 (12.5%)	3 (5.5%)	3 (4.5%)
Grade 3	0	3 (12.5%)	3 (5.5%)	3 (4.5%)
Grade 4	0	0	0	0
Pulmonary oedema	0	2 (8.3%)	2 (3.6%)	2 (3.0%)
Grade 3	0	2 (8.3%)	2 (3.6%)	2 (3.0%)
Acute respiratory distress syndrome	0	0	0	0
Grade 4	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Pulmonary oedemas (cont)				
Pulmonary congestion	0	0	0	0
Grade 3	0	0	0	0
Parenchymal lung disorders NEC	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Atelectasis	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Interstitial lung disease	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Pulmonary oedemas (cont)				
Pulmonary congestion	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 3	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Parenchymal lung disorders NEC	1 (3.2%)	1 (4.2%)	2 (3.6%)	3 (4.5%)
Grade 2	0	0	0	1 (1.5%)
Grade 3	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Atelectasis	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Grade 2	0	0	0	1 (1.5%)
Grade 3	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Interstitial lung disease	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 3	0	1 (4.2%)	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Respiratory failures (excl neonatal)	1 (8.3%)	0	1 (5.6%)	2 (6.7%)
Grade 3	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 5	0	0	0	1 (3.3%)
Respiratory failure	1 (8.3%)	0	1 (5.6%)	2 (6.7%)
Grade 3	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 5	0	0	0	1 (3.3%)
Bronchospasm and obstruction	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Asthma	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Respiratory failures (excl neonatal)	0	0	0	1 (1.5%)
Grade 3	0	0	0	0
Grade 5	0	0	0	1 (1.5%)
Respiratory failure	0	0	0	1 (1.5%)
Grade 3	0	0	0	0
Grade 5	0	0	0	1 (1.5%)
Bronchospasm and obstruction	2 (6.5%)	0	2 (3.6%)	2 (3.0%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Asthma	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Bronchospasm and obstruction (cont)				
Bronchial hyperreactivity	0	0	0	0
Grade 1	0	0	0	0
Pneumothorax and pleural effusions NEC	1 (8.3%)	0	1 (5.6%)	2 (6.7%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 3	0	0	0	1 (3.3%)
Pleural effusion	1 (8.3%)	0	1 (5.6%)	2 (6.7%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 3	0	0	0	1 (3.3%)
Pulmonary hypertensions	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Bronchospasm and obstruction (cont)				
Bronchial hyperreactivity	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Pneumothorax and pleural effusions NEC	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Pleural effusion	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Pulmonary hypertensions	0	0	0	2 (3.0%)
Grade 2	0	0	0	1 (1.5%)
Grade 3	0	0	0	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Pulmonary hypertensions (cont)				
Pulmonary hypertension	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Respiratory tract disorders NEC	0	0	0	0
Grade 2	0	0	0	0
Lung disorder	0	0	0	0
Grade 2	0	0	0	0
Respiratory tract inflammation	0	0	0	0
Grade 2	0	0	0	0
Bronchial conditions NEC	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Pulmonary hypertensions (cont)				
Pulmonary hypertension	0	0	0	2 (3.0%)
Grade 2	0	0	0	1 (1.5%)
Grade 3	0	0	0	1 (1.5%)
Respiratory tract disorders NEC	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Grade 2	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Lung disorder	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Respiratory tract inflammation	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Bronchial conditions NEC	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Bronchial conditions NEC (cont) (cont)				
Grade 1	0	0	0	0
Bronchial wall thickening	0	0	0	0
Grade 1	0	0	0	0
Conditions associated with abnormal gas exchange	0	0	0	0
Grade 4	0	0	0	0
Hypoxia	0	0	0	0
Grade 4	0	0	0	0
Pulmonary thrombotic and embolic conditions	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Bronchial conditions NEC (cont) (cont)				
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Bronchial wall thickening	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Conditions associated with abnormal gas exchange	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 4	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Hypoxia	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 4	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Pulmonary thrombotic and embolic conditions	0	1 (4.2%)	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Pulmonary thrombotic and embolic conditions (cont) (cont)				
Grade 3	0	0	0	0
Pulmonary embolism	0	0	0	0
Grade 3	0	0	0	0
Metabolism and nutrition disorders	3 (25.0%)	3 (50.0%)	6 (33.3%)	17 (56.7%)
Grade 1	2 (16.7%)	0	2 (11.1%)	8 (26.7%)
Grade 2	0	3 (50.0%)	3 (16.7%)	4 (13.3%)
Grade 3	1 (8.3%)	0	1 (5.6%)	5 (16.7%)
Grade 4	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Pulmonary thrombotic and embolic conditions (cont) (cont)				
Grade 3	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Pulmonary embolism	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 3	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Metabolism and nutrition disorders	17 (54.8%)	6 (25.0%)	23 (41.8%)	30 (45.5%)
Grade 1	7 (22.6%)	2 (8.3%)	9 (16.4%)	14 (21.2%)
Grade 2	7 (22.6%)	1 (4.2%)	8 (14.5%)	9 (13.6%)
Grade 3	2 (6.5%)	3 (12.5%)	5 (9.1%)	6 (9.1%)
Grade 4	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Potassium imbalance	1 (8.3%)	1 (16.7%)	2 (11.1%)	5 (16.7%)
Grade 1	0	0	0	1 (3.3%)
Grade 2	0	1 (16.7%)	1 (5.6%)	2 (6.7%)
Grade 3	1 (8.3%)	0	1 (5.6%)	2 (6.7%)
Hyperkalaemia	1 (8.3%)	0	1 (5.6%)	4 (13.3%)
Grade 1	0	0	0	2 (6.7%)
Grade 2	1 (8.3%)	0	1 (5.6%)	2 (6.7%)
Grade 3	0	0	0	0
Hypokalaemia	1 (8.3%)	1 (16.7%)	2 (11.1%)	4 (13.3%)
Grade 1	0	0	0	0
Grade 2	0	1 (16.7%)	1 (5.6%)	2 (6.7%)
Grade 3	1 (8.3%)	0	1 (5.6%)	2 (6.7%)
Water soluble vitamin deficiencies	0	0	0	3 (10.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Potassium imbalance	4 (12.9%)	4 (16.7%)	8 (14.5%)	10 (15.2%)
Grade 1	1 (3.2%)	0	1 (1.8%)	3 (4.5%)
Grade 2	2 (6.5%)	2 (8.3%)	4 (7.3%)	4 (6.1%)
Grade 3	1 (3.2%)	2 (8.3%)	3 (5.5%)	3 (4.5%)
Hyperkalaemia	3 (9.7%)	2 (8.3%)	5 (9.1%)	7 (10.6%)
Grade 1	1 (3.2%)	0	1 (1.8%)	3 (4.5%)
Grade 2	2 (6.5%)	1 (4.2%)	3 (5.5%)	3 (4.5%)
Grade 3	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Hypokalaemia	2 (6.5%)	2 (8.3%)	4 (7.3%)	4 (6.1%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 3	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Water soluble vitamin deficiencies	6 (19.4%)	1 (4.2%)	7 (12.7%)	11 (16.7%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Water soluble vitamin deficiencies (cont)				
(cont)				
Grade 1	0	0	0	2 (6.7%)
Grade 2	0	0	0	1 (3.3%)
Vitamin B1 deficiency	0	0	0	2 (6.7%)
Grade 1	0	0	0	1 (3.3%)
Grade 2	0	0	0	1 (3.3%)
Vitamin B complex deficiency	0	0	0	1 (3.3%)
Grade 1	0	0	0	1 (3.3%)
Grade 2	0	0	0	0
Vitamin B6 deficiency	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Water soluble vitamin deficiencies (cont)				
(cont)				
Grade 1	3 (9.7%)	1 (4.2%)	4 (7.3%)	7 (10.6%)
Grade 2	3 (9.7%)	0	3 (5.5%)	4 (6.1%)
Vitamin B1 deficiency	5 (16.1%)	1 (4.2%)	6 (10.9%)	9 (13.6%)
Grade 1	3 (9.7%)	1 (4.2%)	4 (7.3%)	6 (9.1%)
Grade 2	2 (6.5%)	0	2 (3.6%)	3 (4.5%)
Vitamin B complex deficiency	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	0	0	0	0
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Vitamin B6 deficiency	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Disorders of purine metabolism	0	0	0	3 (10.0%)
Grade 1	0	0	0	2 (6.7%)
Grade 2	0	0	0	0
Grade 3	0	0	0	1 (3.3%)
Grade 4	0	0	0	0
Hyperuricaemia	0	0	0	3 (10.0%)
Grade 1	0	0	0	2 (6.7%)
Grade 2	0	0	0	0
Grade 3	0	0	0	1 (3.3%)
Grade 4	0	0	0	0
Gout	0	0	0	0
Grade 3	0	0	0	0
Appetite disorders	1 (8.3%)	1 (16.7%)	2 (11.1%)	5 (16.7%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Disorders of purine metabolism	5 (16.1%)	1 (4.2%)	6 (10.9%)	7 (10.6%)
Grade 1	3 (9.7%)	0	3 (5.5%)	4 (6.1%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 3	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 4	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Hyperuricaemia	4 (12.9%)	1 (4.2%)	5 (9.1%)	6 (9.1%)
Grade 1	3 (9.7%)	0	3 (5.5%)	4 (6.1%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 3	0	0	0	0
Grade 4	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Gout	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 3	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Appetite disorders	1 (3.2%)	1 (4.2%)	2 (3.6%)	4 (6.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Appetite disorders (cont)				
(cont)				
Grade 1	1 (8.3%)	0	1 (5.6%)	4 (13.3%)
Grade 2	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Decreased appetite	1 (8.3%)	1 (16.7%)	2 (11.1%)	4 (13.3%)
Grade 1	1 (8.3%)	0	1 (5.6%)	3 (10.0%)
Grade 2	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Appetite disorder	0	0	0	1 (3.3%)
Grade 1	0	0	0	1 (3.3%)
Calcium metabolism disorders	1 (8.3%)	1 (16.7%)	2 (11.1%)	4 (13.3%)
Grade 1	1 (8.3%)	1 (16.7%)	2 (11.1%)	4 (13.3%)
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Appetite disorders (cont)				
(cont)				
Grade 1	0	1 (4.2%)	1 (1.8%)	2 (3.0%)
Grade 2	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Decreased appetite	1 (3.2%)	1 (4.2%)	2 (3.6%)	4 (6.1%)
Grade 1	0	1 (4.2%)	1 (1.8%)	2 (3.0%)
Grade 2	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Appetite disorder	0	0	0	0
Grade 1	0	0	0	0
Calcium metabolism disorders	1 (3.2%)	1 (4.2%)	2 (3.6%)	3 (4.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Grade 3	0	1 (4.2%)	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Calcium metabolism disorders (cont)				
Hypocalcaemia	1 (8.3%)	1 (16.7%)	2 (11.1%)	4 (13.3%)
Grade 1	1 (8.3%)	1 (16.7%)	2 (11.1%)	4 (13.3%)
Grade 3	0	0	0	0
Sodium imbalance	0	0	0	1 (3.3%)
Grade 1	0	0	0	1 (3.3%)
Grade 3	0	0	0	0
Hyponatraemia	0	0	0	1 (3.3%)
Grade 1	0	0	0	1 (3.3%)
Grade 3	0	0	0	0
Hypernatraemia	0	0	0	1 (3.3%)
Grade 1	0	0	0	1 (3.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Calcium metabolism disorders (cont)				
Hypocalcaemia	1 (3.2%)	1 (4.2%)	2 (3.6%)	3 (4.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Grade 3	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Sodium imbalance	2 (6.5%)	3 (12.5%)	5 (9.1%)	6 (9.1%)
Grade 1	2 (6.5%)	1 (4.2%)	3 (5.5%)	4 (6.1%)
Grade 3	0	2 (8.3%)	2 (3.6%)	2 (3.0%)
Hyponatraemia	2 (6.5%)	3 (12.5%)	5 (9.1%)	6 (9.1%)
Grade 1	2 (6.5%)	1 (4.2%)	3 (5.5%)	4 (6.1%)
Grade 3	0	2 (8.3%)	2 (3.6%)	2 (3.0%)
Hypernatraemia	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Phosphorus metabolism disorders	0	0	0	2 (6.7%)
Grade 1	0	0	0	1 (3.3%)
Grade 2	0	0	0	1 (3.3%)
Grade 3	0	0	0	0
Hypophosphataemia	0	0	0	1 (3.3%)
Grade 2	0	0	0	1 (3.3%)
Grade 3	0	0	0	0
Hyperphosphataemia	0	0	0	1 (3.3%)
Grade 1	0	0	0	1 (3.3%)
Hyperglycaemic conditions NEC	0	1 (16.7%)	1 (5.6%)	4 (13.3%)
Grade 1	0	0	0	1 (3.3%)
Grade 2	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 3	0	0	0	2 (6.7%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Phosphorus metabolism disorders	1 (3.2%)	2 (8.3%)	3 (5.5%)	3 (4.5%)
Grade 1	0	0	0	0
Grade 2	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Grade 3	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Hypophosphataemia	1 (3.2%)	2 (8.3%)	3 (5.5%)	3 (4.5%)
Grade 2	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Grade 3	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Hyperphosphataemia	0	0	0	0
Grade 1	0	0	0	0
Hyperglycaemic conditions NEC	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Hyperglycaemic conditions NEC (cont)				
Hyperglycaemia	0	1 (16.7%)	1 (5.6%)	4 (13.3%)
Grade 1	0	0	0	1 (3.3%)
Grade 2	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 3	0	0	0	2 (6.7%)
Magnesium metabolism disorders	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Hypomagnesaemia	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Hyperglycaemic conditions NEC (cont)				
Hyperglycaemia	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Magnesium metabolism disorders	2 (6.5%)	1 (4.2%)	3 (5.5%)	3 (4.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 3	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Hypomagnesaemia	2 (6.5%)	1 (4.2%)	3 (5.5%)	3 (4.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 3	0	1 (4.2%)	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Protein metabolism disorders NEC	0	0	0	1 (3.3%)
Grade 2	0	0	0	1 (3.3%)
Hypoalbuminaemia	0	0	0	1 (3.3%)
Grade 2	0	0	0	1 (3.3%)
Total fluid volume decreased	0	0	0	0
Grade 1	0	0	0	0
Dehydration	0	0	0	0
Grade 1	0	0	0	0
Hypovolaemia	0	0	0	0
Grade 1	0	0	0	0
Diabetes mellitus (incl subtypes)	0	1 (16.7%)	1 (5.6%)	1 (3.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Protein metabolism disorders NEC	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Hypoalbuminaemia	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Total fluid volume decreased	0	0	0	2 (3.0%)
Grade 1	0	0	0	2 (3.0%)
Dehydration	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)
Hypovolaemia	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)
Diabetes mellitus (incl subtypes)	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Diabetes mellitus (incl subtypes) (cont) (cont)				
Grade 2	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Diabetes mellitus	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 2	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Electrolyte imbalance NEC	0	0	0	0
Grade 3	0	0	0	0
Tumour lysis syndrome	0	0	0	0
Grade 3	0	0	0	0
Elevated cholesterol	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Diabetes mellitus (incl subtypes) (cont) (cont)				
Grade 2	0	0	0	0
Diabetes mellitus	0	0	0	0
Grade 2	0	0	0	0
Electrolyte imbalance NEC	0	0	0	1 (1.5%)
Grade 3	0	0	0	1 (1.5%)
Tumour lysis syndrome	0	0	0	1 (1.5%)
Grade 3	0	0	0	1 (1.5%)
Elevated cholesterol	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Elevated cholesterol (cont)				
Hypercholesterolaemia	0	0	0	0
Grade 1	0	0	0	0
Total fluid volume increased	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Fluid overload	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Musculoskeletal and connective tissue disorders	4 (33.3%)	4 (66.7%)	8 (44.4%)	15 (50.0%)
Grade 1	2 (16.7%)	2 (33.3%)	4 (22.2%)	9 (30.0%)
Grade 2	2 (16.7%)	2 (33.3%)	4 (22.2%)	5 (16.7%)
Grade 3	0	0	0	1 (3.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

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Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Elevated cholesterol (cont)				
Hypercholesterolaemia	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Total fluid volume increased	0	0	0	0
Grade 2	0	0	0	0
Fluid overload	0	0	0	0
Grade 2	0	0	0	0
Musculoskeletal and connective tissue disorders	14 (45.2%)	7 (29.2%)	21 (38.2%)	28 (42.4%)
Grade 1	7 (22.6%)	5 (20.8%)	12 (21.8%)	15 (22.7%)
Grade 2	7 (22.6%)	2 (8.3%)	9 (16.4%)	12 (18.2%)
Grade 3	0	0	0	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Musculoskeletal and connective tissue pain and discomfort	2 (16.7%)	2 (33.3%)	4 (22.2%)	7 (23.3%)
Grade 1	2 (16.7%)	1 (16.7%)	3 (16.7%)	6 (20.0%)
Grade 2	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Pain in extremity	1 (8.3%)	0	1 (5.6%)	3 (10.0%)
Grade 1	1 (8.3%)	0	1 (5.6%)	3 (10.0%)
Grade 2	0	0	0	0
Back pain	1 (8.3%)	1 (16.7%)	2 (11.1%)	3 (10.0%)
Grade 1	1 (8.3%)	1 (16.7%)	2 (11.1%)	3 (10.0%)
Grade 2	0	0	0	0
Limb discomfort	0	0	0	1 (3.3%)
Grade 1	0	0	0	1 (3.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Musculoskeletal and connective tissue pain and discomfort	9 (29.0%)	2 (8.3%)	11 (20.0%)	12 (18.2%)
Grade 1	4 (12.9%)	2 (8.3%)	6 (10.9%)	7 (10.6%)
Grade 2	5 (16.1%)	0	5 (9.1%)	5 (7.6%)
Pain in extremity	5 (16.1%)	1 (4.2%)	6 (10.9%)	7 (10.6%)
Grade 1	3 (9.7%)	1 (4.2%)	4 (7.3%)	5 (7.6%)
Grade 2	2 (6.5%)	0	2 (3.6%)	2 (3.0%)
Back pain	4 (12.9%)	0	4 (7.3%)	4 (6.1%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	3 (9.7%)	0	3 (5.5%)	3 (4.5%)
Limb discomfort	0	1 (4.2%)	1 (1.8%)	2 (3.0%)
Grade 1	0	1 (4.2%)	1 (1.8%)	2 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Musculoskeletal and connective tissue pain and discomfort (cont)				
Flank pain	0	0	0	0
Grade 1	0	0	0	0
Musculoskeletal chest pain	0	0	0	0
Grade 1	0	0	0	0
Musculoskeletal pain	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 2	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Neck pain	0	0	0	0
Grade 2	0	0	0	0
Joint related signs and symptoms	1 (8.3%)	0	1 (5.6%)	2 (6.7%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Musculoskeletal and connective tissue pain and discomfort (cont)				
Flank pain	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)
Musculoskeletal chest pain	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Musculoskeletal pain	0	0	0	0
Grade 2	0	0	0	0
Neck pain	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Joint related signs and symptoms	2 (6.5%)	0	2 (3.6%)	7 (10.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Joint related signs and symptoms (cont) (cont)				
Grade 1	1 (8.3%)	0	1 (5.6%)	2 (6.7%)
Grade 2	0	0	0	0
Arthralgia	1 (8.3%)	0	1 (5.6%)	2 (6.7%)
Grade 1	1 (8.3%)	0	1 (5.6%)	2 (6.7%)
Grade 2	0	0	0	0
Bone related signs and symptoms	1 (8.3%)	1 (16.7%)	2 (11.1%)	2 (6.7%)
Grade 1	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 2	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Bone pain	1 (8.3%)	1 (16.7%)	2 (11.1%)	2 (6.7%)
Grade 1	0	1 (16.7%)	1 (5.6%)	1 (3.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Joint related signs and symptoms (cont) (cont)				
Grade 1	2 (6.5%)	0	2 (3.6%)	6 (9.1%)
Grade 2	0	0	0	1 (1.5%)
Arthralgia	2 (6.5%)	0	2 (3.6%)	7 (10.6%)
Grade 1	2 (6.5%)	0	2 (3.6%)	6 (9.1%)
Grade 2	0	0	0	1 (1.5%)
Bone related signs and symptoms	1 (3.2%)	2 (8.3%)	3 (5.5%)	6 (9.1%)
Grade 1	1 (3.2%)	2 (8.3%)	3 (5.5%)	3 (4.5%)
Grade 2	0	0	0	3 (4.5%)
Bone pain	0	2 (8.3%)	2 (3.6%)	4 (6.1%)
Grade 1	0	2 (8.3%)	2 (3.6%)	2 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Bone related signs and symptoms (cont)				
Bone pain (cont)				
Grade 2	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Metatarsalgia	0	0	0	0
Grade 1	0	0	0	0
Spinal pain	0	0	0	0
Grade 2	0	0	0	0
Muscle related signs and symptoms NEC	1 (8.3%)	1 (16.7%)	2 (11.1%)	4 (13.3%)
Grade 1	1 (8.3%)	1 (16.7%)	2 (11.1%)	4 (13.3%)
Grade 2	0	0	0	0
Muscle spasms	1 (8.3%)	1 (16.7%)	2 (11.1%)	4 (13.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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(Continued)	>=65 Years			
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Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Bone related signs and symptoms (cont)				
Bone pain (cont)				
Grade 2	0	0	0	2 (3.0%)
Metatarsalgia	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Spinal pain	0	0	0	1 (1.5%)
Grade 2	0	0	0	1 (1.5%)
Muscle related signs and symptoms NEC	2 (6.5%)	1 (4.2%)	3 (5.5%)	4 (6.1%)
Grade 1	1 (3.2%)	1 (4.2%)	2 (3.6%)	3 (4.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Muscle spasms	2 (6.5%)	1 (4.2%)	3 (5.5%)	4 (6.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Muscle related signs and symptoms NEC (cont)				
Muscle spasms (cont)				
Grade 1	1 (8.3%)	1 (16.7%)	2 (11.1%)	4 (13.3%)
Grade 2	0	0	0	0
Muscle pains	1 (8.3%)	0	1 (5.6%)	3 (10.0%)
Grade 1	1 (8.3%)	0	1 (5.6%)	2 (6.7%)
Grade 2	0	0	0	1 (3.3%)
Myalgia	1 (8.3%)	0	1 (5.6%)	3 (10.0%)
Grade 1	1 (8.3%)	0	1 (5.6%)	2 (6.7%)
Grade 2	0	0	0	1 (3.3%)
Bone disorders NEC	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Muscle related signs and symptoms NEC (cont)				
Muscle spasms (cont)				
Grade 1	1 (3.2%)	1 (4.2%)	2 (3.6%)	3 (4.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Muscle pains	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Grade 1	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Grade 2	0	0	0	0
Myalgia	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Grade 1	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Grade 2	0	0	0	0
Bone disorders NEC	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Bone disorders NEC (cont)				
(cont)				
Grade 2	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Osteonecrosis	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Osteosis	0	0	0	0
Grade 1	0	0	0	0
Crystal arthropathic disorders	0	0	0	1 (3.3%)
Grade 2	0	0	0	0
Grade 3	0	0	0	1 (3.3%)
Chondrocalcinosis pyrophosphate	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Bone disorders NEC (cont) (cont)				
Grade 2	0	0	0	0
Osteonecrosis	0	0	0	0
Grade 2	0	0	0	0
Osteosis	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Crystal arthropathic disorders	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 3	0	0	0	0
Chondrocalcinosis pyrophosphate	0	1 (4.2%)	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Crystal arthropathic disorders (cont)				
Chondrocalcinosis pyrophosphate (cont)				
Grade 2	0	0	0	0
Gouty arthritis	0	0	0	1 (3.3%)
Grade 3	0	0	0	1 (3.3%)
Muscle weakness conditions	0	0	0	0
Grade 2	0	0	0	0
Muscular weakness	0	0	0	0
Grade 2	0	0	0	0
Bursal disorders	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Crystal arthropathic disorders (cont)				
Chondrocalcinosis pyrophosphate (cont)				
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Gouty arthritis	0	0	0	0
Grade 3	0	0	0	0
Muscle weakness conditions	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Grade 2	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Muscular weakness	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Grade 2	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Bursal disorders	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Bursal disorders (cont)				
Bursitis	0	0	0	0
Grade 2	0	0	0	0
Extremity deformities	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 2	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Foot deformity	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 2	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Musculoskeletal and connective tissue conditions NEC	0	0	0	0
Grade 1	0	0	0	0
Muscle contracture	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Bursal disorders (cont)				
Bursitis	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Extremity deformities	0	0	0	0
Grade 2	0	0	0	0
Foot deformity	0	0	0	0
Grade 2	0	0	0	0
Musculoskeletal and connective tissue conditions NEC	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Muscle contracture	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Musculoskeletal and connective tissue conditions NEC (cont)				
Muscle contracture (cont)				
Grade 1	0	0	0	0
Soft tissue disorders NEC	0	0	0	0
Grade 3	0	0	0	0
Groin pain	0	0	0	0
Grade 3	0	0	0	0
Spine and neck deformities	0	0	0	0
Grade 2	0	0	0	0
Spinal stenosis	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Musculoskeletal and connective tissue conditions NEC (cont)				
Muscle contracture (cont)				
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Soft tissue disorders NEC	0	0	0	1 (1.5%)
Grade 3	0	0	0	1 (1.5%)
Groin pain	0	0	0	1 (1.5%)
Grade 3	0	0	0	1 (1.5%)
Spine and neck deformities	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Spinal stenosis	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Spine and neck deformities (cont)				
Spinal stenosis (cont)				
Grade 2	0	0	0	0
Tendon disorders	0	0	0	0
Grade 1	0	0	0	0
Tendonitis	0	0	0	0
Grade 1	0	0	0	0
Investigations	4 (33.3%)	2 (33.3%)	6 (33.3%)	14 (46.7%)
Grade 1	1 (8.3%)	1 (16.7%)	2 (11.1%)	5 (16.7%)
Grade 2	3 (25.0%)	1 (16.7%)	4 (22.2%)	7 (23.3%)
Grade 3	0	0	0	2 (6.7%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Spine and neck deformities (cont)				
Spinal stenosis (cont)				
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Tendon disorders	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Tendonitis	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Investigations	14 (45.2%)	7 (29.2%)	21 (38.2%)	26 (39.4%)
Grade 1	6 (19.4%)	2 (8.3%)	8 (14.5%)	13 (19.7%)
Grade 2	4 (12.9%)	3 (12.5%)	7 (12.7%)	7 (10.6%)
Grade 3	4 (12.9%)	2 (8.3%)	6 (10.9%)	6 (9.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Physical examination procedures and organ system status	2 (16.7%)	2 (33.3%)	4 (22.2%)	9 (30.0%)
Grade 1	2 (16.7%)	1 (16.7%)	3 (16.7%)	6 (20.0%)
Grade 2	0	1 (16.7%)	1 (5.6%)	3 (10.0%)
Grade 3	0	0	0	0
Weight decreased	1 (8.3%)	2 (33.3%)	3 (16.7%)	7 (23.3%)
Grade 1	1 (8.3%)	1 (16.7%)	2 (11.1%)	4 (13.3%)
Grade 2	0	1 (16.7%)	1 (5.6%)	3 (10.0%)
Weight increased	0	0	0	0
Grade 1	0	0	0	0
Eastern Cooperative Oncology Group performance status worsened	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Physical examination procedures and organ system status	7 (22.6%)	3 (12.5%)	10 (18.2%)	13 (19.7%)
Grade 1	4 (12.9%)	2 (8.3%)	6 (10.9%)	9 (13.6%)
Grade 2	2 (6.5%)	1 (4.2%)	3 (5.5%)	3 (4.5%)
Grade 3	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Weight decreased	3 (9.7%)	2 (8.3%)	5 (9.1%)	7 (10.6%)
Grade 1	1 (3.2%)	2 (8.3%)	3 (5.5%)	5 (7.6%)
Grade 2	2 (6.5%)	0	2 (3.6%)	2 (3.0%)
Weight increased	2 (6.5%)	0	2 (3.6%)	3 (4.5%)
Grade 1	2 (6.5%)	0	2 (3.6%)	3 (4.5%)
Eastern Cooperative Oncology Group performance status worsened	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-et.pdf 24AUG2023:15:01

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Physical examination procedures and organ system status (cont)				
Eastern Cooperative Oncology Group performance status worsened (cont)				
Grade 3	0	0	0	0
Body temperature increased	0	0	0	1 (3.3%)
Grade 1	0	0	0	1 (3.3%)
Breath sounds abnormal	0	0	0	0
Grade 1	0	0	0	0
General physical condition abnormal	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Physical examination procedures and organ system status (cont)				
Eastern Cooperative Oncology Group performance status worsened (cont)				
Grade 3	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Body temperature increased	0	0	0	0
Grade 1	0	0	0	0
Breath sounds abnormal	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
General physical condition abnormal	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Liver function analyses	1 (8.3%)	0	1 (5.6%)	5 (16.7%)
Grade 1	0	0	0	1 (3.3%)
Grade 2	1 (8.3%)	0	1 (5.6%)	3 (10.0%)
Grade 3	0	0	0	1 (3.3%)
Alanine aminotransferase increased	0	0	0	2 (6.7%)
Grade 1	0	0	0	1 (3.3%)
Grade 3	0	0	0	1 (3.3%)
Blood bilirubin increased	0	0	0	2 (6.7%)
Grade 1	0	0	0	0
Grade 2	0	0	0	2 (6.7%)
Aspartate aminotransferase increased	0	0	0	2 (6.7%)
Grade 1	0	0	0	1 (3.3%)
Grade 2	0	0	0	1 (3.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Liver function analyses	4 (12.9%)	2 (8.3%)	6 (10.9%)	7 (10.6%)
Grade 1	3 (9.7%)	0	3 (5.5%)	4 (6.1%)
Grade 2	0	0	0	0
Grade 3	1 (3.2%)	2 (8.3%)	3 (5.5%)	3 (4.5%)
Alanine aminotransferase increased	2 (6.5%)	1 (4.2%)	3 (5.5%)	3 (4.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 3	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Blood bilirubin increased	2 (6.5%)	0	2 (3.6%)	3 (4.5%)
Grade 1	2 (6.5%)	0	2 (3.6%)	3 (4.5%)
Grade 2	0	0	0	0
Aspartate aminotransferase increased	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 1	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Liver function analyses (cont)				
Aspartate aminotransferase increased (cont)				
Grade 3	0	0	0	0
Gamma-glutamyltransferase increased	0	0	0	1 (3.3%)
Grade 1	0	0	0	0
Grade 3	0	0	0	1 (3.3%)
Hepatic enzyme increased	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Liver function test increased	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Liver function analyses (cont)				
Aspartate aminotransferase increased (cont)				
Grade 3	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Gamma-glutamyltransferase increased	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 3	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Hepatic enzyme increased	0	0	0	0
Grade 2	0	0	0	0
Liver function test increased	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 3	0	1 (4.2%)	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Renal function analyses	2 (16.7%)	0	2 (11.1%)	3 (10.0%)
Grade 1	0	0	0	0
Grade 2	2 (16.7%)	0	2 (11.1%)	2 (6.7%)
Grade 3	0	0	0	1 (3.3%)
Blood creatinine increased	1 (8.3%)	0	1 (5.6%)	2 (6.7%)
Grade 1	0	0	0	0
Grade 2	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 3	0	0	0	1 (3.3%)
Creatinine renal clearance decreased	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Tissue enzyme analyses NEC	0	0	0	1 (3.3%)
Grade 1	0	0	0	0
Grade 2	0	0	0	1 (3.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Renal function analyses	3 (9.7%)	1 (4.2%)	4 (7.3%)	6 (9.1%)
Grade 1	1 (3.2%)	0	1 (1.8%)	3 (4.5%)
Grade 2	2 (6.5%)	1 (4.2%)	3 (5.5%)	3 (4.5%)
Grade 3	0	0	0	0
Blood creatinine increased	3 (9.7%)	1 (4.2%)	4 (7.3%)	6 (9.1%)
Grade 1	1 (3.2%)	0	1 (1.8%)	3 (4.5%)
Grade 2	2 (6.5%)	1 (4.2%)	3 (5.5%)	3 (4.5%)
Grade 3	0	0	0	0
Creatinine renal clearance decreased	0	0	0	0
Grade 2	0	0	0	0
Tissue enzyme analyses NEC	3 (9.7%)	0	3 (5.5%)	5 (7.6%)
Grade 1	1 (3.2%)	0	1 (1.8%)	3 (4.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Tissue enzyme analyses NEC (cont)				
(cont)				
Grade 3	0	0	0	0
Blood alkaline phosphatase increased	0	0	0	1 (3.3%)
Grade 1	0	0	0	0
Grade 2	0	0	0	1 (3.3%)
Blood lactate dehydrogenase increased	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Cardiac auscultatory investigations	0	0	0	0
Grade 1	0	0	0	0
Cardiac murmur	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Tissue enzyme analyses NEC (cont)				
(cont)				
Grade 3	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Blood alkaline phosphatase increased	2 (6.5%)	0	2 (3.6%)	3 (4.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Blood lactate dehydrogenase increased	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Grade 1	0	0	0	1 (1.5%)
Grade 3	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Cardiac auscultatory investigations	2 (6.5%)	0	2 (3.6%)	4 (6.1%)
Grade 1	2 (6.5%)	0	2 (3.6%)	4 (6.1%)
Cardiac murmur	2 (6.5%)	0	2 (3.6%)	4 (6.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Cardiac auscultatory investigations (cont)				
Cardiac murmur (cont)				
Grade 1	0	0	0	0
Coagulation and bleeding analyses	0	0	0	1 (3.3%)
Grade 1	0	0	0	1 (3.3%)
Grade 2	0	0	0	0
International normalised ratio increased	0	0	0	1 (3.3%)
Grade 1	0	0	0	1 (3.3%)
Grade 2	0	0	0	0
Mineral and electrolyte analyses	0	0	0	0
Grade 1	0	0	0	0
Blood bicarbonate decreased	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Cardiac auscultatory investigations (cont)				
Cardiac murmur (cont)				
Grade 1	2 (6.5%)	0	2 (3.6%)	4 (6.1%)
Coagulation and bleeding analyses	2 (6.5%)	1 (4.2%)	3 (5.5%)	3 (4.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
International normalised ratio increased	2 (6.5%)	1 (4.2%)	3 (5.5%)	3 (4.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Mineral and electrolyte analyses	2 (6.5%)	0	2 (3.6%)	2 (3.0%)
Grade 1	2 (6.5%)	0	2 (3.6%)	2 (3.0%)
Blood bicarbonate decreased	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Mineral and electrolyte analyses (cont)				
Blood bicarbonate decreased (cont)				
Grade 1	0	0	0	0
Blood chloride increased	0	0	0	0
Grade 1	0	0	0	0
Cardiac function diagnostic procedures	0	0	0	0
Grade 2	0	0	0	0
Ejection fraction decreased	0	0	0	0
Grade 2	0	0	0	0
Haematological analyses NEC	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Mineral and electrolyte analyses (cont)				
Blood bicarbonate decreased (cont)				
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Blood chloride increased	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Cardiac function diagnostic procedures	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Ejection fraction decreased	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Haematological analyses NEC	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Haematological analyses NEC (cont)				
Blast cell count increased	0	0	0	0
Grade 2	0	0	0	0
Skeletal and cardiac muscle analyses	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Troponin increased	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
White blood cell analyses	0	0	0	0
Grade 3	0	0	0	0
Neutrophil count decreased	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Haematological analyses NEC (cont)				
Blast cell count increased	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Skeletal and cardiac muscle analyses	0	0	0	0
Grade 1	0	0	0	0
Troponin increased	0	0	0	0
Grade 1	0	0	0	0
White blood cell analyses	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 3	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Neutrophil count decreased	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 3	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders	5 (41.7%)	3 (50.0%)	8 (44.4%)	14 (46.7%)
Grade 1	5 (41.7%)	2 (33.3%)	7 (38.9%)	11 (36.7%)
Grade 2	0	0	0	2 (6.7%)
Grade 3	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Pruritus NEC	1 (8.3%)	1 (16.7%)	2 (11.1%)	7 (23.3%)
Grade 1	1 (8.3%)	0	1 (5.6%)	4 (13.3%)
Grade 2	0	0	0	2 (6.7%)
Grade 3	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Pruritus	0	1 (16.7%)	1 (5.6%)	5 (16.7%)
Grade 1	0	0	0	3 (10.0%)
Grade 2	0	0	0	1 (3.3%)
Grade 3	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Pruritus generalised	0	0	0	1 (3.3%)
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders	8 (25.8%)	7 (29.2%)	15 (27.3%)	26 (39.4%)
Grade 1	3 (9.7%)	2 (8.3%)	5 (9.1%)	15 (22.7%)
Grade 2	4 (12.9%)	4 (16.7%)	8 (14.5%)	9 (13.6%)
Grade 3	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Pruritus NEC	4 (12.9%)	2 (8.3%)	6 (10.9%)	12 (18.2%)
Grade 1	3 (9.7%)	1 (4.2%)	4 (7.3%)	8 (12.1%)
Grade 2	1 (3.2%)	1 (4.2%)	2 (3.6%)	4 (6.1%)
Grade 3	0	0	0	0
Pruritus	4 (12.9%)	1 (4.2%)	5 (9.1%)	10 (15.2%)
Grade 1	3 (9.7%)	1 (4.2%)	4 (7.3%)	7 (10.6%)
Grade 2	1 (3.2%)	0	1 (1.8%)	3 (4.5%)
Grade 3	0	0	0	0
Pruritus generalised	1 (3.2%)	1 (4.2%)	2 (3.6%)	3 (4.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	2 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Pruritus NEC (cont)				
Pruritus generalised (cont)				
Grade 2	0	0	0	1 (3.3%)
Aquagenic pruritus	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Apocrine and eccrine gland disorders	1 (8.3%)	2 (33.3%)	3 (16.7%)	6 (20.0%)
Grade 1	1 (8.3%)	1 (16.7%)	2 (11.1%)	4 (13.3%)
Grade 2	0	0	0	1 (3.3%)
Grade 3	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Night sweats	0	1 (16.7%)	1 (5.6%)	3 (10.0%)
Grade 1	0	1 (16.7%)	1 (5.6%)	2 (6.7%)
Grade 2	0	0	0	1 (3.3%)
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Pruritus NEC (cont)				
Pruritus generalised (cont)				
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Aquagenic pruritus	0	0	0	0
Grade 1	0	0	0	0
Apocrine and eccrine gland disorders	2 (6.5%)	4 (16.7%)	6 (10.9%)	9 (13.6%)
Grade 1	0	2 (8.3%)	2 (3.6%)	5 (7.6%)
Grade 2	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Grade 3	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Night sweats	2 (6.5%)	3 (12.5%)	5 (9.1%)	8 (12.1%)
Grade 1	0	1 (4.2%)	1 (1.8%)	4 (6.1%)
Grade 2	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Grade 3	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Apocrine and eccrine gland disorders (cont)				
Hyperhidrosis	1 (8.3%)	1 (16.7%)	2 (11.1%)	3 (10.0%)
Grade 1	1 (8.3%)	0	1 (5.6%)	2 (6.7%)
Grade 3	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Rashes, eruptions and exanthems NEC	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	0	0	0	0
Rash	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Rash maculo-papular	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Apocrine and eccrine gland disorders (cont)				
Hyperhidrosis	0	1 (4.2%)	1 (1.8%)	2 (3.0%)
Grade 1	0	1 (4.2%)	1 (1.8%)	2 (3.0%)
Grade 3	0	0	0	0
Rashes, eruptions and exanthems NEC	1 (3.2%)	2 (8.3%)	3 (5.5%)	6 (9.1%)
Grade 1	1 (3.2%)	1 (4.2%)	2 (3.6%)	5 (7.6%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Rash	0	1 (4.2%)	1 (1.8%)	2 (3.0%)
Grade 1	0	1 (4.2%)	1 (1.8%)	2 (3.0%)
Rash maculo-papular	1 (3.2%)	1 (4.2%)	2 (3.6%)	3 (4.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-et.pdf 24AUG2023:15:01

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Rashes, eruptions and exanthems NEC (cont)				
Rash generalised	0	0	0	0
Grade 1	0	0	0	0
Rash macular	0	0	0	0
Grade 1	0	0	0	0
Dermal and epidermal conditions NEC	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 1	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Dry skin	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 1	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Skin lesion	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Rashes, eruptions and exanthems NEC (cont)				
Rash generalised	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)
Rash macular	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 1	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Dermal and epidermal conditions NEC	2 (6.5%)	1 (4.2%)	3 (5.5%)	4 (6.1%)
Grade 1	2 (6.5%)	1 (4.2%)	3 (5.5%)	4 (6.1%)
Dry skin	1 (3.2%)	1 (4.2%)	2 (3.6%)	3 (4.5%)
Grade 1	1 (3.2%)	1 (4.2%)	2 (3.6%)	3 (4.5%)
Skin lesion	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Purpura and related conditions	0	0	0	1 (3.3%)
Grade 1	0	0	0	1 (3.3%)
Grade 2	0	0	0	0
Petechiae	0	0	0	0
Grade 1	0	0	0	0
Ecchymosis	0	0	0	1 (3.3%)
Grade 1	0	0	0	1 (3.3%)
Purpura	0	0	0	0
Grade 2	0	0	0	0
Purpura senile	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Purpura and related conditions	1 (3.2%)	2 (8.3%)	3 (5.5%)	4 (6.1%)
Grade 1	1 (3.2%)	1 (4.2%)	2 (3.6%)	3 (4.5%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Petechiae	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Grade 1	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Ecchymosis	0	0	0	0
Grade 1	0	0	0	0
Purpura	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Purpura senile	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Erythemas	1 (8.3%)	1 (16.7%)	2 (11.1%)	2 (6.7%)
Grade 1	1 (8.3%)	1 (16.7%)	2 (11.1%)	2 (6.7%)
Erythema	1 (8.3%)	1 (16.7%)	2 (11.1%)	2 (6.7%)
Grade 1	1 (8.3%)	1 (16.7%)	2 (11.1%)	2 (6.7%)
Alopecias	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Alopecia	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Angioedemas	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Swelling face	1 (8.3%)	0	1 (5.6%)	1 (3.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Erythemas	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Erythema	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Alopecias	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 1	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Alopecia	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 1	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Angioedemas	0	0	0	0
Grade 1	0	0	0	0
Swelling face	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-et.pdf 24AUG2023:15:01

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Angioedemas (cont)				
Swelling face (cont)				
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Bullous conditions	0	0	0	0
Grade 2	0	0	0	0
Erythema multiforme	0	0	0	0
Grade 2	0	0	0	0
Dermatitis and eczema	0	0	0	0
Grade 2	0	0	0	0
Dermatitis contact	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Angioedemas (cont)				
Swelling face (cont)				
Grade 1	0	0	0	0
Bullous conditions	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Erythema multiforme	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Dermatitis and eczema	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Dermatitis contact	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Dermatitis ascribed to specific agent	0	0	0	0
Grade 1	0	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	0	0	0	0
Grade 1	0	0	0	0
Rosaceas	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 1	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Rosacea	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 1	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Skin and subcutaneous tissue ulcerations	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Dermatitis ascribed to specific agent	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)
Palmar-plantar erythrodysaesthesia syndrome	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)
Rosaceas	0	0	0	0
Grade 1	0	0	0	0
Rosacea	0	0	0	0
Grade 1	0	0	0	0
Skin and subcutaneous tissue ulcerations	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Skin and subcutaneous tissue ulcerations (cont)				
Skin ulcer	0	0	0	0
Grade 2	0	0	0	0
Skin preneoplastic conditions NEC	0	0	0	0
Grade 2	0	0	0	0
Actinic keratosis	0	0	0	0
Grade 2	0	0	0	0
Renal and urinary disorders	4 (33.3%)	2 (33.3%)	6 (33.3%)	8 (26.7%)
Grade 1	2 (16.7%)	2 (33.3%)	4 (22.2%)	5 (16.7%)
Grade 2	1 (8.3%)	0	1 (5.6%)	2 (6.7%)
Grade 3	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 5	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Skin and subcutaneous tissue ulcerations (cont)				
Skin ulcer	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Skin preneoplastic conditions NEC	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Actinic keratosis	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Renal and urinary disorders	11 (35.5%)	9 (37.5%)	20 (36.4%)	21 (31.8%)
Grade 1	2 (6.5%)	4 (16.7%)	6 (10.9%)	6 (9.1%)
Grade 2	5 (16.1%)	3 (12.5%)	8 (14.5%)	9 (13.6%)
Grade 3	2 (6.5%)	2 (8.3%)	4 (7.3%)	4 (6.1%)
Grade 5	2 (6.5%)	0	2 (3.6%)	2 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal failure and impairment	2 (16.7%)	0	2 (11.1%)	4 (13.3%)
Grade 1	1 (8.3%)	0	1 (5.6%)	2 (6.7%)
Grade 2	1 (8.3%)	0	1 (5.6%)	2 (6.7%)
Grade 3	0	0	0	0
Grade 5	0	0	0	0
Acute kidney injury	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Renal failure	0	0	0	1 (3.3%)
Grade 1	0	0	0	0
Grade 2	0	0	0	1 (3.3%)
Grade 3	0	0	0	0
Grade 5	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal failure and impairment	8 (25.8%)	6 (25.0%)	14 (25.5%)	15 (22.7%)
Grade 1	1 (3.2%)	2 (8.3%)	3 (5.5%)	3 (4.5%)
Grade 2	4 (12.9%)	2 (8.3%)	6 (10.9%)	7 (10.6%)
Grade 3	2 (6.5%)	2 (8.3%)	4 (7.3%)	4 (6.1%)
Grade 5	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Acute kidney injury	3 (9.7%)	4 (16.7%)	7 (12.7%)	8 (12.1%)
Grade 1	1 (3.2%)	2 (8.3%)	3 (5.5%)	3 (4.5%)
Grade 2	2 (6.5%)	1 (4.2%)	3 (5.5%)	4 (6.1%)
Grade 3	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Renal failure	3 (9.7%)	2 (8.3%)	5 (9.1%)	5 (7.6%)
Grade 1	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Grade 3	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 5	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal failure and impairment (cont)				
Chronic kidney disease	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 3	0	0	0	0
Renal impairment	0	0	0	1 (3.3%)
Grade 1	0	0	0	1 (3.3%)
Grade 3	0	0	0	0
Bladder and urethral symptoms	1 (8.3%)	2 (33.3%)	3 (16.7%)	3 (10.0%)
Grade 1	1 (8.3%)	2 (33.3%)	3 (16.7%)	3 (10.0%)
Grade 2	0	0	0	0
Dysuria	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 1	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal failure and impairment (cont)				
Chronic kidney disease	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 3	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Renal impairment	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	0	0	0	0
Grade 3	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Bladder and urethral symptoms	2 (6.5%)	2 (8.3%)	4 (7.3%)	4 (6.1%)
Grade 1	1 (3.2%)	2 (8.3%)	3 (5.5%)	3 (4.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Dysuria	2 (6.5%)	0	2 (3.6%)	2 (3.0%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Bladder and urethral symptoms (cont)				
Urinary incontinence	1 (8.3%)	1 (16.7%)	2 (11.1%)	2 (6.7%)
Grade 1	1 (8.3%)	1 (16.7%)	2 (11.1%)	2 (6.7%)
Bladder spasm	0	0	0	0
Grade 1	0	0	0	0
Micturition urgency	0	0	0	1 (3.3%)
Grade 1	0	0	0	1 (3.3%)
Renal lithiasis	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Nephrolithiasis	1 (8.3%)	0	1 (5.6%)	1 (3.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Bladder and urethral symptoms (cont)				
Urinary incontinence	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 1	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Bladder spasm	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 1	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Micturition urgency	0	0	0	0
Grade 1	0	0	0	0
Renal lithiasis	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Grade 1	0	0	0	0
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 3	0	0	0	1 (1.5%)
Nephrolithiasis	1 (3.2%)	0	1 (1.8%)	2 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal lithiasis (cont)				
Nephrolithiasis (cont)				
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Urinary abnormalities	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	0	0	0	0
Grade 2	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Proteinuria	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	0	0	0	0
Grade 2	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Haematuria	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal lithiasis (cont)				
Nephrolithiasis (cont)				
Grade 1	0	0	0	0
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 3	0	0	0	1 (1.5%)
Urinary abnormalities	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	0	0	0	0
Proteinuria	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	0	0	0	0
Haematuria	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Bladder disorders NEC	0	0	0	0
Grade 2	0	0	0	0
Urinary bladder haemorrhage	0	0	0	0
Grade 2	0	0	0	0
Myoneurogenic bladder disorders	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Hypertonic bladder	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Nephritis NEC	0	0	0	0
Grade 5	0	0	0	0
Nephritis	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Bladder disorders NEC	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Urinary bladder haemorrhage	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Myoneurogenic bladder disorders	0	0	0	0
Grade 2	0	0	0	0
Hypertonic bladder	0	0	0	0
Grade 2	0	0	0	0
Nephritis NEC	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 5	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Nephritis	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Nephritis NEC (cont)				
Nephritis (cont)				
Grade 5	0	0	0	0
Renal neoplasms	0	0	0	0
Grade 1	0	0	0	0
Renal cyst	0	0	0	0
Grade 1	0	0	0	0
Urinary tract lithiasis (excl renal)	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 3	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Ureterolithiasis	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 3	1 (8.3%)	0	1 (5.6%)	1 (3.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Nephritis NEC (cont)				
Nephritis (cont)				
Grade 5	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Renal neoplasms	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Renal cyst	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Urinary tract lithiasis (excl renal)	0	0	0	0
Grade 3	0	0	0	0
Ureterolithiasis	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Urinary tract signs and symptoms NEC	0	0	0	0
Grade 2	0	0	0	0
Renal colic	0	0	0	0
Grade 2	0	0	0	0
Vascular disorders	2 (16.7%)	1 (16.7%)	3 (16.7%)	7 (23.3%)
Grade 1	0	1 (16.7%)	1 (5.6%)	2 (6.7%)
Grade 2	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 3	1 (8.3%)	0	1 (5.6%)	3 (10.0%)
Grade 4	0	0	0	1 (3.3%)
Vascular hypertensive disorders NEC	2 (16.7%)	0	2 (11.1%)	4 (13.3%)
Grade 2	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 3	1 (8.3%)	0	1 (5.6%)	2 (6.7%)
Grade 4	0	0	0	1 (3.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Urinary tract signs and symptoms NEC	0	0	0	1 (1.5%)
Grade 2	0	0	0	1 (1.5%)
Renal colic	0	0	0	1 (1.5%)
Grade 2	0	0	0	1 (1.5%)
Vascular disorders	8 (25.8%)	6 (25.0%)	14 (25.5%)	17 (25.8%)
Grade 1	2 (6.5%)	2 (8.3%)	4 (7.3%)	5 (7.6%)
Grade 2	4 (12.9%)	3 (12.5%)	7 (12.7%)	9 (13.6%)
Grade 3	2 (6.5%)	1 (4.2%)	3 (5.5%)	3 (4.5%)
Grade 4	0	0	0	0
Vascular hypertensive disorders NEC	0	1 (4.2%)	1 (1.8%)	4 (6.1%)
Grade 2	0	1 (4.2%)	1 (1.8%)	4 (6.1%)
Grade 3	0	0	0	0
Grade 4	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Vascular hypertensive disorders NEC (cont)				
Hypertension	2 (16.7%)	0	2 (11.1%)	4 (13.3%)
Grade 2	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 3	1 (8.3%)	0	1 (5.6%)	2 (6.7%)
Grade 4	0	0	0	1 (3.3%)
Vascular hypotensive disorders	0	0	0	1 (3.3%)
Grade 1	0	0	0	1 (3.3%)
Grade 2	0	0	0	0
Hypotension	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Orthostatic hypotension	0	0	0	1 (3.3%)
Grade 1	0	0	0	1 (3.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Vascular hypertensive disorders NEC (cont)				
Hypertension	0	1 (4.2%)	1 (1.8%)	4 (6.1%)
Grade 2	0	1 (4.2%)	1 (1.8%)	4 (6.1%)
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Vascular hypotensive disorders	2 (6.5%)	2 (8.3%)	4 (7.3%)	5 (7.6%)
Grade 1	1 (3.2%)	1 (4.2%)	2 (3.6%)	3 (4.5%)
Grade 2	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Hypotension	2 (6.5%)	2 (8.3%)	4 (7.3%)	5 (7.6%)
Grade 1	1 (3.2%)	1 (4.2%)	2 (3.6%)	3 (4.5%)
Grade 2	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Orthostatic hypotension	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-et.pdf 24AUG2023:15:01

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Haemorrhages NEC	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Haematoma	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Peripheral embolism and thrombosis	0	0	0	0
Grade 2	0	0	0	0
Deep vein thrombosis	0	0	0	0
Grade 2	0	0	0	0
Thrombophlebitis	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Haemorrhages NEC	1 (3.2%)	2 (8.3%)	3 (5.5%)	3 (4.5%)
Grade 1	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 3	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Haematoma	1 (3.2%)	2 (8.3%)	3 (5.5%)	3 (4.5%)
Grade 1	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 3	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Peripheral embolism and thrombosis	2 (6.5%)	1 (4.2%)	3 (5.5%)	3 (4.5%)
Grade 2	2 (6.5%)	1 (4.2%)	3 (5.5%)	3 (4.5%)
Deep vein thrombosis	2 (6.5%)	0	2 (3.6%)	2 (3.0%)
Grade 2	2 (6.5%)	0	2 (3.6%)	2 (3.0%)
Thrombophlebitis	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-et.pdf 24AUG2023:15:01

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Peripheral vascular disorders NEC	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 1	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Hot flush	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 1	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Non-site specific embolism and thrombosis	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Embolism	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Site specific vascular disorders NEC	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Peripheral vascular disorders NEC	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Grade 1	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Hot flush	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Grade 1	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Non-site specific embolism and thrombosis	2 (6.5%)	0	2 (3.6%)	2 (3.0%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 3	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Embolism	2 (6.5%)	0	2 (3.6%)	2 (3.0%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 3	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Site specific vascular disorders NEC	2 (6.5%)	0	2 (3.6%)	2 (3.0%)
Grade 1	2 (6.5%)	0	2 (3.6%)	2 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Site specific vascular disorders NEC (cont)				
Jugular vein distension	0	0	0	0
Grade 1	0	0	0	0
Pallor	0	0	0	0
Grade 1	0	0	0	0
Aortic necrosis and vascular insufficiency	0	0	0	1 (3.3%)
Grade 3	0	0	0	1 (3.3%)
Aortic stenosis	0	0	0	1 (3.3%)
Grade 3	0	0	0	1 (3.3%)
Peripheral vasoconstriction, necrosis and vascular insufficiency	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 1	0	1 (16.7%)	1 (5.6%)	1 (3.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Site specific vascular disorders NEC (cont)				
Jugular vein distension	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Pallor	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Aortic necrosis and vascular insufficiency	0	0	0	0
Grade 3	0	0	0	0
Aortic stenosis	0	0	0	0
Grade 3	0	0	0	0
Peripheral vasoconstriction, necrosis and vascular insufficiency	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Peripheral vasoconstriction, necrosis and vascular insufficiency (cont)				
Peripheral coldness	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 1	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Psychiatric disorders	3 (25.0%)	2 (33.3%)	5 (27.8%)	6 (20.0%)
Grade 1	1 (8.3%)	0	1 (5.6%)	2 (6.7%)
Grade 2	2 (16.7%)	2 (33.3%)	4 (22.2%)	4 (13.3%)
Disturbances in initiating and maintaining sleep	1 (8.3%)	1 (16.7%)	2 (11.1%)	2 (6.7%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Insomnia	1 (8.3%)	1 (16.7%)	2 (11.1%)	2 (6.7%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Peripheral vasoconstriction, necrosis and vascular insufficiency (cont)				
Peripheral coldness	0	0	0	0
Grade 1	0	0	0	0
Psychiatric disorders	7 (22.6%)	5 (20.8%)	12 (21.8%)	17 (25.8%)
Grade 1	4 (12.9%)	3 (12.5%)	7 (12.7%)	9 (13.6%)
Grade 2	3 (9.7%)	2 (8.3%)	5 (9.1%)	8 (12.1%)
Disturbances in initiating and maintaining sleep	3 (9.7%)	2 (8.3%)	5 (9.1%)	7 (10.6%)
Grade 1	2 (6.5%)	2 (8.3%)	4 (7.3%)	5 (7.6%)
Grade 2	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Insomnia	3 (9.7%)	2 (8.3%)	5 (9.1%)	7 (10.6%)
Grade 1	2 (6.5%)	2 (8.3%)	4 (7.3%)	5 (7.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Disturbances in initiating and maintaining sleep (cont)				
Insomnia (cont)				
Grade 2	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Confusion and disorientation	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	0	0	0	0
Confusional state	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	0	0	0	0
Anxiety symptoms	1 (8.3%)	0	1 (5.6%)	2 (6.7%)
Grade 1	0	0	0	1 (3.3%)
Grade 2	1 (8.3%)	0	1 (5.6%)	1 (3.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Disturbances in initiating and maintaining sleep (cont)				
Insomnia (cont)				
Grade 2	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Confusion and disorientation	2 (6.5%)	2 (8.3%)	4 (7.3%)	5 (7.6%)
Grade 1	2 (6.5%)	1 (4.2%)	3 (5.5%)	3 (4.5%)
Grade 2	0	1 (4.2%)	1 (1.8%)	2 (3.0%)
Confusional state	2 (6.5%)	2 (8.3%)	4 (7.3%)	5 (7.6%)
Grade 1	2 (6.5%)	1 (4.2%)	3 (5.5%)	3 (4.5%)
Grade 2	0	1 (4.2%)	1 (1.8%)	2 (3.0%)
Anxiety symptoms	1 (3.2%)	0	1 (1.8%)	3 (4.5%)
Grade 1	0	0	0	2 (3.0%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-et.pdf 24AUG2023:15:01

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Anxiety symptoms (cont)				
Anxiety	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	0	0	0	0
Grade 2	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Agitation	0	0	0	1 (3.3%)
Grade 1	0	0	0	1 (3.3%)
Depressive disorders	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 2	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Depression	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 2	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Increased physical activity levels	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Anxiety symptoms (cont)				
Anxiety	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Grade 1	0	0	0	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Agitation	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)
Depressive disorders	0	0	0	2 (3.0%)
Grade 2	0	0	0	2 (3.0%)
Depression	0	0	0	2 (3.0%)
Grade 2	0	0	0	2 (3.0%)
Increased physical activity levels	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Grade 1	1 (3.2%)	0	1 (1.8%)	2 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Increased physical activity levels (cont)				
Restlessness	0	0	0	0
Grade 1	0	0	0	0
Mood alterations with depressive symptoms	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 1	0	0	0	0
Grade 2	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Depressed mood	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 1	0	0	0	0
Grade 2	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Deliria	0	0	0	0
Grade 2	0	0	0	0
Delirium	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Increased physical activity levels (cont)				
Restlessness	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Grade 1	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Mood alterations with depressive symptoms	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	0	0	0	0
Depressed mood	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	0	0	0	0
Deliria	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Delirium	0	1 (4.2%)	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Deliria (cont)				
Delirium (cont)				
Grade 2	0	0	0	0
Emotional and mood disturbances NEC	0	0	0	0
Grade 1	0	0	0	0
Irritability	0	0	0	0
Grade 1	0	0	0	0
Sexual desire disorders	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Libido increased	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	1 (8.3%)	0	1 (5.6%)	1 (3.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Deliria (cont)				
Delirium (cont)				
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Emotional and mood disturbances NEC	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)
Irritability	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)
Sexual desire disorders	0	0	0	0
Grade 2	0	0	0	0
Libido increased	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Sleep disorders NEC	0	0	0	0
Grade 2	0	0	0	0
Sleep disorder	0	0	0	0
Grade 2	0	0	0	0
Cardiac disorders	1 (8.3%)	0	1 (5.6%)	4 (13.3%)
Grade 1	0	0	0	0
Grade 2	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 3	0	0	0	3 (10.0%)
Grade 4	0	0	0	0
Grade 5	0	0	0	0
Heart failures NEC	0	0	0	1 (3.3%)
Grade 3	0	0	0	1 (3.3%)
Grade 5	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Sleep disorders NEC	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Sleep disorder	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Cardiac disorders	7 (22.6%)	7 (29.2%)	14 (25.5%)	16 (24.2%)
Grade 1	1 (3.2%)	2 (8.3%)	3 (5.5%)	3 (4.5%)
Grade 2	1 (3.2%)	3 (12.5%)	4 (7.3%)	4 (6.1%)
Grade 3	3 (9.7%)	2 (8.3%)	5 (9.1%)	7 (10.6%)
Grade 4	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 5	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Heart failures NEC	4 (12.9%)	2 (8.3%)	6 (10.9%)	8 (12.1%)
Grade 3	3 (9.7%)	2 (8.3%)	5 (9.1%)	7 (10.6%)
Grade 5	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Heart failures NEC (cont)				
Cardiac failure	0	0	0	1 (3.3%)
Grade 3	0	0	0	1 (3.3%)
Grade 5	0	0	0	0
Cardiac failure congestive	0	0	0	0
Grade 3	0	0	0	0
Cardiac failure acute	0	0	0	0
Grade 3	0	0	0	0
Supraventricular arrhythmias	1 (8.3%)	0	1 (5.6%)	4 (13.3%)
Grade 2	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 3	0	0	0	3 (10.0%)
Grade 4	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Heart failures NEC (cont)				
Cardiac failure	2 (6.5%)	1 (4.2%)	3 (5.5%)	4 (6.1%)
Grade 3	1 (3.2%)	1 (4.2%)	2 (3.6%)	3 (4.5%)
Grade 5	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Cardiac failure congestive	1 (3.2%)	1 (4.2%)	2 (3.6%)	3 (4.5%)
Grade 3	1 (3.2%)	1 (4.2%)	2 (3.6%)	3 (4.5%)
Cardiac failure acute	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 3	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Supraventricular arrhythmias	3 (9.7%)	1 (4.2%)	4 (7.3%)	4 (6.1%)
Grade 2	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Grade 3	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 4	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-et.pdf 24AUG2023:15:01

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Supraventricular arrhythmias (cont)				
Atrial fibrillation	0	0	0	1 (3.3%)
Grade 2	0	0	0	0
Grade 3	0	0	0	1 (3.3%)
Grade 4	0	0	0	0
Sinus tachycardia	1 (8.3%)	0	1 (5.6%)	2 (6.7%)
Grade 2	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 3	0	0	0	1 (3.3%)
Supraventricular tachycardia	0	0	0	1 (3.3%)
Grade 3	0	0	0	1 (3.3%)
Cardiac signs and symptoms NEC	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Supraventricular arrhythmias (cont)				
Atrial fibrillation	2 (6.5%)	1 (4.2%)	3 (5.5%)	3 (4.5%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 3	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 4	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Sinus tachycardia	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 3	0	0	0	0
Supraventricular tachycardia	0	0	0	0
Grade 3	0	0	0	0
Cardiac signs and symptoms NEC	1 (3.2%)	1 (4.2%)	2 (3.6%)	3 (4.5%)
Grade 1	1 (3.2%)	1 (4.2%)	2 (3.6%)	3 (4.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Cardiac signs and symptoms NEC (cont)				
Palpitations	0	0	0	0
Grade 1	0	0	0	0
Left ventricular failures	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Left ventricular failure	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Ischaemic coronary artery disorders	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Cardiac signs and symptoms NEC (cont)				
Palpitations	1 (3.2%)	1 (4.2%)	2 (3.6%)	3 (4.5%)
Grade 1	1 (3.2%)	1 (4.2%)	2 (3.6%)	3 (4.5%)
Left ventricular failures	2 (6.5%)	1 (4.2%)	3 (5.5%)	3 (4.5%)
Grade 2	2 (6.5%)	0	2 (3.6%)	2 (3.0%)
Grade 3	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Left ventricular failure	2 (6.5%)	1 (4.2%)	3 (5.5%)	3 (4.5%)
Grade 2	2 (6.5%)	0	2 (3.6%)	2 (3.0%)
Grade 3	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Ischaemic coronary artery disorders	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 3	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Ischaemic coronary artery disorders (cont)				
Acute myocardial infarction	0	0	0	0
Grade 3	0	0	0	0
Myocardial ischaemia	0	0	0	0
Grade 2	0	0	0	0
Pericardial disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Pericardial effusion	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Rate and rhythm disorders NEC	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Ischaemic coronary artery disorders (cont)				
Acute myocardial infarction	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 3	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Myocardial ischaemia	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Pericardial disorders NEC	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Pericardial effusion	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Rate and rhythm disorders NEC	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Rate and rhythm disorders NEC (cont)				
(cont)				
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Extrasystoles	0	0	0	0
Grade 1	0	0	0	0
Tachycardia	0	0	0	0
Grade 3	0	0	0	0
Aortic valvular disorders	0	0	0	0
Grade 1	0	0	0	0
Aortic valve calcification	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
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Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Rate and rhythm disorders NEC (cont)				
(cont)				
Grade 1	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 3	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Extrasystoles	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 1	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Tachycardia	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 3	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Aortic valvular disorders	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Aortic valve calcification	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Cardiomyopathies	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Cardiomyopathy	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Coronary artery disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Arteriosclerosis coronary artery	0	0	0	0
Grade 1	0	0	0	0
Myocardial disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Cardiomegaly	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Cardiomyopathies	0	0	0	0
Grade 1	0	0	0	0
Cardiomyopathy	0	0	0	0
Grade 1	0	0	0	0
Coronary artery disorders NEC	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Arteriosclerosis coronary artery	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Myocardial disorders NEC	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Cardiomegaly	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Myocardial disorders NEC (cont)				
Cardiomegaly (cont)				
Grade 1	0	0	0	0
Injury, poisoning and procedural complications	2 (16.7%)	1 (16.7%)	3 (16.7%)	3 (10.0%)
Grade 1	1 (8.3%)	1 (16.7%)	2 (11.1%)	2 (6.7%)
Grade 2	0	0	0	0
Grade 3	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Skin injuries NEC	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 1	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Contusion	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 1	0	1 (16.7%)	1 (5.6%)	1 (3.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Myocardial disorders NEC (cont)				
Cardiomegaly (cont)				
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Injury, poisoning and procedural complications	5 (16.1%)	2 (8.3%)	7 (12.7%)	13 (19.7%)
Grade 1	1 (3.2%)	1 (4.2%)	2 (3.6%)	6 (9.1%)
Grade 2	2 (6.5%)	1 (4.2%)	3 (5.5%)	4 (6.1%)
Grade 3	2 (6.5%)	0	2 (3.6%)	3 (4.5%)
Skin injuries NEC	0	0	0	5 (7.6%)
Grade 1	0	0	0	5 (7.6%)
Contusion	0	0	0	5 (7.6%)
Grade 1	0	0	0	5 (7.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Non-site specific injuries NEC	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Fall	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Limb fractures and dislocations	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Femur fracture	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Non-site specific injuries NEC	2 (6.5%)	1 (4.2%)	3 (5.5%)	4 (6.1%)
Grade 1	2 (6.5%)	1 (4.2%)	3 (5.5%)	3 (4.5%)
Grade 2	0	0	0	1 (1.5%)
Grade 3	0	0	0	0
Fall	2 (6.5%)	1 (4.2%)	3 (5.5%)	4 (6.1%)
Grade 1	2 (6.5%)	1 (4.2%)	3 (5.5%)	3 (4.5%)
Grade 2	0	0	0	1 (1.5%)
Grade 3	0	0	0	0
Limb fractures and dislocations	0	0	0	2 (3.0%)
Grade 2	0	0	0	1 (1.5%)
Grade 3	0	0	0	1 (1.5%)
Femur fracture	0	0	0	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Limb fractures and dislocations (cont)				
Femur fracture (cont)				
Grade 3	0	0	0	0
Radius fracture	0	0	0	0
Grade 2	0	0	0	0
Muscle, tendon and ligament injuries	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	0	0	0	0
Ligament sprain	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Muscle rupture	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Limb fractures and dislocations (cont)				
Femur fracture (cont)				
Grade 3	0	0	0	1 (1.5%)
Radius fracture	0	0	0	1 (1.5%)
Grade 2	0	0	0	1 (1.5%)
Muscle, tendon and ligament injuries	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 1	0	0	0	0
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Ligament sprain	0	0	0	0
Grade 1	0	0	0	0
Muscle rupture	0	1 (4.2%)	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Muscle, tendon and ligament injuries (cont)				
Muscle rupture (cont)				
Grade 2	0	0	0	0
Non-site specific procedural complications	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 1	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 3	0	0	0	0
Procedural pain	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 1	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 3	0	0	0	0
Cerebral injuries NEC	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Muscle, tendon and ligament injuries (cont)				
Muscle rupture (cont)				
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Non-site specific procedural complications	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	0	0	0	0
Grade 3	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Procedural pain	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	0	0	0	0
Grade 3	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Cerebral injuries NEC	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 3	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Cerebral injuries NEC (cont)				
Subdural haematoma	0	0	0	0
Grade 3	0	0	0	0
Fractures and dislocations NEC	0	0	0	0
Grade 2	0	0	0	0
Joint dislocation	0	0	0	0
Grade 2	0	0	0	0
Site specific injuries NEC	0	0	0	0
Grade 2	0	0	0	0
Tooth fracture	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Cerebral injuries NEC (cont)				
Subdural haematoma	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 3	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Fractures and dislocations NEC	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Joint dislocation	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Site specific injuries NEC	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Tooth fracture	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders	1 (8.3%)	2 (33.3%)	3 (16.7%)	5 (16.7%)
Grade 1	1 (8.3%)	1 (16.7%)	2 (11.1%)	3 (10.0%)
Grade 2	0	0	0	1 (3.3%)
Grade 3	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Visual disorders NEC	1 (8.3%)	1 (16.7%)	2 (11.1%)	3 (10.0%)
Grade 1	1 (8.3%)	1 (16.7%)	2 (11.1%)	3 (10.0%)
Grade 2	0	0	0	0
Vision blurred	1 (8.3%)	0	1 (5.6%)	2 (6.7%)
Grade 1	1 (8.3%)	0	1 (5.6%)	2 (6.7%)
Grade 2	0	0	0	0
Photopsia	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 1	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders	3 (9.7%)	3 (12.5%)	6 (10.9%)	10 (15.2%)
Grade 1	2 (6.5%)	1 (4.2%)	3 (5.5%)	6 (9.1%)
Grade 2	1 (3.2%)	2 (8.3%)	3 (5.5%)	4 (6.1%)
Grade 3	0	0	0	0
Visual disorders NEC	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	0	0	0	1 (1.5%)
Vision blurred	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	0	0	0	1 (1.5%)
Photopsia	0	0	0	1 (1.5%)
Grade 1	0	0	0	0
Grade 2	0	0	0	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Cataract conditions	0	0	0	1 (3.3%)
Grade 1	0	0	0	0
Grade 2	0	0	0	1 (3.3%)
Cataract subcapsular	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Cataract	0	0	0	1 (3.3%)
Grade 2	0	0	0	1 (3.3%)
Cataract nuclear	0	0	0	0
Grade 1	0	0	0	0
Lacrimation disorders	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 1	0	1 (16.7%)	1 (5.6%)	1 (3.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Cataract conditions	1 (3.2%)	0	1 (1.8%)	3 (4.5%)
Grade 1	0	0	0	2 (3.0%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Cataract subcapsular	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Grade 1	0	0	0	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Cataract	0	0	0	0
Grade 2	0	0	0	0
Cataract nuclear	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)
Lacrimation disorders	0	1 (4.2%)	1 (1.8%)	2 (3.0%)
Grade 1	0	0	0	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Lacrimation disorders (cont) (cont)				
Grade 2	0	0	0	0
Dry eye	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 1	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 2	0	0	0	0
Lacrimation increased	0	0	0	0
Grade 1	0	0	0	0
Conjunctival and corneal bleeding and vascular disorders	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Lacrimation disorders (cont) (cont)				
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Dry eye	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 1	0	0	0	0
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Lacrimation increased	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)
Conjunctival and corneal bleeding and vascular disorders	0	0	0	2 (3.0%)
Grade 1	0	0	0	1 (1.5%)
Grade 2	0	0	0	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Conjunctival and corneal bleeding and vascular disorders (cont)				
Conjunctival haemorrhage	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Visual impairment and blindness (excl colour blindness)	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Visual acuity reduced	0	0	0	0
Grade 2	0	0	0	0
Visual impairment	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Conjunctival and corneal bleeding and vascular disorders (cont)				
Conjunctival haemorrhage	0	0	0	2 (3.0%)
Grade 1	0	0	0	1 (1.5%)
Grade 2	0	0	0	1 (1.5%)
Visual impairment and blindness (excl colour blindness)	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Visual acuity reduced	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 2	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Visual impairment	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Choroid and vitreous structural change, deposit and degeneration	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 3	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Vitreous detachment	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 3	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Conjunctival infections, irritations and inflammations	0	0	0	0
Grade 1	0	0	0	0
Conjunctival hyperaemia	0	0	0	0
Grade 1	0	0	0	0
Retinal structural change, deposit and degeneration	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Choroid and vitreous structural change, deposit and degeneration	0	0	0	0
Grade 3	0	0	0	0
Vitreous detachment	0	0	0	0
Grade 3	0	0	0	0
Conjunctival infections, irritations and inflammations	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 1	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Conjunctival hyperaemia	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 1	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Retinal structural change, deposit and degeneration	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Retinal structural change, deposit and degeneration (cont) (cont)				
Grade 1	0	0	0	0
Retinal drusen	0	0	0	0
Grade 1	0	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (25.0%)	1 (16.7%)	4 (22.2%)	5 (16.7%)
Grade 1	0	0	0	0
Grade 2	1 (8.3%)	1 (16.7%)	2 (11.1%)	2 (6.7%)
Grade 3	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 4	0	0	0	1 (3.3%)
Grade 5	1 (8.3%)	0	1 (5.6%)	1 (3.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Retinal structural change, deposit and degeneration (cont) (cont)				
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Retinal drusen	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	6 (19.4%)	2 (8.3%)	8 (14.5%)	10 (15.2%)
Grade 1	0	0	0	1 (1.5%)
Grade 2	3 (9.7%)	1 (4.2%)	4 (7.3%)	4 (6.1%)
Grade 3	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Grade 4	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 5	1 (3.2%)	0	1 (1.8%)	2 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Skin neoplasms malignant and unspecified (excl melanoma)	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Basal cell carcinoma	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Squamous cell carcinoma of skin	0	0	0	0
Grade 2	0	0	0	0
Bowen's disease	0	0	0	0
Grade 2	0	0	0	0
Carcinoma in situ of skin	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Skin neoplasms malignant and unspecified (excl melanoma)	2 (6.5%)	1 (4.2%)	3 (5.5%)	4 (6.1%)
Grade 2	2 (6.5%)	1 (4.2%)	3 (5.5%)	4 (6.1%)
Basal cell carcinoma	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Grade 2	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Squamous cell carcinoma of skin	2 (6.5%)	1 (4.2%)	3 (5.5%)	3 (4.5%)
Grade 2	2 (6.5%)	1 (4.2%)	3 (5.5%)	3 (4.5%)
Bowen's disease	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Carcinoma in situ of skin	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Skin neoplasms malignant and unspecified (excl melanoma) (cont)				
Keratoacanthoma	0	0	0	0
Grade 2	0	0	0	0
Leukaemias NEC	0	0	0	1 (3.3%)
Grade 3	0	0	0	0
Grade 4	0	0	0	1 (3.3%)
Leukaemia	0	0	0	1 (3.3%)
Grade 3	0	0	0	0
Grade 4	0	0	0	1 (3.3%)
Leukaemias acute myeloid	0	0	0	0
Grade 5	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Skin neoplasms malignant and unspecified (excl melanoma) (cont)				
Keratoacanthoma	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Leukaemias NEC	2 (6.5%)	0	2 (3.6%)	2 (3.0%)
Grade 3	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 4	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Leukaemia	2 (6.5%)	0	2 (3.6%)	2 (3.0%)
Grade 3	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 4	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Leukaemias acute myeloid	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Grade 5	1 (3.2%)	0	1 (1.8%)	2 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-et.pdf 24AUG2023:15:01

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Leukaemias acute myeloid (cont)				
Acute myeloid leukaemia	0	0	0	0
Grade 5	0	0	0	0
Urinary tract neoplasms unspecified malignancy NEC	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	0	0	0	0
Grade 3	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Bladder neoplasm	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	0	0	0	0
Grade 3	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Bladder neoplasms malignant	0	0	0	1 (3.3%)
Grade 2	0	0	0	1 (3.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Leukaemias acute myeloid (cont)				
Acute myeloid leukaemia	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Grade 5	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Urinary tract neoplasms unspecified malignancy NEC	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 3	0	0	0	0
Bladder neoplasm	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 3	0	0	0	0
Bladder neoplasms malignant	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Bladder neoplasms malignant (cont)				
Bladder cancer	0	0	0	1 (3.3%)
Grade 2	0	0	0	1 (3.3%)
Gastric neoplasms malignant	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 2	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Adenocarcinoma gastric	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 2	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Myeloproliferative disorders (excl leukaemias)	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 5	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Myelofibrosis	1 (8.3%)	0	1 (5.6%)	1 (3.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Bladder neoplasms malignant (cont)				
Bladder cancer	0	0	0	0
Grade 2	0	0	0	0
Gastric neoplasms malignant	0	0	0	0
Grade 2	0	0	0	0
Adenocarcinoma gastric	0	0	0	0
Grade 2	0	0	0	0
Myeloproliferative disorders (excl leukaemias)	0	0	0	0
Grade 5	0	0	0	0
Myelofibrosis	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Myeloproliferative disorders (excl leukaemias) (cont)				
Myelofibrosis (cont)				
Grade 5	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Plasma cell neoplasms NEC	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Hypergammaglobulinaemia benign monoclonal	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Thyroid neoplasms malignant	0	0	0	0
Grade 3	0	0	0	0
Papillary thyroid cancer	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Myeloproliferative disorders (excl leukaemias) (cont)				
Myelofibrosis (cont)				
Grade 5	0	0	0	0
Plasma cell neoplasms NEC	0	0	0	0
Grade 1	0	0	0	0
Hypergammaglobulinaemia benign monoclonal	0	0	0	0
Grade 1	0	0	0	0
Thyroid neoplasms malignant	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 3	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Papillary thyroid cancer	0	1 (4.2%)	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Thyroid neoplasms malignant (cont)				
Papillary thyroid cancer (cont)				
Grade 3	0	0	0	0
Upper gastrointestinal neoplasms benign	0	0	0	0
Grade 1	0	0	0	0
Oesophageal papilloma	0	0	0	0
Grade 1	0	0	0	0
Urinary tract neoplasms malignant NEC	0	0	0	0
Grade 2	0	0	0	0
Transitional cell carcinoma	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Thyroid neoplasms malignant (cont)				
Papillary thyroid cancer (cont)				
Grade 3	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Upper gastrointestinal neoplasms benign	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)
Oesophageal papilloma	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)
Urinary tract neoplasms malignant NEC	0	0	0	1 (1.5%)
Grade 2	0	0	0	1 (1.5%)
Transitional cell carcinoma	0	0	0	1 (1.5%)
Grade 2	0	0	0	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Ear and labyrinth disorders	2 (16.7%)	0	2 (11.1%)	2 (6.7%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Inner ear signs and symptoms	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	0	0	0	0
Vertigo	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Tinnitus	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Hearing losses	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Ear and labyrinth disorders	1 (3.2%)	2 (8.3%)	3 (5.5%)	6 (9.1%)
Grade 1	0	2 (8.3%)	2 (3.6%)	4 (6.1%)
Grade 2	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Inner ear signs and symptoms	0	1 (4.2%)	1 (1.8%)	4 (6.1%)
Grade 1	0	1 (4.2%)	1 (1.8%)	3 (4.5%)
Grade 2	0	0	0	1 (1.5%)
Vertigo	0	1 (4.2%)	1 (1.8%)	2 (3.0%)
Grade 1	0	1 (4.2%)	1 (1.8%)	2 (3.0%)
Tinnitus	0	0	0	2 (3.0%)
Grade 1	0	0	0	1 (1.5%)
Grade 2	0	0	0	1 (1.5%)
Hearing losses	1 (3.2%)	1 (4.2%)	2 (3.6%)	2 (3.0%)
Grade 1	0	1 (4.2%)	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Ear and labyrinth disorders (cont)				
Hearing losses (cont)				
(cont)				
Grade 2	0	0	0	0
Deafness bilateral	0	0	0	0
Grade 1	0	0	0	0
Hypoacusis	0	0	0	0
Grade 2	0	0	0	0
Inner ear disorders NEC	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Vestibular disorder	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	1 (8.3%)	0	1 (5.6%)	1 (3.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Ear and labyrinth disorders (cont)				
Hearing losses (cont)				
(cont)				
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Deafness bilateral	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 1	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Hypoacusis	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Inner ear disorders NEC	0	0	0	0
Grade 2	0	0	0	0
Vestibular disorder	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Hepatobiliary disorders	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 1	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 2	0	0	0	0
Grade 5	0	0	0	0
Cholecystitis and cholelithiasis	0	0	0	0
Grade 2	0	0	0	0
Cholecystitis	0	0	0	0
Grade 2	0	0	0	0
Cholecystitis acute	0	0	0	0
Grade 2	0	0	0	0
Cholestasis and jaundice	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Hepatobiliary disorders	4 (12.9%)	0	4 (7.3%)	5 (7.6%)
Grade 1	1 (3.2%)	0	1 (1.8%)	2 (3.0%)
Grade 2	2 (6.5%)	0	2 (3.6%)	2 (3.0%)
Grade 5	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Cholecystitis and cholelithiasis	2 (6.5%)	0	2 (3.6%)	2 (3.0%)
Grade 2	2 (6.5%)	0	2 (3.6%)	2 (3.0%)
Cholecystitis	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Cholecystitis acute	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Cholestasis and jaundice	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Hepatobiliary disorders (cont)				
Cholestasis and jaundice (cont)				
Jaundice	0	0	0	0
Grade 1	0	0	0	0
Hepatic failure and associated disorders	0	0	0	0
Grade 5	0	0	0	0
Hepatic failure	0	0	0	0
Grade 5	0	0	0	0
Hepatic vascular disorders	0	0	0	0
Grade 1	0	0	0	0
Portal hypertension	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Hepatobiliary disorders (cont)				
Cholestasis and jaundice (cont)				
Jaundice	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Hepatic failure and associated disorders	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 5	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Hepatic failure	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 5	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Hepatic vascular disorders	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)
Portal hypertension	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Hepatobiliary disorders (cont)				
Hepatobiliary signs and symptoms	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 1	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Hepatic pain	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 1	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Endocrine disorders	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Thyroid hypofunction disorders	0	0	0	0
Grade 2	0	0	0	0
Hypothyroidism	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Hepatobiliary disorders (cont)				
Hepatobiliary signs and symptoms	0	0	0	0
Grade 1	0	0	0	0
Hepatic pain	0	0	0	0
Grade 1	0	0	0	0
Endocrine disorders	2 (6.5%)	2 (8.3%)	4 (7.3%)	5 (7.6%)
Grade 1	0	2 (8.3%)	2 (3.6%)	2 (3.0%)
Grade 2	2 (6.5%)	0	2 (3.6%)	3 (4.5%)
Thyroid hypofunction disorders	2 (6.5%)	0	2 (3.6%)	3 (4.5%)
Grade 2	2 (6.5%)	0	2 (3.6%)	3 (4.5%)
Hypothyroidism	2 (6.5%)	0	2 (3.6%)	3 (4.5%)
Grade 2	2 (6.5%)	0	2 (3.6%)	3 (4.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Endocrine disorders (cont)				
Acute and chronic thyroiditis	0	0	0	0
Grade 1	0	0	0	0
Autoimmune thyroiditis	0	0	0	0
Grade 1	0	0	0	0
Thyroid disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Thyroid mass	0	0	0	0
Grade 1	0	0	0	0
Reproductive system and breast disorders	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	0	0	0	0
Grade 2	1 (8.3%)	0	1 (5.6%)	1 (3.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Endocrine disorders (cont)				
Acute and chronic thyroiditis	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 1	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Autoimmune thyroiditis	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 1	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Thyroid disorders NEC	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 1	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Thyroid mass	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Grade 1	0	1 (4.2%)	1 (1.8%)	1 (1.5%)
Reproductive system and breast disorders	1 (3.2%)	0	1 (1.8%)	3 (4.5%)
Grade 1	0	0	0	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	2 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Reproductive system and breast disorders (cont)				
Prostatic neoplasms and hypertrophy	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Benign prostatic hyperplasia	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 2	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Breast signs and symptoms	0	0	0	0
Grade 1	0	0	0	0
Breast pain	0	0	0	0
Grade 1	0	0	0	0
Scrotal disorders NEC	0	0	0	0
Grade 2	0	0	0	0
Scrotal pain	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Reproductive system and breast disorders (cont)				
Prostatic neoplasms and hypertrophy	0	0	0	1 (1.5%)
Grade 2	0	0	0	1 (1.5%)
Benign prostatic hyperplasia	0	0	0	1 (1.5%)
Grade 2	0	0	0	1 (1.5%)
Breast signs and symptoms	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)
Breast pain	0	0	0	1 (1.5%)
Grade 1	0	0	0	1 (1.5%)
Scrotal disorders NEC	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Scrotal pain	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Reproductive system and breast disorders (cont)				
Scrotal disorders NEC (cont)				
Scrotal pain (cont)				
Grade 2	0	0	0	0
Immune system disorders	1 (8.3%)	1 (16.7%)	2 (11.1%)	2 (6.7%)
Grade 1	1 (8.3%)	1 (16.7%)	2 (11.1%)	2 (6.7%)
Allergic conditions NEC	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Allergic oedema	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Grade 1	1 (8.3%)	0	1 (5.6%)	1 (3.3%)
Allergies to foods, food additives, drugs and other chemicals	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 1	0	1 (16.7%)	1 (5.6%)	1 (3.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Reproductive system and breast disorders (cont)				
Scrotal disorders NEC (cont)				
Scrotal pain (cont)				
Grade 2	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Immune system disorders	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Allergic conditions NEC	0	0	0	0
Grade 1	0	0	0	0
Allergic oedema	0	0	0	0
Grade 1	0	0	0	0
Allergies to foods, food additives, drugs and other chemicals	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	<65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 Onward) Total (N=18)	Overall Exposed to MMB Total (N=30)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	6 (100.0%)	18 (100.0%)	30 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Immune system disorders (cont)				
Allergies to foods, food additives, drugs and other chemicals (cont)				
Drug hypersensitivity	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Grade 1	0	1 (16.7%)	1 (5.6%)	1 (3.3%)
Atopic disorders	0	0	0	0
Grade 1	0	0	0	0
Seasonal allergy	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0404: TEAEs by SOC, HLT, PT and Severity by Age Group
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	>=65 Years			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 Onward) Total (N=55)	Overall Exposed to MMB Total (N=66)
Number of Subjects with Any Treatment-Emergent AE	30 (96.8%)	24 (100.0%)	54 (98.2%)	66 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Immune system disorders (cont)				
Allergies to foods, food additives, drugs and other chemicals (cont)				
Drug hypersensitivity	0	0	0	0
Grade 1	0	0	0	0
Atopic disorders	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Seasonal allergy	1 (3.2%)	0	1 (1.8%)	1 (1.5%)
Grade 1	1 (3.2%)	0	1 (1.8%)	1 (1.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders	16 (66.7%)	6 (66.7%)	22 (66.7%)	3 (25.0%)	3 (50.0%)	6 (33.3%)
Grade 1	7 (29.2%)	1 (11.1%)	8 (24.2%)	3 (25.0%)	1 (16.7%)	4 (22.2%)
Grade 2	8 (33.3%)	3 (33.3%)	11 (33.3%)	0	1 (16.7%)	1 (5.6%)
Grade 3	1 (4.2%)	2 (22.2%)	3 (9.1%)	0	1 (16.7%)	1 (5.6%)
Diarrhoea (excl infective)	8 (33.3%)	1 (11.1%)	9 (27.3%)	2 (16.7%)	2 (33.3%)	4 (22.2%)
Grade 1	4 (16.7%)	1 (11.1%)	5 (15.2%)	2 (16.7%)	0	2 (11.1%)
Grade 2	4 (16.7%)	0	4 (12.1%)	0	1 (16.7%)	1 (5.6%)
Grade 3	0	0	0	0	1 (16.7%)	1 (5.6%)
Diarrhoea	8 (33.3%)	1 (11.1%)	9 (27.3%)	2 (16.7%)	2 (33.3%)	4 (22.2%)
Grade 1	4 (16.7%)	1 (11.1%)	5 (15.2%)	2 (16.7%)	0	2 (11.1%)
Grade 2	4 (16.7%)	0	4 (12.1%)	0	1 (16.7%)	1 (5.6%)
Grade 3	0	0	0	0	1 (16.7%)	1 (5.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders	24 (57.1%)	11 (36.7%)	35 (48.6%)	10 (32.3%)	12 (50.0%)	22 (40.0%)
Grade 1	10 (23.8%)	5 (16.7%)	15 (20.8%)	2 (6.5%)	6 (25.0%)	8 (14.5%)
Grade 2	10 (23.8%)	5 (16.7%)	15 (20.8%)	5 (16.1%)	4 (16.7%)	9 (16.4%)
Grade 3	4 (9.5%)	1 (3.3%)	5 (6.9%)	3 (9.7%)	2 (8.3%)	5 (9.1%)
Diarrhoea (excl infective)	13 (31.0%)	4 (13.3%)	17 (23.6%)	7 (22.6%)	4 (16.7%)	11 (20.0%)
Grade 1	10 (23.8%)	1 (3.3%)	11 (15.3%)	4 (12.9%)	2 (8.3%)	6 (10.9%)
Grade 2	2 (4.8%)	3 (10.0%)	5 (6.9%)	2 (6.5%)	1 (4.2%)	3 (5.5%)
Grade 3	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Diarrhoea	13 (31.0%)	4 (13.3%)	17 (23.6%)	7 (22.6%)	4 (16.7%)	11 (20.0%)
Grade 1	10 (23.8%)	1 (3.3%)	11 (15.3%)	4 (12.9%)	2 (8.3%)	6 (10.9%)
Grade 2	2 (4.8%)	3 (10.0%)	5 (6.9%)	2 (6.5%)	1 (4.2%)	3 (5.5%)
Grade 3	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	1 (4.2%)	2 (3.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal and abdominal pains (excl oral and throat)	8 (33.3%)	4 (44.4%)	12 (36.4%)	0	0	0
Grade 1	5 (20.8%)	0	5 (15.2%)	0	0	0
Grade 2	2 (8.3%)	2 (22.2%)	4 (12.1%)	0	0	0
Grade 3	1 (4.2%)	2 (22.2%)	3 (9.1%)	0	0	0
Abdominal pain	7 (29.2%)	3 (33.3%)	10 (30.3%)	0	0	0
Grade 1	4 (16.7%)	0	4 (12.1%)	0	0	0
Grade 2	2 (8.3%)	1 (11.1%)	3 (9.1%)	0	0	0
Grade 3	1 (4.2%)	2 (22.2%)	3 (9.1%)	0	0	0
Abdominal pain upper	1 (4.2%)	1 (11.1%)	2 (6.1%)	0	0	0
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 2	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal and abdominal pains (excl oral and throat)	8 (19.0%)	3 (10.0%)	11 (15.3%)	3 (9.7%)	4 (16.7%)	7 (12.7%)
Grade 1	2 (4.8%)	1 (3.3%)	3 (4.2%)	0	3 (12.5%)	3 (5.5%)
Grade 2	5 (11.9%)	1 (3.3%)	6 (8.3%)	2 (6.5%)	1 (4.2%)	3 (5.5%)
Grade 3	1 (2.4%)	1 (3.3%)	2 (2.8%)	1 (3.2%)	0	1 (1.8%)
Abdominal pain	3 (7.1%)	2 (6.7%)	5 (6.9%)	3 (9.7%)	1 (4.2%)	4 (7.3%)
Grade 1	1 (2.4%)	1 (3.3%)	2 (2.8%)	0	0	0
Grade 2	2 (4.8%)	0	2 (2.8%)	2 (6.5%)	1 (4.2%)	3 (5.5%)
Grade 3	0	1 (3.3%)	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Abdominal pain upper	4 (9.5%)	0	4 (5.6%)	0	3 (12.5%)	3 (5.5%)
Grade 1	0	0	0	0	3 (12.5%)	3 (5.5%)
Grade 2	3 (7.1%)	0	3 (4.2%)	0	0	0
Grade 3	1 (2.4%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal and abdominal pains (excl oral and throat) (cont)						
Abdominal pain lower	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Abdominal tenderness	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Nausea and vomiting symptoms	4 (16.7%)	3 (33.3%)	7 (21.2%)	2 (16.7%)	2 (33.3%)	4 (22.2%)
Grade 1	3 (12.5%)	2 (22.2%)	5 (15.2%)	2 (16.7%)	1 (16.7%)	3 (16.7%)
Grade 2	1 (4.2%)	0	1 (3.0%)	0	1 (16.7%)	1 (5.6%)
Grade 3	0	1 (11.1%)	1 (3.0%)	0	0	0
Nausea	4 (16.7%)	2 (22.2%)	6 (18.2%)	2 (16.7%)	2 (33.3%)	4 (22.2%)
Grade 1	3 (12.5%)	1 (11.1%)	4 (12.1%)	2 (16.7%)	1 (16.7%)	3 (16.7%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal and abdominal pains (excl oral and throat) (cont)						
Abdominal pain lower	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Abdominal tenderness	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 2	0	1 (3.3%)	1 (1.4%)	0	0	0
Nausea and vomiting symptoms	8 (19.0%)	1 (3.3%)	9 (12.5%)	3 (9.7%)	2 (8.3%)	5 (9.1%)
Grade 1	8 (19.0%)	1 (3.3%)	9 (12.5%)	3 (9.7%)	0	3 (5.5%)
Grade 2	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 3	0	0	0	0	1 (4.2%)	1 (1.8%)
Nausea	8 (19.0%)	1 (3.3%)	9 (12.5%)	3 (9.7%)	1 (4.2%)	4 (7.3%)
Grade 1	8 (19.0%)	1 (3.3%)	9 (12.5%)	3 (9.7%)	0	3 (5.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Nausea and vomiting symptoms (cont)						
Nausea (cont)						
Grade 2	1 (4.2%)	0	1 (3.0%)	0	1 (16.7%)	1 (5.6%)
Grade 3	0	1 (11.1%)	1 (3.0%)	0	0	0
Vomiting	2 (8.3%)	1 (11.1%)	3 (9.1%)	1 (8.3%)	1 (16.7%)	2 (11.1%)
Grade 1	2 (8.3%)	1 (11.1%)	3 (9.1%)	1 (8.3%)	1 (16.7%)	2 (11.1%)
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Gastrointestinal atonic and hypomotility disorders NEC	5 (20.8%)	2 (22.2%)	7 (21.2%)	1 (8.3%)	0	1 (5.6%)
Grade 1	3 (12.5%)	2 (22.2%)	5 (15.2%)	1 (8.3%)	0	1 (5.6%)
Grade 2	2 (8.3%)	0	2 (6.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Nausea and vomiting symptoms (cont)						
Nausea (cont)						
Grade 2	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 3	0	0	0	0	0	0
Vomiting	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	2 (8.3%)	3 (5.5%)
Grade 1	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Grade 2	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 3	0	0	0	0	1 (4.2%)	1 (1.8%)
Gastrointestinal atonic and hypomotility disorders NEC	5 (11.9%)	1 (3.3%)	6 (8.3%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 1	5 (11.9%)	1 (3.3%)	6 (8.3%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal atonic and hypomotility disorders NEC (cont)						
Constipation	1 (4.2%)	2 (22.2%)	3 (9.1%)	1 (8.3%)	0	1 (5.6%)
Grade 1	1 (4.2%)	2 (22.2%)	3 (9.1%)	1 (8.3%)	0	1 (5.6%)
Gastrooesophageal reflux disease	4 (16.7%)	0	4 (12.1%)	0	0	0
Grade 1	2 (8.3%)	0	2 (6.1%)	0	0	0
Grade 2	2 (8.3%)	0	2 (6.1%)	0	0	0
Impaired gastric emptying	0	0	0	1 (8.3%)	0	1 (5.6%)
Grade 1	0	0	0	1 (8.3%)	0	1 (5.6%)
Dyspeptic signs and symptoms	2 (8.3%)	0	2 (6.1%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	2 (8.3%)	0	2 (6.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal atonic and hypomotility disorders NEC (cont)						
Constipation	5 (11.9%)	0	5 (6.9%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 1	5 (11.9%)	0	5 (6.9%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Gastrooesophageal reflux disease	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 1	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 2	0	0	0	0	0	0
Impaired gastric emptying	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dyspeptic signs and symptoms	6 (14.3%)	0	6 (8.3%)	0	0	0
Grade 1	4 (9.5%)	0	4 (5.6%)	0	0	0
Grade 2	2 (4.8%)	0	2 (2.8%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Dyspeptic signs and symptoms (cont)						
Dyspepsia	2 (8.3%)	0	2 (6.1%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	2 (8.3%)	0	2 (6.1%)	0	0	0
Epigastric discomfort	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Non-site specific gastrointestinal haemorrhages	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Gastrointestinal haemorrhage	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Dyspeptic signs and symptoms (cont)						
Dyspepsia	5 (11.9%)	0	5 (6.9%)	0	0	0
Grade 1	3 (7.1%)	0	3 (4.2%)	0	0	0
Grade 2	2 (4.8%)	0	2 (2.8%)	0	0	0
Epigastric discomfort	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Non-site specific gastrointestinal haemorrhages	3 (7.1%)	2 (6.7%)	5 (6.9%)	2 (6.5%)	3 (12.5%)	5 (9.1%)
Grade 1	0	1 (3.3%)	1 (1.4%)	0	2 (8.3%)	2 (3.6%)
Grade 2	0	1 (3.3%)	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Grade 3	3 (7.1%)	0	3 (4.2%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Gastrointestinal haemorrhage	2 (4.8%)	0	2 (2.8%)	2 (6.5%)	1 (4.2%)	3 (5.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Non-site specific gastrointestinal haemorrhages (cont)						
Gastrointestinal haemorrhage (cont)						
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Haematemesis	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Upper gastrointestinal haemorrhage	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Melaena	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Non-site specific gastrointestinal haemorrhages (cont)						
Gastrointestinal haemorrhage (cont)						
Grade 2	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Grade 3	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Haematemesis	2 (4.8%)	0	2 (2.8%)	0	0	0
Grade 3	2 (4.8%)	0	2 (2.8%)	0	0	0
Upper gastrointestinal haemorrhage	2 (4.8%)	1 (3.3%)	3 (4.2%)	0	0	0
Grade 2	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 3	2 (4.8%)	0	2 (2.8%)	0	0	0
Melaena	1 (2.4%)	1 (3.3%)	2 (2.8%)	0	2 (8.3%)	2 (3.6%)
Grade 1	0	1 (3.3%)	1 (1.4%)	0	2 (8.3%)	2 (3.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Non-site specific gastrointestinal haemorrhages (cont)						
Melaena (cont)						
Grade 3	0	0	0	0	0	0
Peritoneal and retroperitoneal disorders	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Ascites	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Non-site specific gastrointestinal haemorrhages (cont)						
Melaena (cont)						
Grade 3	1 (2.4%)	0	1 (1.4%)	0	0	0
Peritoneal and retroperitoneal disorders	3 (7.1%)	1 (3.3%)	4 (5.6%)	1 (3.2%)	2 (8.3%)	3 (5.5%)
Grade 1	2 (4.8%)	0	2 (2.8%)	0	0	0
Grade 2	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	2 (8.3%)	3 (5.5%)
Grade 3	0	1 (3.3%)	1 (1.4%)	0	0	0
Ascites	3 (7.1%)	1 (3.3%)	4 (5.6%)	1 (3.2%)	2 (8.3%)	3 (5.5%)
Grade 1	2 (4.8%)	0	2 (2.8%)	0	0	0
Grade 2	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	2 (8.3%)	3 (5.5%)
Grade 3	0	1 (3.3%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Flatulence, bloating and distension	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 2	0	0	0	0	0	0
Flatulence	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Abdominal distension	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 2	0	0	0	0	0	0
Gastrointestinal spastic and hypermotility disorders	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Flatulence, bloating and distension	2 (4.8%)	0	2 (2.8%)	1 (3.2%)	0	1 (1.8%)
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 2	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Flatulence	2 (4.8%)	0	2 (2.8%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0
Abdominal distension	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	1 (3.2%)	0	1 (1.8%)
Gastrointestinal spastic and hypermotility disorders	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal spastic and hypermotility disorders (cont)						
Defaecation urgency	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Frequent bowel movements	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Anal and rectal signs and symptoms	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Anorectal discomfort	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dental pain and sensation disorders	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal spastic and hypermotility disorders (cont)						
Defaecation urgency	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Frequent bowel movements	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Anal and rectal signs and symptoms	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Anorectal discomfort	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Dental pain and sensation disorders	1 (2.4%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Dental pain and sensation disorders (cont)						
(cont)						
Grade 2	0	0	0	0	0	0
Toothache	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Gastric and oesophageal haemorrhages	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Oesophageal haemorrhage	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Gastric ulcers and perforation	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Dental pain and sensation disorders (cont)						
(cont)						
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0
Toothache	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0
Gastric and oesophageal haemorrhages	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0
Oesophageal haemorrhage	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0
Gastric ulcers and perforation	1 (2.4%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastric ulcers and perforation (cont) (cont)						
Grade 3	0	0	0	0	0	0
Gastric ulcer	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Gastritis (excl infective)	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Gastritis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Gastrointestinal mucosal dystrophies and secretion disorders	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastric ulcers and perforation (cont) (cont)						
Grade 3	1 (2.4%)	0	1 (1.4%)	0	0	0
Gastric ulcer	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 3	1 (2.4%)	0	1 (1.4%)	0	0	0
Gastritis (excl infective)	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Gastritis	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Gastrointestinal mucosal dystrophies and secretion disorders	1 (2.4%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal mucosal dystrophies and secretion disorders (cont) (cont)						
Grade 1	0	0	0	0	0	0
Gastrointestinal melanosis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Gastrointestinal signs and symptoms NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Abdominal discomfort	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dysphagia	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal mucosal dystrophies and secretion disorders (cont) (cont)						
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Gastrointestinal melanosis	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Gastrointestinal signs and symptoms NEC	1 (2.4%)	0	1 (1.4%)	0	2 (8.3%)	2 (3.6%)
Grade 1	1 (2.4%)	0	1 (1.4%)	0	2 (8.3%)	2 (3.6%)
Abdominal discomfort	1 (2.4%)	0	1 (1.4%)	0	1 (4.2%)	1 (1.8%)
Grade 1	1 (2.4%)	0	1 (1.4%)	0	1 (4.2%)	1 (1.8%)
Dysphagia	0	0	0	0	1 (4.2%)	1 (1.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal signs and symptoms NEC (cont)						
Dysphagia (cont)						
Grade 1	0	0	0	0	0	0
Intestinal haemorrhages	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Anal haemorrhage	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Stomatitis and ulceration	0	0	0	0	1 (16.7%)	1 (5.6%)
Grade 1	0	0	0	0	1 (16.7%)	1 (5.6%)
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal signs and symptoms NEC (cont)						
Dysphagia (cont)						
Grade 1	0	0	0	0	1 (4.2%)	1 (1.8%)
Intestinal haemorrhages	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Anal haemorrhage	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Stomatitis and ulceration	1 (2.4%)	1 (3.3%)	2 (2.8%)	1 (3.2%)	0	1 (1.8%)
Grade 1	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Grade 2	0	1 (3.3%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Stomatitis and ulceration (cont)						
Mouth ulceration	0	0	0	0	1 (16.7%)	1 (5.6%)
Grade 1	0	0	0	0	1 (16.7%)	1 (5.6%)
Palatal ulcer	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Stomatitis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Anal and rectal disorders NEC	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Anal fissure	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Stomatitis and ulceration (cont)						
Mouth ulceration	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Palatal ulcer	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 1	0	0	0	1 (3.2%)	0	1 (1.8%)
Stomatitis	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 2	0	1 (3.3%)	1 (1.4%)	0	0	0
Anal and rectal disorders NEC	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 2	0	0	0	0	1 (4.2%)	1 (1.8%)
Anal fissure	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 2	0	0	0	0	1 (4.2%)	1 (1.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Dental and periodontal infections and inflammations	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Dental caries	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Oesophageal varices	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Varices oesophageal	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Oral dryness and saliva altered	0	1 (11.1%)	1 (3.0%)	0	1 (16.7%)	1 (5.6%)
Grade 1	0	0	0	0	1 (16.7%)	1 (5.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Dental and periodontal infections and inflammations	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 2	0	1 (3.3%)	1 (1.4%)	0	0	0
Dental caries	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 2	0	1 (3.3%)	1 (1.4%)	0	0	0
Oesophageal varices	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 2	0	0	0	0	1 (4.2%)	1 (1.8%)
Varices oesophageal	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 2	0	0	0	0	1 (4.2%)	1 (1.8%)
Oral dryness and saliva altered	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Oral dryness and saliva altered (cont) (cont)						
Grade 2	0	1 (11.1%)	1 (3.0%)	0	0	0
Dry mouth	0	1 (11.1%)	1 (3.0%)	0	1 (16.7%)	1 (5.6%)
Grade 1	0	0	0	0	1 (16.7%)	1 (5.6%)
Grade 2	0	1 (11.1%)	1 (3.0%)	0	0	0
Oral soft tissue pain and paraesthesia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Odynophagia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Umbilical hernias	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Oral dryness and saliva altered (cont)						
(cont)						
Grade 2	0	0	0	0	1 (4.2%)	1 (1.8%)
Dry mouth	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (4.2%)	1 (1.8%)
Oral soft tissue pain and paraesthesia	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 1	0	1 (3.3%)	1 (1.4%)	0	0	0
Odynophagia	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 1	0	1 (3.3%)	1 (1.4%)	0	0	0
Umbilical hernias	0	0	0	1 (3.2%)	0	1 (1.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Umbilical hernias (cont)						
(cont)						
Grade 1	0	0	0	0	0	0
Umbilical hernia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Infections and infestations	12 (50.0%)	3 (33.3%)	15 (45.5%)	2 (16.7%)	2 (33.3%)	4 (22.2%)
Grade 1	5 (20.8%)	1 (11.1%)	6 (18.2%)	0	1 (16.7%)	1 (5.6%)
Grade 2	1 (4.2%)	1 (11.1%)	2 (6.1%)	2 (16.7%)	1 (16.7%)	3 (16.7%)
Grade 3	4 (16.7%)	0	4 (12.1%)	0	0	0
Grade 4	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 5	1 (4.2%)	1 (11.1%)	2 (6.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Umbilical hernias (cont)						
(cont)						
Grade 1	0	0	0	1 (3.2%)	0	1 (1.8%)
Umbilical hernia	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 1	0	0	0	1 (3.2%)	0	1 (1.8%)
Infections and infestations	22 (52.4%)	13 (43.3%)	35 (48.6%)	16 (51.6%)	12 (50.0%)	28 (50.9%)
Grade 1	5 (11.9%)	2 (6.7%)	7 (9.7%)	2 (6.5%)	4 (16.7%)	6 (10.9%)
Grade 2	14 (33.3%)	8 (26.7%)	22 (30.6%)	10 (32.3%)	6 (25.0%)	16 (29.1%)
Grade 3	2 (4.8%)	2 (6.7%)	4 (5.6%)	2 (6.5%)	1 (4.2%)	3 (5.5%)
Grade 4	1 (2.4%)	0	1 (1.4%)	2 (6.5%)	1 (4.2%)	3 (5.5%)
Grade 5	0	1 (3.3%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Upper respiratory tract infections	4 (16.7%)	1 (11.1%)	5 (15.2%)	2 (16.7%)	1 (16.7%)	3 (16.7%)
Grade 1	3 (12.5%)	1 (11.1%)	4 (12.1%)	1 (8.3%)	1 (16.7%)	2 (11.1%)
Grade 2	0	0	0	1 (8.3%)	0	1 (5.6%)
Grade 4	1 (4.2%)	0	1 (3.0%)	0	0	0
Upper respiratory tract infection	3 (12.5%)	0	3 (9.1%)	0	0	0
Grade 1	2 (8.3%)	0	2 (6.1%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 4	1 (4.2%)	0	1 (3.0%)	0	0	0
Nasopharyngitis	1 (4.2%)	1 (11.1%)	2 (6.1%)	1 (8.3%)	1 (16.7%)	2 (11.1%)
Grade 1	1 (4.2%)	1 (11.1%)	2 (6.1%)	1 (8.3%)	1 (16.7%)	2 (11.1%)
Grade 2	0	0	0	0	0	0
Sinusitis	0	0	0	1 (8.3%)	0	1 (5.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Upper respiratory tract infections	7 (16.7%)	4 (13.3%)	11 (15.3%)	6 (19.4%)	4 (16.7%)	10 (18.2%)
Grade 1	2 (4.8%)	2 (6.7%)	4 (5.6%)	1 (3.2%)	3 (12.5%)	4 (7.3%)
Grade 2	5 (11.9%)	2 (6.7%)	7 (9.7%)	5 (16.1%)	1 (4.2%)	6 (10.9%)
Grade 4	0	0	0	0	0	0
Upper respiratory tract infection	4 (9.5%)	3 (10.0%)	7 (9.7%)	3 (9.7%)	3 (12.5%)	6 (10.9%)
Grade 1	1 (2.4%)	1 (3.3%)	2 (2.8%)	1 (3.2%)	2 (8.3%)	3 (5.5%)
Grade 2	3 (7.1%)	2 (6.7%)	5 (6.9%)	2 (6.5%)	1 (4.2%)	3 (5.5%)
Grade 4	0	0	0	0	0	0
Nasopharyngitis	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 1	1 (2.4%)	0	1 (1.4%)	0	1 (4.2%)	1 (1.8%)
Grade 2	0	0	0	1 (3.2%)	0	1 (1.8%)
Sinusitis	2 (4.8%)	0	2 (2.8%)	2 (6.5%)	0	2 (3.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Upper respiratory tract infections (cont)						
Sinusitis (cont)						
Grade 2	0	0	0	1 (8.3%)	0	1 (5.6%)
Rhinitis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Urinary tract infections	1 (4.2%)	1 (11.1%)	2 (6.1%)	0	0	0
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	1 (4.2%)	0	1 (3.0%)	0	0	0
Urinary tract infection	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Upper respiratory tract infections (cont)						
Sinusitis (cont)						
Grade 2	2 (4.8%)	0	2 (2.8%)	2 (6.5%)	0	2 (3.6%)
Rhinitis	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 1	0	1 (3.3%)	1 (1.4%)	0	0	0
Urinary tract infections	7 (16.7%)	3 (10.0%)	10 (13.9%)	4 (12.9%)	3 (12.5%)	7 (12.7%)
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 2	5 (11.9%)	3 (10.0%)	8 (11.1%)	3 (9.7%)	3 (12.5%)	6 (10.9%)
Grade 3	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Urinary tract infection	5 (11.9%)	3 (10.0%)	8 (11.1%)	3 (9.7%)	3 (12.5%)	6 (10.9%)
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Urinary tract infections (cont)						
Urinary tract infection (cont)						
Grade 2	0	0	0	0	0	0
Grade 3	1 (4.2%)	0	1 (3.0%)	0	0	0
Cystitis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Kidney infection	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Urinary tract infections (cont)						
Urinary tract infection (cont)						
Grade 2	3 (7.1%)	3 (10.0%)	6 (8.3%)	2 (6.5%)	3 (12.5%)	5 (9.1%)
Grade 3	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Cystitis	2 (4.8%)	0	2 (2.8%)	1 (3.2%)	0	1 (1.8%)
Grade 2	2 (4.8%)	0	2 (2.8%)	1 (3.2%)	0	1 (1.8%)
Kidney infection	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Lower respiratory tract and lung infections	2 (8.3%)	1 (11.1%)	3 (9.1%)	0	1 (16.7%)	1 (5.6%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (16.7%)	1 (5.6%)
Grade 3	1 (4.2%)	1 (11.1%)	2 (6.1%)	0	0	0
Grade 4	1 (4.2%)	0	1 (3.0%)	0	0	0
Pneumonia	2 (8.3%)	0	2 (6.1%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 4	1 (4.2%)	0	1 (3.0%)	0	0	0
Bronchitis	0	0	0	0	1 (16.7%)	1 (5.6%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (16.7%)	1 (5.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Lower respiratory tract and lung infections	5 (11.9%)	2 (6.7%)	7 (9.7%)	7 (22.6%)	2 (8.3%)	9 (16.4%)
Grade 1	0	0	0	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 2	5 (11.9%)	1 (3.3%)	6 (8.3%)	3 (9.7%)	0	3 (5.5%)
Grade 3	0	1 (3.3%)	1 (1.4%)	3 (9.7%)	1 (4.2%)	4 (7.3%)
Grade 4	0	0	0	0	0	0
Pneumonia	1 (2.4%)	1 (3.3%)	2 (2.8%)	4 (12.9%)	1 (4.2%)	5 (9.1%)
Grade 2	1 (2.4%)	0	1 (1.4%)	2 (6.5%)	0	2 (3.6%)
Grade 3	0	1 (3.3%)	1 (1.4%)	2 (6.5%)	1 (4.2%)	3 (5.5%)
Grade 4	0	0	0	0	0	0
Bronchitis	2 (4.8%)	0	2 (2.8%)	3 (9.7%)	1 (4.2%)	4 (7.3%)
Grade 1	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 2	2 (4.8%)	0	2 (2.8%)	3 (9.7%)	0	3 (5.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Lower respiratory tract and lung infections (cont)						
Lung infection	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Atypical pneumonia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Lower respiratory tract infection	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	1 (11.1%)	1 (3.0%)	0	0	0
Herpes viral infections	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Lower respiratory tract and lung infections (cont)						
Lung infection	2 (4.8%)	0	2 (2.8%)	1 (3.2%)	0	1 (1.8%)
Grade 2	2 (4.8%)	0	2 (2.8%)	0	0	0
Grade 3	0	0	0	1 (3.2%)	0	1 (1.8%)
Atypical pneumonia	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 1	0	0	0	1 (3.2%)	0	1 (1.8%)
Lower respiratory tract infection	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 2	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 3	0	0	0	0	0	0
Herpes viral infections	4 (9.5%)	1 (3.3%)	5 (6.9%)	1 (3.2%)	2 (8.3%)	3 (5.5%)
Grade 1	2 (4.8%)	0	2 (2.8%)	1 (3.2%)	0	1 (1.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Herpes viral infections (cont)						
(cont)						
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Oral herpes	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 2	0	0	0	0	0	0
Herpes zoster	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Herpes viral infections (cont)						
(cont)						
Grade 2	1 (2.4%)	0	1 (1.4%)	0	2 (8.3%)	2 (3.6%)
Grade 3	1 (2.4%)	1 (3.3%)	2 (2.8%)	0	0	0
Oral herpes	3 (7.1%)	0	3 (4.2%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 1	2 (4.8%)	0	2 (2.8%)	1 (3.2%)	0	1 (1.8%)
Grade 2	1 (2.4%)	0	1 (1.4%)	0	1 (4.2%)	1 (1.8%)
Herpes zoster	1 (2.4%)	1 (3.3%)	2 (2.8%)	0	1 (4.2%)	1 (1.8%)
Grade 2	1 (2.4%)	0	1 (1.4%)	0	1 (4.2%)	1 (1.8%)
Grade 3	0	1 (3.3%)	1 (1.4%)	0	0	0
Ophthalmic herpes zoster	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 3	1 (2.4%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Herpes viral infections (cont)						
Herpes simplex	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Bacterial infections NEC	2 (8.3%)	0	2 (6.1%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 5	1 (4.2%)	0	1 (3.0%)	0	0	0
Bacterial sepsis	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 5	1 (4.2%)	0	1 (3.0%)	0	0	0
Cellulitis	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Herpes viral infections (cont)						
Herpes simplex	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 2	0	0	0	0	1 (4.2%)	1 (1.8%)
Bacterial infections NEC	2 (4.8%)	0	2 (2.8%)	3 (9.7%)	0	3 (5.5%)
Grade 2	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Grade 3	1 (2.4%)	0	1 (1.4%)	2 (6.5%)	0	2 (3.6%)
Grade 5	0	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Cellulitis	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Grade 3	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	0	1 (1.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Bacterial infections NEC (cont)						
Peritonitis bacterial	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 3	1 (4.2%)	0	1 (3.0%)	0	0	0
Propionibacterium infection	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Citrobacter infection	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Urinary tract infection bacterial	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Candida infections	2 (8.3%)	0	2 (6.1%)	0	0	0
Grade 1	2 (8.3%)	0	2 (6.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Bacterial infections NEC (cont)						
Peritonitis bacterial	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Propionibacterium infection	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0
Citrobacter infection	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 3	0	0	0	1 (3.2%)	0	1 (1.8%)
Urinary tract infection bacterial	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 2	0	0	0	1 (3.2%)	0	1 (1.8%)
Candida infections	1 (2.4%)	1 (3.3%)	2 (2.8%)	0	1 (4.2%)	1 (1.8%)
Grade 1	0	1 (3.3%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Candida infections (cont)						
(cont)						
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Oral candidiasis	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Oropharyngeal candidiasis	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Candida infections (cont)						
(cont)						
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 3	0	0	0	0	1 (4.2%)	1 (1.8%)
Oral candidiasis	1 (2.4%)	1 (3.3%)	2 (2.8%)	0	1 (4.2%)	1 (1.8%)
Grade 1	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 3	0	0	0	0	1 (4.2%)	1 (1.8%)
Oropharyngeal candidiasis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Sepsis, bacteraemia, viraemia and fungaemia NEC	2 (8.3%)	1 (11.1%)	3 (9.1%)	0	0	0
Grade 3	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 4	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 5	0	1 (11.1%)	1 (3.0%)	0	0	0
Sepsis	2 (8.3%)	1 (11.1%)	3 (9.1%)	0	0	0
Grade 3	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 4	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 5	0	1 (11.1%)	1 (3.0%)	0	0	0
Urosepsis	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Sepsis, bacteraemia, viraemia and fungaemia NEC	1 (2.4%)	1 (3.3%)	2 (2.8%)	2 (6.5%)	1 (4.2%)	3 (5.5%)
Grade 3	0	0	0	0	0	0
Grade 4	1 (2.4%)	0	1 (1.4%)	2 (6.5%)	1 (4.2%)	3 (5.5%)
Grade 5	0	1 (3.3%)	1 (1.4%)	0	0	0
Sepsis	1 (2.4%)	1 (3.3%)	2 (2.8%)	2 (6.5%)	1 (4.2%)	3 (5.5%)
Grade 3	0	0	0	0	0	0
Grade 4	1 (2.4%)	0	1 (1.4%)	2 (6.5%)	1 (4.2%)	3 (5.5%)
Grade 5	0	1 (3.3%)	1 (1.4%)	0	0	0
Urosepsis	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 3	0	0	0	0	1 (4.2%)	1 (1.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Skin structures and soft tissue infections	2 (8.3%)	0	2 (6.1%)	0	0	0
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 2	1 (4.2%)	0	1 (3.0%)	0	0	0
Folliculitis	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Skin infection	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 2	1 (4.2%)	0	1 (3.0%)	0	0	0
Rash pustular	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Skin structures and soft tissue infections	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (3.3%)	1 (1.4%)	0	0	0
Folliculitis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Skin infection	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Rash pustular	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 2	0	1 (3.3%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Abdominal and gastrointestinal infections	1 (4.2%)	1 (11.1%)	2 (6.1%)	0	0	0
Grade 2	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 3	1 (4.2%)	0	1 (3.0%)	0	0	0
Diverticulitis	1 (4.2%)	1 (11.1%)	2 (6.1%)	0	0	0
Grade 2	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 3	1 (4.2%)	0	1 (3.0%)	0	0	0
Gastroenteritis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Enterococcal infections	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Abdominal and gastrointestinal infections	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 2	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 3	0	0	0	0	0	0
Diverticulitis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Gastroenteritis	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 2	0	1 (3.3%)	1 (1.4%)	0	0	0
Enterococcal infections	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Enterococcal infections (cont)						
Urinary tract infection enterococcal	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Escherichia infections	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Escherichia urinary tract infection	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Eye and eyelid infections	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Enterococcal infections (cont)						
Urinary tract infection enterococcal	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0
Escherichia infections	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Grade 2	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 3	1 (2.4%)	0	1 (1.4%)	0	0	0
Escherichia urinary tract infection	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Grade 2	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 3	1 (2.4%)	0	1 (1.4%)	0	0	0
Eye and eyelid infections	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Eye and eyelid infections (cont)						
Conjunctivitis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Infections NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Localised infection	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Eye and eyelid infections (cont)						
Conjunctivitis	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0
Infections NEC	1 (2.4%)	2 (6.7%)	3 (4.2%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 2	0	2 (6.7%)	2 (2.8%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Respiratory tract infection	1 (2.4%)	2 (6.7%)	3 (4.2%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 2	0	2 (6.7%)	2 (2.8%)	0	0	0
Localised infection	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 2	0	0	0	0	1 (4.2%)	1 (1.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Infections NEC (cont)						
Wound infection	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Influenza viral infections	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 2	0	0	0	0	0	0
Influenza	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 2	0	0	0	0	0	0
Staphylococcal infections	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Infections NEC (cont)						
Wound infection	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 2	0	0	0	1 (3.2%)	0	1 (1.8%)
Influenza viral infections	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (4.2%)	1 (1.8%)
Influenza	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (4.2%)	1 (1.8%)
Staphylococcal infections	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Staphylococcal infections (cont)						
Staphylococcal infection	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Streptococcal infections	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Erysipelas	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Clostridia infections	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Staphylococcal infections (cont)						
Staphylococcal infection	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0
Streptococcal infections	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0
Erysipelas	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0
Clostridia infections	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 3	0	0	0	1 (3.2%)	0	1 (1.8%)
Clostridium difficile infection	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 3	0	0	0	1 (3.2%)	0	1 (1.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Dental and oral soft tissue infections	0	0	0	1 (8.3%)	0	1 (5.6%)
Grade 2	0	0	0	1 (8.3%)	0	1 (5.6%)
Dental fistula	0	0	0	1 (8.3%)	0	1 (5.6%)
Grade 2	0	0	0	1 (8.3%)	0	1 (5.6%)
Viral infections NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Viral rash	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Dental and oral soft tissue infections	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Dental fistula	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Viral infections NEC	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 1	0	0	0	0	1 (4.2%)	1 (1.8%)
Viral rash	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 1	0	0	0	0	1 (4.2%)	1 (1.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions	11 (45.8%)	3 (33.3%)	14 (42.4%)	1 (8.3%)	3 (50.0%)	4 (22.2%)
Grade 1	4 (16.7%)	0	4 (12.1%)	1 (8.3%)	0	1 (5.6%)
Grade 2	5 (20.8%)	3 (33.3%)	8 (24.2%)	0	2 (33.3%)	2 (11.1%)
Grade 3	2 (8.3%)	0	2 (6.1%)	0	1 (16.7%)	1 (5.6%)
Asthenic conditions	8 (33.3%)	3 (33.3%)	11 (33.3%)	0	3 (50.0%)	3 (16.7%)
Grade 1	2 (8.3%)	0	2 (6.1%)	0	1 (16.7%)	1 (5.6%)
Grade 2	5 (20.8%)	3 (33.3%)	8 (24.2%)	0	1 (16.7%)	1 (5.6%)
Grade 3	1 (4.2%)	0	1 (3.0%)	0	1 (16.7%)	1 (5.6%)
Asthenia	6 (25.0%)	2 (22.2%)	8 (24.2%)	0	2 (33.3%)	2 (11.1%)
Grade 1	1 (4.2%)	0	1 (3.0%)	0	1 (16.7%)	1 (5.6%)
Grade 2	4 (16.7%)	2 (22.2%)	6 (18.2%)	0	0	0
Grade 3	1 (4.2%)	0	1 (3.0%)	0	1 (16.7%)	1 (5.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions	22 (52.4%)	17 (56.7%)	39 (54.2%)	12 (38.7%)	12 (50.0%)	24 (43.6%)
Grade 1	6 (14.3%)	5 (16.7%)	11 (15.3%)	6 (19.4%)	4 (16.7%)	10 (18.2%)
Grade 2	10 (23.8%)	11 (36.7%)	21 (29.2%)	4 (12.9%)	5 (20.8%)	9 (16.4%)
Grade 3	6 (14.3%)	1 (3.3%)	7 (9.7%)	2 (6.5%)	3 (12.5%)	5 (9.1%)
Asthenic conditions	14 (33.3%)	11 (36.7%)	25 (34.7%)	4 (12.9%)	7 (29.2%)	11 (20.0%)
Grade 1	5 (11.9%)	2 (6.7%)	7 (9.7%)	1 (3.2%)	2 (8.3%)	3 (5.5%)
Grade 2	6 (14.3%)	8 (26.7%)	14 (19.4%)	2 (6.5%)	3 (12.5%)	5 (9.1%)
Grade 3	3 (7.1%)	1 (3.3%)	4 (5.6%)	1 (3.2%)	2 (8.3%)	3 (5.5%)
Asthenia	7 (16.7%)	6 (20.0%)	13 (18.1%)	3 (9.7%)	6 (25.0%)	9 (16.4%)
Grade 1	2 (4.8%)	0	2 (2.8%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 2	2 (4.8%)	5 (16.7%)	7 (9.7%)	1 (3.2%)	3 (12.5%)	4 (7.3%)
Grade 3	3 (7.1%)	1 (3.3%)	4 (5.6%)	1 (3.2%)	2 (8.3%)	3 (5.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Asthenic conditions (cont)						
Fatigue	2 (8.3%)	2 (22.2%)	4 (12.1%)	0	2 (33.3%)	2 (11.1%)
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 2	1 (4.2%)	2 (22.2%)	3 (9.1%)	0	1 (16.7%)	1 (5.6%)
Grade 3	0	0	0	0	1 (16.7%)	1 (5.6%)
Febrile disorders	3 (12.5%)	0	3 (9.1%)	1 (8.3%)	1 (16.7%)	2 (11.1%)
Grade 1	2 (8.3%)	0	2 (6.1%)	1 (8.3%)	0	1 (5.6%)
Grade 2	0	0	0	0	1 (16.7%)	1 (5.6%)
Grade 3	1 (4.2%)	0	1 (3.0%)	0	0	0
Pyrexia	3 (12.5%)	0	3 (9.1%)	1 (8.3%)	1 (16.7%)	2 (11.1%)
Grade 1	2 (8.3%)	0	2 (6.1%)	1 (8.3%)	0	1 (5.6%)
Grade 2	0	0	0	0	1 (16.7%)	1 (5.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Asthenic conditions (cont)						
Fatigue	8 (19.0%)	5 (16.7%)	13 (18.1%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 1	4 (9.5%)	2 (6.7%)	6 (8.3%)	0	1 (4.2%)	1 (1.8%)
Grade 2	4 (9.5%)	3 (10.0%)	7 (9.7%)	1 (3.2%)	0	1 (1.8%)
Grade 3	0	0	0	0	0	0
Febrile disorders	8 (19.0%)	3 (10.0%)	11 (15.3%)	6 (19.4%)	6 (25.0%)	12 (21.8%)
Grade 1	5 (11.9%)	2 (6.7%)	7 (9.7%)	3 (9.7%)	5 (20.8%)	8 (14.5%)
Grade 2	2 (4.8%)	1 (3.3%)	3 (4.2%)	2 (6.5%)	1 (4.2%)	3 (5.5%)
Grade 3	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Pyrexia	8 (19.0%)	3 (10.0%)	11 (15.3%)	6 (19.4%)	6 (25.0%)	12 (21.8%)
Grade 1	5 (11.9%)	2 (6.7%)	7 (9.7%)	3 (9.7%)	5 (20.8%)	8 (14.5%)
Grade 2	2 (4.8%)	1 (3.3%)	3 (4.2%)	2 (6.5%)	1 (4.2%)	3 (5.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Febrile disorders (cont)						
Pyrexia (cont)						
Grade 3	1 (4.2%)	0	1 (3.0%)	0	0	0
Oedema NEC	4 (16.7%)	1 (11.1%)	5 (15.2%)	0	0	0
Grade 1	2 (8.3%)	1 (11.1%)	3 (9.1%)	0	0	0
Grade 2	2 (8.3%)	0	2 (6.1%)	0	0	0
Grade 3	0	0	0	0	0	0
Oedema peripheral	4 (16.7%)	0	4 (12.1%)	0	0	0
Grade 1	2 (8.3%)	0	2 (6.1%)	0	0	0
Grade 2	2 (8.3%)	0	2 (6.1%)	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Febrile disorders (cont)						
Pyrexia (cont)						
Grade 3	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Oedema NEC	4 (9.5%)	5 (16.7%)	9 (12.5%)	4 (12.9%)	3 (12.5%)	7 (12.7%)
Grade 1	2 (4.8%)	4 (13.3%)	6 (8.3%)	2 (6.5%)	1 (4.2%)	3 (5.5%)
Grade 2	2 (4.8%)	1 (3.3%)	3 (4.2%)	2 (6.5%)	1 (4.2%)	3 (5.5%)
Grade 3	0	0	0	0	1 (4.2%)	1 (1.8%)
Oedema peripheral	4 (9.5%)	5 (16.7%)	9 (12.5%)	4 (12.9%)	3 (12.5%)	7 (12.7%)
Grade 1	2 (4.8%)	4 (13.3%)	6 (8.3%)	2 (6.5%)	1 (4.2%)	3 (5.5%)
Grade 2	2 (4.8%)	1 (3.3%)	3 (4.2%)	2 (6.5%)	1 (4.2%)	3 (5.5%)
Grade 3	0	0	0	0	1 (4.2%)	1 (1.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Oedema NEC (cont)						
Generalised oedema	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0
Feelings and sensations NEC	2 (8.3%)	1 (11.1%)	3 (9.1%)	1 (8.3%)	0	1 (5.6%)
Grade 1	1 (4.2%)	1 (11.1%)	2 (6.1%)	1 (8.3%)	0	1 (5.6%)
Grade 2	1 (4.2%)	0	1 (3.0%)	0	0	0
Early satiety	1 (4.2%)	1 (11.1%)	2 (6.1%)	0	0	0
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 2	1 (4.2%)	0	1 (3.0%)	0	0	0
Chills	0	0	0	1 (8.3%)	0	1 (5.6%)
Grade 1	0	0	0	1 (8.3%)	0	1 (5.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Oedema NEC (cont)						
Generalised oedema	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Feelings and sensations NEC	2 (4.8%)	3 (10.0%)	5 (6.9%)	2 (6.5%)	1 (4.2%)	3 (5.5%)
Grade 1	2 (4.8%)	2 (6.7%)	4 (5.6%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 2	0	1 (3.3%)	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Early satiety	1 (2.4%)	3 (10.0%)	4 (5.6%)	0	1 (4.2%)	1 (1.8%)
Grade 1	1 (2.4%)	2 (6.7%)	3 (4.2%)	0	1 (4.2%)	1 (1.8%)
Grade 2	0	1 (3.3%)	1 (1.4%)	0	0	0
Chills	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Feelings and sensations NEC (cont)						
Chills (cont)						
Grade 2	0	0	0	0	0	0
Feeling hot	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Pain and discomfort NEC	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Chest pain	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Non-cardiac chest pain	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Feelings and sensations NEC (cont)						
Chills (cont)						
Grade 2	0	0	0	1 (3.2%)	0	1 (1.8%)
Feeling hot	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 1	0	0	0	1 (3.2%)	0	1 (1.8%)
Pain and discomfort NEC	3 (7.1%)	0	3 (4.2%)	1 (3.2%)	0	1 (1.8%)
Grade 2	3 (7.1%)	0	3 (4.2%)	1 (3.2%)	0	1 (1.8%)
Chest pain	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Grade 2	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Non-cardiac chest pain	1 (2.4%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Pain and discomfort NEC (cont)						
Non-cardiac chest pain (cont)						
Grade 2	0	0	0	0	0	0
Pain	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Gait disturbances	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 2	0	0	0	0	0	0
Gait disturbance	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Pain and discomfort NEC (cont)						
Non-cardiac chest pain (cont)						
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0
Pain	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0
Gait disturbances	2 (4.8%)	0	2 (2.8%)	1 (3.2%)	0	1 (1.8%)
Grade 1	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 2	2 (4.8%)	0	2 (2.8%)	0	0	0
Gait disturbance	2 (4.8%)	0	2 (2.8%)	1 (3.2%)	0	1 (1.8%)
Grade 1	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 2	2 (4.8%)	0	2 (2.8%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
General signs and symptoms NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Disease progression	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
General physical health deterioration	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Influenza like illness	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
General signs and symptoms NEC	2 (4.8%)	3 (10.0%)	5 (6.9%)	0	0	0
Grade 1	0	2 (6.7%)	2 (2.8%)	0	0	0
Grade 2	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 3	2 (4.8%)	0	2 (2.8%)	0	0	0
Disease progression	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 3	1 (2.4%)	0	1 (1.4%)	0	0	0
General physical health deterioration	1 (2.4%)	1 (3.3%)	2 (2.8%)	0	0	0
Grade 2	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 3	1 (2.4%)	0	1 (1.4%)	0	0	0
Influenza like illness	0	1 (3.3%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
General signs and symptoms NEC (cont)						
Influenza like illness (cont)						
Grade 1	0	0	0	0	0	0
Peripheral swelling	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Injection site reactions	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Injection site pain	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Body temperature altered	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
General signs and symptoms NEC (cont)						
Influenza like illness (cont)						
Grade 1	0	1 (3.3%)	1 (1.4%)	0	0	0
Peripheral swelling	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 1	0	1 (3.3%)	1 (1.4%)	0	0	0
Injection site reactions	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Injection site pain	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Body temperature altered	0	1 (3.3%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Body temperature altered (cont) (cont)						
Grade 1	0	0	0	0	0	0
Temperature regulation disorder	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Nervous system disorders	12 (50.0%)	5 (55.6%)	17 (51.5%)	4 (33.3%)	2 (33.3%)	6 (33.3%)
Grade 1	8 (33.3%)	4 (44.4%)	12 (36.4%)	4 (33.3%)	1 (16.7%)	5 (27.8%)
Grade 2	3 (12.5%)	0	3 (9.1%)	0	0	0
Grade 3	1 (4.2%)	1 (11.1%)	2 (6.1%)	0	1 (16.7%)	1 (5.6%)
Neurological signs and symptoms NEC	4 (16.7%)	2 (22.2%)	6 (18.2%)	2 (16.7%)	0	2 (11.1%)
Grade 1	2 (8.3%)	2 (22.2%)	4 (12.1%)	2 (16.7%)	0	2 (11.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Body temperature altered (cont)						
(cont)						
Grade 1	0	1 (3.3%)	1 (1.4%)	0	0	0
Temperature regulation disorder	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 1	0	1 (3.3%)	1 (1.4%)	0	0	0
Nervous system disorders	20 (47.6%)	3 (10.0%)	23 (31.9%)	7 (22.6%)	12 (50.0%)	19 (34.5%)
Grade 1	14 (33.3%)	1 (3.3%)	15 (20.8%)	5 (16.1%)	9 (37.5%)	14 (25.5%)
Grade 2	5 (11.9%)	2 (6.7%)	7 (9.7%)	0	3 (12.5%)	3 (5.5%)
Grade 3	1 (2.4%)	0	1 (1.4%)	2 (6.5%)	0	2 (3.6%)
Neurological signs and symptoms NEC	10 (23.8%)	1 (3.3%)	11 (15.3%)	4 (12.9%)	2 (8.3%)	6 (10.9%)
Grade 1	8 (19.0%)	1 (3.3%)	9 (12.5%)	2 (6.5%)	2 (8.3%)	4 (7.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Neurological signs and symptoms NEC (cont) (cont)						
Grade 2	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 3	1 (4.2%)	0	1 (3.0%)	0	0	0
Dizziness	4 (16.7%)	2 (22.2%)	6 (18.2%)	2 (16.7%)	0	2 (11.1%)
Grade 1	3 (12.5%)	2 (22.2%)	5 (15.2%)	2 (16.7%)	0	2 (11.1%)
Grade 2	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 3	0	0	0	0	0	0
Presyncope	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	1 (4.2%)	0	1 (3.0%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Neurological signs and symptoms NEC (cont) (cont)						
Grade 2	2 (4.8%)	0	2 (2.8%)	1 (3.2%)	0	1 (1.8%)
Grade 3	0	0	0	1 (3.2%)	0	1 (1.8%)
Dizziness	7 (16.7%)	1 (3.3%)	8 (11.1%)	3 (9.7%)	2 (8.3%)	5 (9.1%)
Grade 1	6 (14.3%)	1 (3.3%)	7 (9.7%)	2 (6.5%)	2 (8.3%)	4 (7.3%)
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 3	0	0	0	1 (3.2%)	0	1 (1.8%)
Presyncope	2 (4.8%)	0	2 (2.8%)	1 (3.2%)	0	1 (1.8%)
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 2	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Neurological signs and symptoms NEC (cont)						
Dizziness exertional	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dizziness postural	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Headaches NEC	1 (4.2%)	1 (11.1%)	2 (6.1%)	0	2 (33.3%)	2 (11.1%)
Grade 1	1 (4.2%)	0	1 (3.0%)	0	1 (16.7%)	1 (5.6%)
Grade 2	0	0	0	0	0	0
Grade 3	0	1 (11.1%)	1 (3.0%)	0	1 (16.7%)	1 (5.6%)
Headache	1 (4.2%)	1 (11.1%)	2 (6.1%)	0	2 (33.3%)	2 (11.1%)
Grade 1	1 (4.2%)	0	1 (3.0%)	0	1 (16.7%)	1 (5.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Neurological signs and symptoms NEC (cont)						
Dizziness exertional	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Dizziness postural	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Headaches NEC	7 (16.7%)	2 (6.7%)	9 (12.5%)	0	3 (12.5%)	3 (5.5%)
Grade 1	5 (11.9%)	0	5 (6.9%)	0	1 (4.2%)	1 (1.8%)
Grade 2	2 (4.8%)	2 (6.7%)	4 (5.6%)	0	2 (8.3%)	2 (3.6%)
Grade 3	0	0	0	0	0	0
Headache	7 (16.7%)	2 (6.7%)	9 (12.5%)	0	3 (12.5%)	3 (5.5%)
Grade 1	5 (11.9%)	0	5 (6.9%)	0	1 (4.2%)	1 (1.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Headaches NEC (cont)						
Headache (cont)						
Grade 2	0	0	0	0	0	0
Grade 3	0	1 (11.1%)	1 (3.0%)	0	1 (16.7%)	1 (5.6%)
Peripheral neuropathies NEC	3 (12.5%)	0	3 (9.1%)	0	0	0
Grade 1	2 (8.3%)	0	2 (6.1%)	0	0	0
Grade 2	1 (4.2%)	0	1 (3.0%)	0	0	0
Peripheral sensory neuropathy	2 (8.3%)	0	2 (6.1%)	0	0	0
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 2	1 (4.2%)	0	1 (3.0%)	0	0	0
Peripheral motor neuropathy	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Headaches NEC (cont)						
Headache (cont)						
Grade 2	2 (4.8%)	2 (6.7%)	4 (5.6%)	0	2 (8.3%)	2 (3.6%)
Grade 3	0	0	0	0	0	0
Peripheral neuropathies NEC	4 (9.5%)	0	4 (5.6%)	1 (3.2%)	4 (16.7%)	5 (9.1%)
Grade 1	4 (9.5%)	0	4 (5.6%)	1 (3.2%)	4 (16.7%)	5 (9.1%)
Grade 2	0	0	0	0	0	0
Peripheral sensory neuropathy	4 (9.5%)	0	4 (5.6%)	1 (3.2%)	4 (16.7%)	5 (9.1%)
Grade 1	4 (9.5%)	0	4 (5.6%)	1 (3.2%)	4 (16.7%)	5 (9.1%)
Grade 2	0	0	0	0	0	0
Peripheral motor neuropathy	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Paraesthesias and dysaesthesias	1 (4.2%)	0	1 (3.0%)	1 (8.3%)	0	1 (5.6%)
Grade 1	1 (4.2%)	0	1 (3.0%)	1 (8.3%)	0	1 (5.6%)
Grade 2	0	0	0	0	0	0
Paraesthesia	1 (4.2%)	0	1 (3.0%)	1 (8.3%)	0	1 (5.6%)
Grade 1	1 (4.2%)	0	1 (3.0%)	1 (8.3%)	0	1 (5.6%)
Grade 2	0	0	0	0	0	0
Hypoaesthesia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Sensory abnormalities NEC	2 (8.3%)	0	2 (6.1%)	1 (8.3%)	0	1 (5.6%)
Grade 1	1 (4.2%)	0	1 (3.0%)	1 (8.3%)	0	1 (5.6%)
Grade 2	1 (4.2%)	0	1 (3.0%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Paraesthesias and dysaesthesias	3 (7.1%)	1 (3.3%)	4 (5.6%)	1 (3.2%)	2 (8.3%)	3 (5.5%)
Grade 1	2 (4.8%)	1 (3.3%)	3 (4.2%)	1 (3.2%)	2 (8.3%)	3 (5.5%)
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0
Paraesthesia	3 (7.1%)	1 (3.3%)	4 (5.6%)	0	2 (8.3%)	2 (3.6%)
Grade 1	2 (4.8%)	1 (3.3%)	3 (4.2%)	0	2 (8.3%)	2 (3.6%)
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0
Hypoaesthesia	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 1	0	0	0	1 (3.2%)	0	1 (1.8%)
Sensory abnormalities NEC	2 (4.8%)	0	2 (2.8%)	0	1 (4.2%)	1 (1.8%)
Grade 1	2 (4.8%)	0	2 (2.8%)	0	0	0
Grade 2	0	0	0	0	1 (4.2%)	1 (1.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Sensory abnormalities NEC (cont)						
Restless legs syndrome	2 (8.3%)	0	2 (6.1%)	0	0	0
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 2	1 (4.2%)	0	1 (3.0%)	0	0	0
Neuralgia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Taste disorder	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hypogeusia	0	0	0	1 (8.3%)	0	1 (5.6%)
Grade 1	0	0	0	1 (8.3%)	0	1 (5.6%)
Post herpetic neuralgia	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Sensory abnormalities NEC (cont)						
Restless legs syndrome	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Neuralgia	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Taste disorder	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Hypogeusia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Post herpetic neuralgia	0	0	0	0	1 (4.2%)	1 (1.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Sensory abnormalities NEC (cont)						
Post herpetic neuralgia (cont)						
Grade 2	0	0	0	0	0	0
Disturbances in consciousness NEC	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 3	0	0	0	0	0	0
Loss of consciousness	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Somnolence	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0
Syncope	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Sensory abnormalities NEC (cont)						
Post herpetic neuralgia (cont)						
Grade 2	0	0	0	0	1 (4.2%)	1 (1.8%)
Disturbances in consciousness NEC	2 (4.8%)	0	2 (2.8%)	1 (3.2%)	2 (8.3%)	3 (5.5%)
Grade 1	1 (2.4%)	0	1 (1.4%)	0	2 (8.3%)	2 (3.6%)
Grade 3	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Loss of consciousness	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 3	1 (2.4%)	0	1 (1.4%)	0	0	0
Somnolence	1 (2.4%)	0	1 (1.4%)	0	2 (8.3%)	2 (3.6%)
Grade 1	1 (2.4%)	0	1 (1.4%)	0	2 (8.3%)	2 (3.6%)
Syncope	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	0	1 (1.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Disturbances in consciousness NEC (cont)						
Syncope (cont)						
Grade 3	0	0	0	0	0	0
Tremor (excl congenital)	2 (8.3%)	0	2 (6.1%)	0	0	0
Grade 1	2 (8.3%)	0	2 (6.1%)	0	0	0
Tremor	2 (8.3%)	0	2 (6.1%)	0	0	0
Grade 1	2 (8.3%)	0	2 (6.1%)	0	0	0
Cervical spinal cord and nerve root disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Disturbances in consciousness NEC (cont)						
Syncope (cont)						
Grade 3	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Tremor (excl congenital)	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Tremor	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Cervical spinal cord and nerve root disorders	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Cervical spinal cord and nerve root disorders (cont)						
Cervical radiculopathy	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Coordination and balance disturbances	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Balance disorder	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Memory loss (excl dementia)	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Memory impairment	1 (4.2%)	0	1 (3.0%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Cervical spinal cord and nerve root disorders (cont)						
Cervical radiculopathy	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Coordination and balance disturbances	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Balance disorder	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Memory loss (excl dementia)	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Memory impairment	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Memory loss (excl dementia) (cont)						
Memory impairment (cont)						
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Mental impairment (excl dementia and memory loss)	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Disturbance in attention	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Cognitive disorder	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Mononeuropathies	1 (4.2%)	0	1 (3.0%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Memory loss (excl dementia) (cont)						
Memory impairment (cont)						
Grade 1	0	0	0	0	0	0
Mental impairment (excl dementia and memory loss)	1 (2.4%)	0	1 (1.4%)	2 (6.5%)	1 (4.2%)	3 (5.5%)
Grade 1	1 (2.4%)	0	1 (1.4%)	2 (6.5%)	1 (4.2%)	3 (5.5%)
Disturbance in attention	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 1	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Cognitive disorder	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 1	0	0	0	1 (3.2%)	0	1 (1.8%)
Mononeuropathies	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Mononeuropathies (cont)						
(cont)						
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Nerve compression	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Neurologic visual problems NEC	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Visual field defect	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Olfactory nerve disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Mononeuropathies (cont)						
(cont)						
Grade 1	0	0	0	0	0	0
Nerve compression	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Neurologic visual problems NEC	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0
Visual field defect	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0
Olfactory nerve disorders	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Olfactory nerve disorders (cont)						
Parosmia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Speech and language abnormalities	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Speech disorder	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Central nervous system haemorrhages and cerebrovascular accidents	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Cerebral infarction	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Olfactory nerve disorders (cont)						
Parosmia	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Speech and language abnormalities	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Speech disorder	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Central nervous system haemorrhages and cerebrovascular accidents	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 1	0	0	0	0	1 (4.2%)	1 (1.8%)
Cerebral infarction	0	0	0	0	1 (4.2%)	1 (1.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Central nervous system haemorrhages and cerebrovascular accidents (cont)						
Cerebral infarction (cont)						
Grade 1	0	0	0	0	0	0
Dementia (excl Alzheimer's type)	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dementia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Muscle tone abnormal	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0
Hypertonia	0	1 (11.1%)	1 (3.0%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Central nervous system haemorrhages and cerebrovascular accidents (cont)						
Cerebral infarction (cont)						
Grade 1	0	0	0	0	1 (4.2%)	1 (1.8%)
Dementia (excl Alzheimer's type)	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 1	0	0	0	0	1 (4.2%)	1 (1.8%)
Dementia	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 1	0	0	0	0	1 (4.2%)	1 (1.8%)
Muscle tone abnormal	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hypertonia	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Muscle tone abnormal (cont)						
Hypertonia (cont)						
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0
Nervous system cysts and polyps	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Arachnoid cyst	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Blood and lymphatic system disorders	8 (33.3%)	2 (22.2%)	10 (30.3%)	1 (8.3%)	1 (16.7%)	2 (11.1%)
Grade 1	0	0	0	0	0	0
Grade 2	2 (8.3%)	1 (11.1%)	3 (9.1%)	0	1 (16.7%)	1 (5.6%)
Grade 3	3 (12.5%)	1 (11.1%)	4 (12.1%)	1 (8.3%)	0	1 (5.6%)
Grade 4	3 (12.5%)	0	3 (9.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Muscle tone abnormal (cont)						
Hypertonia (cont)						
Grade 1	0	0	0	0	0	0
Nervous system cysts and polyps	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 1	0	0	0	0	1 (4.2%)	1 (1.8%)
Arachnoid cyst	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 1	0	0	0	0	1 (4.2%)	1 (1.8%)
Blood and lymphatic system disorders	18 (42.9%)	14 (46.7%)	32 (44.4%)	6 (19.4%)	14 (58.3%)	20 (36.4%)
Grade 1	4 (9.5%)	1 (3.3%)	5 (6.9%)	0	1 (4.2%)	1 (1.8%)
Grade 2	2 (4.8%)	2 (6.7%)	4 (5.6%)	2 (6.5%)	4 (16.7%)	6 (10.9%)
Grade 3	10 (23.8%)	10 (33.3%)	20 (27.8%)	3 (9.7%)	7 (29.2%)	10 (18.2%)
Grade 4	2 (4.8%)	1 (3.3%)	3 (4.2%)	1 (3.2%)	2 (8.3%)	3 (5.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Anaemias NEC	4 (16.7%)	1 (11.1%)	5 (15.2%)	1 (8.3%)	0	1 (5.6%)
Grade 2	0	0	0	0	0	0
Grade 3	4 (16.7%)	1 (11.1%)	5 (15.2%)	1 (8.3%)	0	1 (5.6%)
Grade 4	0	0	0	0	0	0
Anaemia	4 (16.7%)	1 (11.1%)	5 (15.2%)	1 (8.3%)	0	1 (5.6%)
Grade 2	0	0	0	0	0	0
Grade 3	4 (16.7%)	1 (11.1%)	5 (15.2%)	1 (8.3%)	0	1 (5.6%)
Grade 4	0	0	0	0	0	0
Thrombocytopenias	5 (20.8%)	0	5 (15.2%)	0	1 (16.7%)	1 (5.6%)
Grade 1	0	0	0	0	0	0
Grade 2	2 (8.3%)	0	2 (6.1%)	0	1 (16.7%)	1 (5.6%)
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Anaemias NEC	9 (21.4%)	9 (30.0%)	18 (25.0%)	3 (9.7%)	5 (20.8%)	8 (14.5%)
Grade 2	1 (2.4%)	1 (3.3%)	2 (2.8%)	0	0	0
Grade 3	7 (16.7%)	8 (26.7%)	15 (20.8%)	3 (9.7%)	5 (20.8%)	8 (14.5%)
Grade 4	1 (2.4%)	0	1 (1.4%)	0	0	0
Anaemia	9 (21.4%)	9 (30.0%)	18 (25.0%)	3 (9.7%)	5 (20.8%)	8 (14.5%)
Grade 2	1 (2.4%)	1 (3.3%)	2 (2.8%)	0	0	0
Grade 3	7 (16.7%)	8 (26.7%)	15 (20.8%)	3 (9.7%)	5 (20.8%)	8 (14.5%)
Grade 4	1 (2.4%)	0	1 (1.4%)	0	0	0
Thrombocytopenias	6 (14.3%)	4 (13.3%)	10 (13.9%)	2 (6.5%)	6 (25.0%)	8 (14.5%)
Grade 1	2 (4.8%)	0	2 (2.8%)	0	0	0
Grade 2	1 (2.4%)	2 (6.7%)	3 (4.2%)	2 (6.5%)	2 (8.3%)	4 (7.3%)
Grade 3	2 (4.8%)	2 (6.7%)	4 (5.6%)	0	2 (8.3%)	2 (3.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Thrombocytopenias (cont) (cont)						
Grade 4	3 (12.5%)	0	3 (9.1%)	0	0	0
Thrombocytopenia	5 (20.8%)	0	5 (15.2%)	0	1 (16.7%)	1 (5.6%)
Grade 1	0	0	0	0	0	0
Grade 2	2 (8.3%)	0	2 (6.1%)	0	1 (16.7%)	1 (5.6%)
Grade 3	0	0	0	0	0	0
Grade 4	3 (12.5%)	0	3 (9.1%)	0	0	0
Neutropenias	2 (8.3%)	0	2 (6.1%)	0	0	0
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Thrombocytopenias (cont) (cont)						
Grade 4	1 (2.4%)	0	1 (1.4%)	0	2 (8.3%)	2 (3.6%)
Thrombocytopenia	6 (14.3%)	4 (13.3%)	10 (13.9%)	2 (6.5%)	6 (25.0%)	8 (14.5%)
Grade 1	2 (4.8%)	0	2 (2.8%)	0	0	0
Grade 2	1 (2.4%)	2 (6.7%)	3 (4.2%)	2 (6.5%)	2 (8.3%)	4 (7.3%)
Grade 3	2 (4.8%)	2 (6.7%)	4 (5.6%)	0	2 (8.3%)	2 (3.6%)
Grade 4	1 (2.4%)	0	1 (1.4%)	0	2 (8.3%)	2 (3.6%)
Neutropenias	5 (11.9%)	1 (3.3%)	6 (8.3%)	1 (3.2%)	2 (8.3%)	3 (5.5%)
Grade 1	0	0	0	0	0	0
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 3	2 (4.8%)	0	2 (2.8%)	0	2 (8.3%)	2 (3.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Neutropenias (cont) (cont)						
Grade 4	1 (4.2%)	0	1 (3.0%)	0	0	0
Neutropenia	2 (8.3%)	0	2 (6.1%)	0	0	0
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Grade 4	1 (4.2%)	0	1 (3.0%)	0	0	0
Spleen disorders	1 (4.2%)	1 (11.1%)	2 (6.1%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 3	1 (4.2%)	0	1 (3.0%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Neutropenias (cont) (cont)						
Grade 4	2 (4.8%)	1 (3.3%)	3 (4.2%)	1 (3.2%)	0	1 (1.8%)
Neutropenia	5 (11.9%)	1 (3.3%)	6 (8.3%)	1 (3.2%)	2 (8.3%)	3 (5.5%)
Grade 1	0	0	0	0	0	0
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 3	2 (4.8%)	0	2 (2.8%)	0	2 (8.3%)	2 (3.6%)
Grade 4	2 (4.8%)	1 (3.3%)	3 (4.2%)	1 (3.2%)	0	1 (1.8%)
Spleen disorders	1 (2.4%)	1 (3.3%)	2 (2.8%)	0	2 (8.3%)	2 (3.6%)
Grade 1	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 2	1 (2.4%)	0	1 (1.4%)	0	2 (8.3%)	2 (3.6%)
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Spleen disorders (cont)						
Splenic infarction	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Splenomegaly	1 (4.2%)	1 (11.1%)	2 (6.1%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 3	1 (4.2%)	0	1 (3.0%)	0	0	0
Bleeding tendencies	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Increased tendency to bruise	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Spleen disorders (cont)						
Splenic infarction	1 (2.4%)	0	1 (1.4%)	0	1 (4.2%)	1 (1.8%)
Grade 2	1 (2.4%)	0	1 (1.4%)	0	1 (4.2%)	1 (1.8%)
Splenomegaly	0	1 (3.3%)	1 (1.4%)	0	1 (4.2%)	1 (1.8%)
Grade 1	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 2	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 3	0	0	0	0	0	0
Bleeding tendencies	1 (2.4%)	0	1 (1.4%)	0	1 (4.2%)	1 (1.8%)
Grade 1	1 (2.4%)	0	1 (1.4%)	0	1 (4.2%)	1 (1.8%)
Increased tendency to bruise	1 (2.4%)	0	1 (1.4%)	0	1 (4.2%)	1 (1.8%)
Grade 1	1 (2.4%)	0	1 (1.4%)	0	1 (4.2%)	1 (1.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Coagulopathies	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hyperfibrinogenaemia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Leukocytoses NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Neutrophilia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Leukopenias NEC	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Coagulopathies	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Hyperfibrinogenaemia	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Leukocytoses NEC	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Neutrophilia	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Leukopenias NEC	1 (2.4%)	0	1 (1.4%)	0	1 (4.2%)	1 (1.8%)
Grade 3	1 (2.4%)	0	1 (1.4%)	0	1 (4.2%)	1 (1.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Leukopenias NEC (cont)						
Leukopenia	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Lymphatic system disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Lymphadenopathy	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Anaemias haemolytic NEC	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Leukopenias NEC (cont)						
Leukopenia	1 (2.4%)	0	1 (1.4%)	0	1 (4.2%)	1 (1.8%)
Grade 3	1 (2.4%)	0	1 (1.4%)	0	1 (4.2%)	1 (1.8%)
Lymphatic system disorders NEC	1 (2.4%)	1 (3.3%)	2 (2.8%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 3	0	1 (3.3%)	1 (1.4%)	0	0	0
Lymphadenopathy	1 (2.4%)	1 (3.3%)	2 (2.8%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 3	0	1 (3.3%)	1 (1.4%)	0	0	0
Anaemias haemolytic NEC	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 3	0	1 (3.3%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Anaemias haemolytic NEC (cont)						
Haemolytic anaemia	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Metabolism and nutrition disorders	12 (50.0%)	3 (33.3%)	15 (45.5%)	1 (8.3%)	2 (33.3%)	3 (16.7%)
Grade 1	7 (29.2%)	1 (11.1%)	8 (24.2%)	1 (8.3%)	0	1 (5.6%)
Grade 2	1 (4.2%)	2 (22.2%)	3 (9.1%)	0	2 (33.3%)	2 (11.1%)
Grade 3	4 (16.7%)	0	4 (12.1%)	0	0	0
Grade 4	0	0	0	0	0	0
Water soluble vitamin deficiencies	3 (12.5%)	1 (11.1%)	4 (12.1%)	0	0	0
Grade 1	2 (8.3%)	1 (11.1%)	3 (9.1%)	0	0	0
Grade 2	1 (4.2%)	0	1 (3.0%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Anaemias haemolytic NEC (cont)						
Haemolytic anaemia	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 3	0	1 (3.3%)	1 (1.4%)	0	0	0
Metabolism and nutrition disorders	13 (31.0%)	5 (16.7%)	18 (25.0%)	7 (22.6%)	5 (20.8%)	12 (21.8%)
Grade 1	10 (23.8%)	1 (3.3%)	11 (15.3%)	3 (9.7%)	3 (12.5%)	6 (10.9%)
Grade 2	2 (4.8%)	0	2 (2.8%)	3 (9.7%)	1 (4.2%)	4 (7.3%)
Grade 3	1 (2.4%)	3 (10.0%)	4 (5.6%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 4	0	1 (3.3%)	1 (1.4%)	0	0	0
Water soluble vitamin deficiencies	6 (14.3%)	0	6 (8.3%)	3 (9.7%)	1 (4.2%)	4 (7.3%)
Grade 1	5 (11.9%)	0	5 (6.9%)	2 (6.5%)	1 (4.2%)	3 (5.5%)
Grade 2	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	0	1 (1.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Water soluble vitamin deficiencies (cont)						
Vitamin B1 deficiency	2 (8.3%)	1 (11.1%)	3 (9.1%)	0	0	0
Grade 1	1 (4.2%)	1 (11.1%)	2 (6.1%)	0	0	0
Grade 2	1 (4.2%)	0	1 (3.0%)	0	0	0
Vitamin B complex deficiency	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Vitamin B6 deficiency	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Potassium imbalance	4 (16.7%)	0	4 (12.1%)	0	1 (16.7%)	1 (5.6%)
Grade 1	2 (8.3%)	0	2 (6.1%)	0	1 (16.7%)	1 (5.6%)
Grade 2	1 (4.2%)	0	1 (3.0%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Water soluble vitamin deficiencies (cont)						
Vitamin B1 deficiency	5 (11.9%)	0	5 (6.9%)	3 (9.7%)	1 (4.2%)	4 (7.3%)
Grade 1	4 (9.5%)	0	4 (5.6%)	2 (6.5%)	1 (4.2%)	3 (5.5%)
Grade 2	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Vitamin B complex deficiency	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Vitamin B6 deficiency	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Potassium imbalance	2 (4.8%)	0	2 (2.8%)	2 (6.5%)	2 (8.3%)	4 (7.3%)
Grade 1	2 (4.8%)	0	2 (2.8%)	0	0	0
Grade 2	0	0	0	1 (3.2%)	1 (4.2%)	2 (3.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Potassium imbalance (cont)						
(cont)						
Grade 3	1 (4.2%)	0	1 (3.0%)	0	0	0
Hyperkalaemia	4 (16.7%)	0	4 (12.1%)	0	0	0
Grade 1	3 (12.5%)	0	3 (9.1%)	0	0	0
Grade 2	1 (4.2%)	0	1 (3.0%)	0	0	0
Hypokalaemia	2 (8.3%)	0	2 (6.1%)	0	1 (16.7%)	1 (5.6%)
Grade 1	0	0	0	0	1 (16.7%)	1 (5.6%)
Grade 2	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 3	1 (4.2%)	0	1 (3.0%)	0	0	0
Appetite disorders	3 (12.5%)	1 (11.1%)	4 (12.1%)	0	1 (16.7%)	1 (5.6%)
Grade 1	3 (12.5%)	0	3 (9.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Potassium imbalance (cont)						
(cont)						
Grade 3	0	0	0	1 (3.2%)	1 (4.2%)	2 (3.6%)
Hyperkalaemia	2 (4.8%)	0	2 (2.8%)	2 (6.5%)	1 (4.2%)	3 (5.5%)
Grade 1	2 (4.8%)	0	2 (2.8%)	1 (3.2%)	0	1 (1.8%)
Grade 2	0	0	0	1 (3.2%)	1 (4.2%)	2 (3.6%)
Hypokalaemia	0	0	0	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	1 (3.2%)	1 (4.2%)	2 (3.6%)
Appetite disorders	2 (4.8%)	1 (3.3%)	3 (4.2%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 1	1 (2.4%)	0	1 (1.4%)	0	1 (4.2%)	1 (1.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Appetite disorders (cont)						
(cont)						
Grade 2	0	1 (11.1%)	1 (3.0%)	0	1 (16.7%)	1 (5.6%)
Grade 3	0	0	0	0	0	0
Decreased appetite	2 (8.3%)	1 (11.1%)	3 (9.1%)	0	1 (16.7%)	1 (5.6%)
Grade 1	2 (8.3%)	0	2 (6.1%)	0	0	0
Grade 2	0	1 (11.1%)	1 (3.0%)	0	1 (16.7%)	1 (5.6%)
Grade 3	0	0	0	0	0	0
Appetite disorder	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Calcium metabolism disorders	2 (8.3%)	0	2 (6.1%)	1 (8.3%)	1 (16.7%)	2 (11.1%)
Grade 1	2 (8.3%)	0	2 (6.1%)	1 (8.3%)	1 (16.7%)	2 (11.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Appetite disorders (cont)						
(cont)						
Grade 2	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Grade 3	0	1 (3.3%)	1 (1.4%)	0	0	0
Decreased appetite	2 (4.8%)	1 (3.3%)	3 (4.2%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 1	1 (2.4%)	0	1 (1.4%)	0	1 (4.2%)	1 (1.8%)
Grade 2	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Grade 3	0	1 (3.3%)	1 (1.4%)	0	0	0
Appetite disorder	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Calcium metabolism disorders	2 (4.8%)	1 (3.3%)	3 (4.2%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 1	2 (4.8%)	1 (3.3%)	3 (4.2%)	1 (3.2%)	0	1 (1.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Calcium metabolism disorders (cont)						
(cont)						
Grade 3	0	0	0	0	0	0
Hypocalcaemia	2 (8.3%)	0	2 (6.1%)	1 (8.3%)	1 (16.7%)	2 (11.1%)
Grade 1	2 (8.3%)	0	2 (6.1%)	1 (8.3%)	1 (16.7%)	2 (11.1%)
Grade 3	0	0	0	0	0	0
Disorders of purine metabolism	3 (12.5%)	1 (11.1%)	4 (12.1%)	0	0	0
Grade 1	2 (8.3%)	0	2 (6.1%)	0	0	0
Grade 2	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 3	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 4	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Calcium metabolism disorders (cont)						
(cont)						
Grade 3	0	0	0	0	1 (4.2%)	1 (1.8%)
Hypocalcaemia	2 (4.8%)	1 (3.3%)	3 (4.2%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 1	2 (4.8%)	1 (3.3%)	3 (4.2%)	1 (3.2%)	0	1 (1.8%)
Grade 3	0	0	0	0	1 (4.2%)	1 (1.8%)
Disorders of purine metabolism	1 (2.4%)	2 (6.7%)	3 (4.2%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 1	1 (2.4%)	1 (3.3%)	2 (2.8%)	1 (3.2%)	0	1 (1.8%)
Grade 2	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 3	0	0	0	0	0	0
Grade 4	0	1 (3.3%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Disorders of purine metabolism (cont)						
Hyperuricaemia	3 (12.5%)	0	3 (9.1%)	0	0	0
Grade 1	2 (8.3%)	0	2 (6.1%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 4	0	0	0	0	0	0
Gout	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 2	0	1 (11.1%)	1 (3.0%)	0	0	0
Hyperglycaemic conditions NEC	3 (12.5%)	0	3 (9.1%)	0	1 (16.7%)	1 (5.6%)
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 2	0	0	0	0	1 (16.7%)	1 (5.6%)
Grade 3	2 (8.3%)	0	2 (6.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Disorders of purine metabolism (cont)						
Hyperuricaemia	1 (2.4%)	2 (6.7%)	3 (4.2%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 1	1 (2.4%)	1 (3.3%)	2 (2.8%)	1 (3.2%)	0	1 (1.8%)
Grade 2	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 3	0	0	0	0	0	0
Grade 4	0	1 (3.3%)	1 (1.4%)	0	0	0
Gout	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Hyperglycaemic conditions NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Hyperglycaemic conditions NEC (cont)						
Hyperglycaemia	3 (12.5%)	0	3 (9.1%)	0	1 (16.7%)	1 (5.6%)
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 2	0	0	0	0	1 (16.7%)	1 (5.6%)
Grade 3	2 (8.3%)	0	2 (6.1%)	0	0	0
Sodium imbalance	1 (4.2%)	1 (11.1%)	2 (6.1%)	0	0	0
Grade 1	1 (4.2%)	1 (11.1%)	2 (6.1%)	0	0	0
Hyponatraemia	1 (4.2%)	1 (11.1%)	2 (6.1%)	0	0	0
Grade 1	1 (4.2%)	1 (11.1%)	2 (6.1%)	0	0	0
Hypernatraemia	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Hyperglycaemic conditions NEC (cont)						
Hyperglycaemia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Sodium imbalance	2 (4.8%)	0	2 (2.8%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 1	2 (4.8%)	0	2 (2.8%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Hyponatraemia	2 (4.8%)	0	2 (2.8%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 1	2 (4.8%)	0	2 (2.8%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Hypernatraemia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Phosphorus metabolism disorders	2 (8.3%)	0	2 (6.1%)	0	0	0
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 2	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 3	0	0	0	0	0	0
Hyperphosphataemia	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Hypophosphataemia	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 2	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 3	0	0	0	0	0	0
Total fluid volume decreased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Phosphorus metabolism disorders	0	0	0	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 3	0	0	0	0	1 (4.2%)	1 (1.8%)
Hyperphosphataemia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hypophosphataemia	0	0	0	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 2	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 3	0	0	0	0	1 (4.2%)	1 (1.8%)
Total fluid volume decreased	2 (4.8%)	0	2 (2.8%)	0	0	0
Grade 1	2 (4.8%)	0	2 (2.8%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Total fluid volume decreased (cont)						
Dehydration	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hypovolaemia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Electrolyte imbalance NEC	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Magnesium metabolism disorders	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Total fluid volume decreased (cont)						
Dehydration	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Hypovolaemia	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Electrolyte imbalance NEC	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 3	1 (2.4%)	0	1 (1.4%)	0	0	0
Tumour lysis syndrome	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 3	1 (2.4%)	0	1 (1.4%)	0	0	0
Magnesium metabolism disorders	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 1	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	0	1 (1.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Magnesium metabolism disorders (cont) (cont)						
Grade 3	0	0	0	0	0	0
Hypomagnesaemia	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 3	0	0	0	0	0	0
Protein metabolism disorders NEC	1 (4.2%)	1 (11.1%)	2 (6.1%)	0	0	0
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 2	1 (4.2%)	0	1 (3.0%)	0	0	0
Hypoalbuminaemia	1 (4.2%)	1 (11.1%)	2 (6.1%)	0	0	0
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 2	1 (4.2%)	0	1 (3.0%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Magnesium metabolism disorders (cont)						
(cont)						
Grade 3	0	0	0	0	1 (4.2%)	1 (1.8%)
Hypomagnesaemia	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 1	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Grade 3	0	0	0	0	1 (4.2%)	1 (1.8%)
Protein metabolism disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Hypoalbuminaemia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Fat soluble vitamin deficiencies and disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Vitamin D deficiency	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
General nutritional disorders NEC	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 2	0	1 (11.1%)	1 (3.0%)	0	0	0
Cachexia	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 2	0	1 (11.1%)	1 (3.0%)	0	0	0
Iron excess	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Fat soluble vitamin deficiencies and disorders	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 1	0	1 (3.3%)	1 (1.4%)	0	0	0
Vitamin D deficiency	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 1	0	1 (3.3%)	1 (1.4%)	0	0	0
General nutritional disorders NEC	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Cachexia	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Iron excess	0	2 (6.7%)	2 (2.8%)	0	0	0
Grade 3	0	2 (6.7%)	2 (2.8%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Iron excess (cont)						
Iron overload	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Respiratory, thoracic and mediastinal disorders	8 (33.3%)	4 (44.4%)	12 (36.4%)	3 (25.0%)	3 (50.0%)	6 (33.3%)
Grade 1	4 (16.7%)	1 (11.1%)	5 (15.2%)	3 (25.0%)	1 (16.7%)	4 (22.2%)
Grade 2	2 (8.3%)	3 (33.3%)	5 (15.2%)	0	1 (16.7%)	1 (5.6%)
Grade 3	0	0	0	0	1 (16.7%)	1 (5.6%)
Grade 4	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 5	1 (4.2%)	0	1 (3.0%)	0	0	0
Coughing and associated symptoms	4 (16.7%)	1 (11.1%)	5 (15.2%)	1 (8.3%)	3 (50.0%)	4 (22.2%)
Grade 1	4 (16.7%)	1 (11.1%)	5 (15.2%)	1 (8.3%)	1 (16.7%)	2 (11.1%)
Grade 2	0	0	0	0	1 (16.7%)	1 (5.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Iron excess (cont)						
Iron overload	0	2 (6.7%)	2 (2.8%)	0	0	0
Grade 3	0	2 (6.7%)	2 (2.8%)	0	0	0
Respiratory, thoracic and mediastinal disorders	16 (38.1%)	9 (30.0%)	25 (34.7%)	10 (32.3%)	9 (37.5%)	19 (34.5%)
Grade 1	6 (14.3%)	5 (16.7%)	11 (15.3%)	7 (22.6%)	4 (16.7%)	11 (20.0%)
Grade 2	7 (16.7%)	3 (10.0%)	10 (13.9%)	1 (3.2%)	3 (12.5%)	4 (7.3%)
Grade 3	2 (4.8%)	1 (3.3%)	3 (4.2%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 4	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 5	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Coughing and associated symptoms	7 (16.7%)	3 (10.0%)	10 (13.9%)	9 (29.0%)	3 (12.5%)	12 (21.8%)
Grade 1	4 (9.5%)	2 (6.7%)	6 (8.3%)	6 (19.4%)	2 (8.3%)	8 (14.5%)
Grade 2	3 (7.1%)	1 (3.3%)	4 (5.6%)	2 (6.5%)	1 (4.2%)	3 (5.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Coughing and associated symptoms (cont) (cont)						
Grade 3	0	0	0	0	1 (16.7%)	1 (5.6%)
Cough	3 (12.5%)	1 (11.1%)	4 (12.1%)	1 (8.3%)	3 (50.0%)	4 (22.2%)
Grade 1	3 (12.5%)	1 (11.1%)	4 (12.1%)	1 (8.3%)	1 (16.7%)	2 (11.1%)
Grade 2	0	0	0	0	1 (16.7%)	1 (5.6%)
Grade 3	0	0	0	0	1 (16.7%)	1 (5.6%)
Haemoptysis	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 2	0	0	0	0	0	0
Productive cough	1 (4.2%)	0	1 (3.0%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Coughing and associated symptoms (cont)						
(cont)						
Grade 3	0	0	0	1 (3.2%)	0	1 (1.8%)
Cough	6 (14.3%)	3 (10.0%)	9 (12.5%)	9 (29.0%)	3 (12.5%)	12 (21.8%)
Grade 1	4 (9.5%)	2 (6.7%)	6 (8.3%)	6 (19.4%)	2 (8.3%)	8 (14.5%)
Grade 2	2 (4.8%)	1 (3.3%)	3 (4.2%)	2 (6.5%)	1 (4.2%)	3 (5.5%)
Grade 3	0	0	0	1 (3.2%)	0	1 (1.8%)
Haemoptysis	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0
Productive cough	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Coughing and associated symptoms (cont)						
Productive cough (cont)						
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Sputum discoloured	0	0	0	0	1 (16.7%)	1 (5.6%)
Grade 2	0	0	0	0	1 (16.7%)	1 (5.6%)
Breathing abnormalities	1 (4.2%)	3 (33.3%)	4 (12.1%)	0	1 (16.7%)	1 (5.6%)
Grade 1	0	1 (11.1%)	1 (3.0%)	0	1 (16.7%)	1 (5.6%)
Grade 2	1 (4.2%)	2 (22.2%)	3 (9.1%)	0	0	0
Grade 3	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Dyspnoea	1 (4.2%)	3 (33.3%)	4 (12.1%)	0	1 (16.7%)	1 (5.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Coughing and associated symptoms (cont)						
Productive cough (cont)						
Grade 1	0	0	0	0	0	0
Sputum discoloured	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Breathing abnormalities	8 (19.0%)	4 (13.3%)	12 (16.7%)	3 (9.7%)	2 (8.3%)	5 (9.1%)
Grade 1	3 (7.1%)	3 (10.0%)	6 (8.3%)	2 (6.5%)	1 (4.2%)	3 (5.5%)
Grade 2	3 (7.1%)	1 (3.3%)	4 (5.6%)	0	1 (4.2%)	1 (1.8%)
Grade 3	2 (4.8%)	0	2 (2.8%)	0	0	0
Grade 5	0	0	0	1 (3.2%)	0	1 (1.8%)
Dyspnoea	7 (16.7%)	3 (10.0%)	10 (13.9%)	1 (3.2%)	2 (8.3%)	3 (5.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Breathing abnormalities (cont)						
Dyspnoea (cont)						
Grade 1	0	1 (11.1%)	1 (3.0%)	0	1 (16.7%)	1 (5.6%)
Grade 2	1 (4.2%)	2 (22.2%)	3 (9.1%)	0	0	0
Grade 3	0	0	0	0	0	0
Dyspnoea exertional	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Respiratory distress	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Nasal disorders NEC	2 (8.3%)	2 (22.2%)	4 (12.1%)	1 (8.3%)	0	1 (5.6%)
Grade 1	1 (4.2%)	1 (11.1%)	2 (6.1%)	1 (8.3%)	0	1 (5.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Breathing abnormalities (cont)						
Dyspnoea (cont)						
Grade 1	2 (4.8%)	2 (6.7%)	4 (5.6%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 2	3 (7.1%)	1 (3.3%)	4 (5.6%)	0	1 (4.2%)	1 (1.8%)
Grade 3	2 (4.8%)	0	2 (2.8%)	0	0	0
Dyspnoea exertional	1 (2.4%)	1 (3.3%)	2 (2.8%)	1 (3.2%)	0	1 (1.8%)
Grade 1	1 (2.4%)	1 (3.3%)	2 (2.8%)	1 (3.2%)	0	1 (1.8%)
Respiratory distress	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 5	0	0	0	1 (3.2%)	0	1 (1.8%)
Nasal disorders NEC	4 (9.5%)	3 (10.0%)	7 (9.7%)	0	2 (8.3%)	2 (3.6%)
Grade 1	3 (7.1%)	2 (6.7%)	5 (6.9%)	0	1 (4.2%)	1 (1.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Nasal disorders NEC (cont) (cont)						
Grade 2	1 (4.2%)	1 (11.1%)	2 (6.1%)	0	0	0
Epistaxis	2 (8.3%)	2 (22.2%)	4 (12.1%)	0	0	0
Grade 1	1 (4.2%)	1 (11.1%)	2 (6.1%)	0	0	0
Grade 2	1 (4.2%)	1 (11.1%)	2 (6.1%)	0	0	0
Nasal septum ulceration	0	0	0	1 (8.3%)	0	1 (5.6%)
Grade 1	0	0	0	1 (8.3%)	0	1 (5.6%)
Upper respiratory tract signs and symptoms	1 (4.2%)	0	1 (3.0%)	1 (8.3%)	0	1 (5.6%)
Grade 1	1 (4.2%)	0	1 (3.0%)	1 (8.3%)	0	1 (5.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Nasal disorders NEC (cont) (cont)						
Grade 2	1 (2.4%)	1 (3.3%)	2 (2.8%)	0	1 (4.2%)	1 (1.8%)
Epistaxis	4 (9.5%)	3 (10.0%)	7 (9.7%)	0	2 (8.3%)	2 (3.6%)
Grade 1	3 (7.1%)	2 (6.7%)	5 (6.9%)	0	1 (4.2%)	1 (1.8%)
Grade 2	1 (2.4%)	1 (3.3%)	2 (2.8%)	0	1 (4.2%)	1 (1.8%)
Nasal septum ulceration	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Upper respiratory tract signs and symptoms	2 (4.8%)	0	2 (2.8%)	2 (6.5%)	0	2 (3.6%)
Grade 1	2 (4.8%)	0	2 (2.8%)	2 (6.5%)	0	2 (3.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Upper respiratory tract signs and symptoms (cont)						
Dysphonia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Oropharyngeal pain	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Rhinorrhoea	0	0	0	1 (8.3%)	0	1 (5.6%)
Grade 1	0	0	0	1 (8.3%)	0	1 (5.6%)
Upper-airway cough syndrome	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Upper respiratory tract signs and symptoms (cont)						
Dysphonia	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Oropharyngeal pain	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 1	0	0	0	1 (3.2%)	0	1 (1.8%)
Rhinorrhoea	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Upper-airway cough syndrome	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 1	0	0	0	1 (3.2%)	0	1 (1.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Pulmonary hypertensions	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Pulmonary hypertension	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Respiratory failures (excl neonatal)	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 5	1 (4.2%)	0	1 (3.0%)	0	0	0
Respiratory failure	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 5	1 (4.2%)	0	1 (3.0%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Pulmonary hypertensions	2 (4.8%)	1 (3.3%)	3 (4.2%)	0	0	0
Grade 2	1 (2.4%)	1 (3.3%)	2 (2.8%)	0	0	0
Grade 3	1 (2.4%)	0	1 (1.4%)	0	0	0
Pulmonary hypertension	2 (4.8%)	1 (3.3%)	3 (4.2%)	0	0	0
Grade 2	1 (2.4%)	1 (3.3%)	2 (2.8%)	0	0	0
Grade 3	1 (2.4%)	0	1 (1.4%)	0	0	0
Respiratory failures (excl neonatal)	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 5	1 (2.4%)	0	1 (1.4%)	0	0	0
Respiratory failure	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 5	1 (2.4%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Parenchymal lung disorders NEC	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Atelectasis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Interstitial lung disease	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Pneumothorax and pleural effusions NEC	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 3	1 (4.2%)	0	1 (3.0%)	0	0	0
Pleural effusion	1 (4.2%)	0	1 (3.0%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Parenchymal lung disorders NEC	1 (2.4%)	0	1 (1.4%)	0	1 (4.2%)	1 (1.8%)
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 3	0	0	0	0	1 (4.2%)	1 (1.8%)
Atelectasis	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0
Interstitial lung disease	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 3	0	0	0	0	1 (4.2%)	1 (1.8%)
Pneumothorax and pleural effusions NEC	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Pleural effusion	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Pneumothorax and pleural effusions NEC (cont)						
Pleural effusion (cont)						
Grade 3	1 (4.2%)	0	1 (3.0%)	0	0	0
Pulmonary oedemas	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 3	0	0	0	0	0	0
Grade 4	1 (4.2%)	0	1 (3.0%)	0	0	0
Acute respiratory distress syndrome	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 4	1 (4.2%)	0	1 (3.0%)	0	0	0
Pulmonary congestion	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Pneumothorax and pleural effusions NEC (cont)						
Pleural effusion (cont)						
Grade 3	0	0	0	0	0	0
Pulmonary oedemas	0	1 (3.3%)	1 (1.4%)	0	2 (8.3%)	2 (3.6%)
Grade 3	0	1 (3.3%)	1 (1.4%)	0	2 (8.3%)	2 (3.6%)
Grade 4	0	0	0	0	0	0
Acute respiratory distress syndrome	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Pulmonary congestion	0	1 (3.3%)	1 (1.4%)	0	1 (4.2%)	1 (1.8%)
Grade 3	0	1 (3.3%)	1 (1.4%)	0	1 (4.2%)	1 (1.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Pulmonary oedemas (cont)						
Pulmonary oedema	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Conditions associated with abnormal gas exchange	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Hypoxia	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Lower respiratory tract inflammatory and immunologic conditions	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Pulmonary oedemas (cont)						
Pulmonary oedema	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 3	0	0	0	0	1 (4.2%)	1 (1.8%)
Conditions associated with abnormal gas exchange	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 4	0	0	0	0	1 (4.2%)	1 (1.8%)
Hypoxia	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 4	0	0	0	0	1 (4.2%)	1 (1.8%)
Lower respiratory tract inflammatory and immunologic conditions	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 2	0	0	0	1 (3.2%)	0	1 (1.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Lower respiratory tract inflammatory and immunologic conditions (cont)						
Pneumonitis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Nasal congestion and inflammations	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Rhinitis allergic	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Paranasal sinus disorders (excl infections and neoplasms)	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Lower respiratory tract inflammatory and immunologic conditions (cont)						
Pneumonitis	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 2	0	0	0	1 (3.2%)	0	1 (1.8%)
Nasal congestion and inflammations	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 1	0	1 (3.3%)	1 (1.4%)	0	0	0
Rhinitis allergic	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 1	0	1 (3.3%)	1 (1.4%)	0	0	0
Paranasal sinus disorders (excl infections and neoplasms)	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 1	0	1 (3.3%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Paranasal sinus disorders (excl infections and neoplasms) (cont)						
Sinus congestion	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Skin and subcutaneous tissue disorders	8 (33.3%)	3 (33.3%)	11 (33.3%)	5 (41.7%)	1 (16.7%)	6 (33.3%)
Grade 1	6 (25.0%)	2 (22.2%)	8 (24.2%)	5 (41.7%)	0	5 (27.8%)
Grade 2	2 (8.3%)	1 (11.1%)	3 (9.1%)	0	0	0
Grade 3	0	0	0	0	1 (16.7%)	1 (5.6%)
Pruritus NEC	5 (20.8%)	0	5 (15.2%)	0	1 (16.7%)	1 (5.6%)
Grade 1	3 (12.5%)	0	3 (9.1%)	0	0	0
Grade 2	2 (8.3%)	0	2 (6.1%)	0	0	0
Grade 3	0	0	0	0	1 (16.7%)	1 (5.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Paranasal sinus disorders (excl infections and neoplasms) (cont)						
Sinus congestion	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 1	0	1 (3.3%)	1 (1.4%)	0	0	0
Skin and subcutaneous tissue disorders	14 (33.3%)	8 (26.7%)	22 (30.6%)	4 (12.9%)	5 (20.8%)	9 (16.4%)
Grade 1	12 (28.6%)	5 (16.7%)	17 (23.6%)	2 (6.5%)	3 (12.5%)	5 (9.1%)
Grade 2	2 (4.8%)	2 (6.7%)	4 (5.6%)	2 (6.5%)	1 (4.2%)	3 (5.5%)
Grade 3	0	1 (3.3%)	1 (1.4%)	0	1 (4.2%)	1 (1.8%)
Pruritus NEC	7 (16.7%)	4 (13.3%)	11 (15.3%)	2 (6.5%)	1 (4.2%)	3 (5.5%)
Grade 1	5 (11.9%)	2 (6.7%)	7 (9.7%)	2 (6.5%)	0	2 (3.6%)
Grade 2	2 (4.8%)	2 (6.7%)	4 (5.6%)	0	1 (4.2%)	1 (1.8%)
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Pruritus NEC (cont)						
Pruritus	4 (16.7%)	0	4 (12.1%)	0	1 (16.7%)	1 (5.6%)
Grade 1	3 (12.5%)	0	3 (9.1%)	0	0	0
Grade 2	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 3	0	0	0	0	1 (16.7%)	1 (5.6%)
Pruritus generalised	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	1 (4.2%)	0	1 (3.0%)	0	0	0
Apocrine and eccrine gland disorders	3 (12.5%)	2 (22.2%)	5 (15.2%)	1 (8.3%)	1 (16.7%)	2 (11.1%)
Grade 1	2 (8.3%)	1 (11.1%)	3 (9.1%)	1 (8.3%)	0	1 (5.6%)
Grade 2	1 (4.2%)	1 (11.1%)	2 (6.1%)	0	0	0
Grade 3	0	0	0	0	1 (16.7%)	1 (5.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Pruritus NEC (cont)						
Pruritus	6 (14.3%)	3 (10.0%)	9 (12.5%)	2 (6.5%)	0	2 (3.6%)
Grade 1	4 (9.5%)	2 (6.7%)	6 (8.3%)	2 (6.5%)	0	2 (3.6%)
Grade 2	2 (4.8%)	1 (3.3%)	3 (4.2%)	0	0	0
Grade 3	0	0	0	0	0	0
Pruritus generalised	1 (2.4%)	1 (3.3%)	2 (2.8%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 1	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Grade 2	0	1 (3.3%)	1 (1.4%)	0	1 (4.2%)	1 (1.8%)
Apocrine and eccrine gland disorders	3 (7.1%)	3 (10.0%)	6 (8.3%)	2 (6.5%)	3 (12.5%)	5 (9.1%)
Grade 1	3 (7.1%)	2 (6.7%)	5 (6.9%)	0	2 (8.3%)	2 (3.6%)
Grade 2	0	0	0	2 (6.5%)	0	2 (3.6%)
Grade 3	0	1 (3.3%)	1 (1.4%)	0	1 (4.2%)	1 (1.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Apocrine and eccrine gland disorders (cont)						
Night sweats	2 (8.3%)	1 (11.1%)	3 (9.1%)	0	0	0
Grade 1	1 (4.2%)	1 (11.1%)	2 (6.1%)	0	0	0
Grade 2	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 3	0	0	0	0	0	0
Hyperhidrosis	1 (4.2%)	1 (11.1%)	2 (6.1%)	1 (8.3%)	1 (16.7%)	2 (11.1%)
Grade 1	1 (4.2%)	0	1 (3.0%)	1 (8.3%)	0	1 (5.6%)
Grade 2	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 3	0	0	0	0	1 (16.7%)	1 (5.6%)
Rashes, eruptions and exanthems NEC	0	0	0	1 (8.3%)	0	1 (5.6%)
Grade 1	0	0	0	1 (8.3%)	0	1 (5.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Apocrine and eccrine gland disorders (cont)						
Night sweats	3 (7.1%)	1 (3.3%)	4 (5.6%)	2 (6.5%)	2 (8.3%)	4 (7.3%)
Grade 1	3 (7.1%)	1 (3.3%)	4 (5.6%)	0	1 (4.2%)	1 (1.8%)
Grade 2	0	0	0	2 (6.5%)	0	2 (3.6%)
Grade 3	0	0	0	0	1 (4.2%)	1 (1.8%)
Hyperhidrosis	1 (2.4%)	3 (10.0%)	4 (5.6%)	0	1 (4.2%)	1 (1.8%)
Grade 1	1 (2.4%)	2 (6.7%)	3 (4.2%)	0	1 (4.2%)	1 (1.8%)
Grade 2	0	0	0	0	0	0
Grade 3	0	1 (3.3%)	1 (1.4%)	0	0	0
Rashes, eruptions and exanthems NEC	3 (7.1%)	1 (3.3%)	4 (5.6%)	1 (3.2%)	0	1 (1.8%)
Grade 1	3 (7.1%)	1 (3.3%)	4 (5.6%)	1 (3.2%)	0	1 (1.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Rashes, eruptions and exanthems NEC (cont)						
Rash	0	0	0	1 (8.3%)	0	1 (5.6%)
Grade 1	0	0	0	1 (8.3%)	0	1 (5.6%)
Rash generalised	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Rash maculo-papular	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Purpura and related conditions	1 (4.2%)	1 (11.1%)	2 (6.1%)	0	0	0
Grade 1	1 (4.2%)	1 (11.1%)	2 (6.1%)	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Rashes, eruptions and exanthems NEC (cont)						
Rash	1 (2.4%)	1 (3.3%)	2 (2.8%)	0	0	0
Grade 1	1 (2.4%)	1 (3.3%)	2 (2.8%)	0	0	0
Rash generalised	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Rash maculo-papular	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Grade 1	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Purpura and related conditions	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	2 (8.3%)	3 (5.5%)
Grade 1	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 2	0	0	0	0	1 (4.2%)	1 (1.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Purpura and related conditions (cont)						
Ecchymosis	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Purpura senile	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Petechiae	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0
Purpura	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Dermal and epidermal conditions NEC	0	1 (11.1%)	1 (3.0%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Purpura and related conditions (cont)						
Ecchymosis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Purpura senile	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Petechiae	0	0	0	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 1	0	0	0	1 (3.2%)	1 (4.2%)	2 (3.6%)
Purpura	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 2	0	0	0	0	1 (4.2%)	1 (1.8%)
Dermal and epidermal conditions NEC	1 (2.4%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Dermal and epidermal conditions NEC (cont)						
(cont)						
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0
Dry skin	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Skin lesion	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0
Dermatitis ascribed to specific agent	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Dermal and epidermal conditions NEC (cont)						
(cont)						
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Dry skin	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Skin lesion	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dermatitis ascribed to specific agent	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Dermatitis ascribed to specific agent (cont)						
Palmar-plantar erythrodysaesthesia syndrome	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Alopecias	0	0	0	1 (8.3%)	0	1 (5.6%)
Grade 1	0	0	0	1 (8.3%)	0	1 (5.6%)
Alopecia	0	0	0	1 (8.3%)	0	1 (5.6%)
Grade 1	0	0	0	1 (8.3%)	0	1 (5.6%)
Angioedemas	0	0	0	1 (8.3%)	0	1 (5.6%)
Grade 1	0	0	0	1 (8.3%)	0	1 (5.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Dermatitis ascribed to specific agent (cont)						
Palmar-plantar erythrodysaesthesia syndrome	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Alopecias	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Alopecia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Angioedemas	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Angioedemas (cont)						
Swelling face	0	0	0	1 (8.3%)	0	1 (5.6%)
Grade 1	0	0	0	1 (8.3%)	0	1 (5.6%)
Erythemas	0	0	0	1 (8.3%)	0	1 (5.6%)
Grade 1	0	0	0	1 (8.3%)	0	1 (5.6%)
Erythema	0	0	0	1 (8.3%)	0	1 (5.6%)
Grade 1	0	0	0	1 (8.3%)	0	1 (5.6%)
Ichthyoses	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Xeroderma	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Angioedemas (cont)						
Swelling face	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Erythemas	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Erythema	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Ichthyoses	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 1	0	1 (3.3%)	1 (1.4%)	0	0	0
Xeroderma	0	1 (3.3%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Ichthyoses (cont)						
Xeroderma (cont)						
Grade 1	0	0	0	0	0	0
Skin and subcutaneous tissue ulcerations	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Skin ulcer	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Ichthyoses (cont)						
Xeroderma (cont)						
Grade 1	0	1 (3.3%)	1 (1.4%)	0	0	0
Skin and subcutaneous tissue ulcerations	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 2	0	1 (3.3%)	1 (1.4%)	0	0	0
Skin ulcer	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 2	0	1 (3.3%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders	8 (33.3%)	4 (44.4%)	12 (36.4%)	2 (16.7%)	3 (50.0%)	5 (27.8%)
Grade 1	6 (25.0%)	1 (11.1%)	7 (21.2%)	1 (8.3%)	2 (33.3%)	3 (16.7%)
Grade 2	1 (4.2%)	3 (33.3%)	4 (12.1%)	1 (8.3%)	1 (16.7%)	2 (11.1%)
Grade 3	1 (4.2%)	0	1 (3.0%)	0	0	0
Joint related signs and symptoms	1 (4.2%)	1 (11.1%)	2 (6.1%)	0	0	0
Grade 1	1 (4.2%)	1 (11.1%)	2 (6.1%)	0	0	0
Grade 2	0	0	0	0	0	0
Arthralgia	1 (4.2%)	1 (11.1%)	2 (6.1%)	0	0	0
Grade 1	1 (4.2%)	1 (11.1%)	2 (6.1%)	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders	13 (31.0%)	10 (33.3%)	23 (31.9%)	9 (29.0%)	2 (8.3%)	11 (20.0%)
Grade 1	7 (16.7%)	7 (23.3%)	14 (19.4%)	4 (12.9%)	1 (4.2%)	5 (9.1%)
Grade 2	5 (11.9%)	3 (10.0%)	8 (11.1%)	5 (16.1%)	1 (4.2%)	6 (10.9%)
Grade 3	1 (2.4%)	0	1 (1.4%)	0	0	0
Joint related signs and symptoms	7 (16.7%)	2 (6.7%)	9 (12.5%)	0	0	0
Grade 1	6 (14.3%)	2 (6.7%)	8 (11.1%)	0	0	0
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0
Arthralgia	7 (16.7%)	2 (6.7%)	9 (12.5%)	0	0	0
Grade 1	6 (14.3%)	2 (6.7%)	8 (11.1%)	0	0	0
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Musculoskeletal and connective tissue pain and discomfort	4 (16.7%)	2 (22.2%)	6 (18.2%)	1 (8.3%)	2 (33.3%)	3 (16.7%)
Grade 1	4 (16.7%)	1 (11.1%)	5 (15.2%)	1 (8.3%)	1 (16.7%)	2 (11.1%)
Grade 2	0	1 (11.1%)	1 (3.0%)	0	1 (16.7%)	1 (5.6%)
Pain in extremity	2 (8.3%)	0	2 (6.1%)	0	0	0
Grade 1	2 (8.3%)	0	2 (6.1%)	0	0	0
Grade 2	0	0	0	0	0	0
Back pain	1 (4.2%)	0	1 (3.0%)	1 (8.3%)	1 (16.7%)	2 (11.1%)
Grade 1	1 (4.2%)	0	1 (3.0%)	1 (8.3%)	1 (16.7%)	2 (11.1%)
Grade 2	0	0	0	0	0	0
Limb discomfort	1 (4.2%)	0	1 (3.0%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Musculoskeletal and connective tissue pain and discomfort	3 (7.1%)	6 (20.0%)	9 (12.5%)	7 (22.6%)	1 (4.2%)	8 (14.5%)
Grade 1	2 (4.8%)	6 (20.0%)	8 (11.1%)	3 (9.7%)	1 (4.2%)	4 (7.3%)
Grade 2	1 (2.4%)	0	1 (1.4%)	4 (12.9%)	0	4 (7.3%)
Pain in extremity	1 (2.4%)	4 (13.3%)	5 (6.9%)	5 (16.1%)	0	5 (9.1%)
Grade 1	1 (2.4%)	4 (13.3%)	5 (6.9%)	3 (9.7%)	0	3 (5.5%)
Grade 2	0	0	0	2 (6.5%)	0	2 (3.6%)
Back pain	1 (2.4%)	2 (6.7%)	3 (4.2%)	2 (6.5%)	0	2 (3.6%)
Grade 1	0	2 (6.7%)	2 (2.8%)	0	0	0
Grade 2	1 (2.4%)	0	1 (1.4%)	2 (6.5%)	0	2 (3.6%)
Limb discomfort	1 (2.4%)	1 (3.3%)	2 (2.8%)	0	1 (4.2%)	1 (1.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Musculoskeletal and connective tissue pain and discomfort (cont)						
Limb discomfort (cont)						
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Flank pain	0	2 (22.2%)	2 (6.1%)	0	0	0
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 2	0	1 (11.1%)	1 (3.0%)	0	0	0
Musculoskeletal chest pain	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Musculoskeletal pain	0	0	0	0	1 (16.7%)	1 (5.6%)
Grade 2	0	0	0	0	1 (16.7%)	1 (5.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Musculoskeletal and connective tissue pain and discomfort (cont)						
Limb discomfort (cont)						
Grade 1	1 (2.4%)	1 (3.3%)	2 (2.8%)	0	1 (4.2%)	1 (1.8%)
Flank pain	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 2	0	0	0	0	0	0
Musculoskeletal chest pain	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 1	0	0	0	1 (3.2%)	0	1 (1.8%)
Musculoskeletal pain	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Musculoskeletal and connective tissue pain and discomfort (cont)						
Neck pain	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Bone related signs and symptoms	0	2 (22.2%)	2 (6.1%)	1 (8.3%)	1 (16.7%)	2 (11.1%)
Grade 1	0	0	0	0	1 (16.7%)	1 (5.6%)
Grade 2	0	2 (22.2%)	2 (6.1%)	1 (8.3%)	0	1 (5.6%)
Bone pain	0	2 (22.2%)	2 (6.1%)	1 (8.3%)	1 (16.7%)	2 (11.1%)
Grade 1	0	0	0	0	1 (16.7%)	1 (5.6%)
Grade 2	0	2 (22.2%)	2 (6.1%)	1 (8.3%)	0	1 (5.6%)
Spinal pain	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Musculoskeletal and connective tissue pain and discomfort (cont)						
Neck pain	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 2	0	0	0	1 (3.2%)	0	1 (1.8%)
Bone related signs and symptoms	3 (7.1%)	2 (6.7%)	5 (6.9%)	1 (3.2%)	0	1 (1.8%)
Grade 1	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 2	3 (7.1%)	2 (6.7%)	5 (6.9%)	0	0	0
Bone pain	2 (4.8%)	2 (6.7%)	4 (5.6%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	2 (4.8%)	2 (6.7%)	4 (5.6%)	0	0	0
Spinal pain	1 (2.4%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Bone related signs and symptoms (cont)						
Spinal pain (cont)						
Grade 2	0	0	0	0	0	0
Metatarsalgia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Muscle related signs and symptoms NEC	2 (8.3%)	0	2 (6.1%)	0	1 (16.7%)	1 (5.6%)
Grade 1	2 (8.3%)	0	2 (6.1%)	0	1 (16.7%)	1 (5.6%)
Grade 2	0	0	0	0	0	0
Muscle spasms	2 (8.3%)	0	2 (6.1%)	0	1 (16.7%)	1 (5.6%)
Grade 1	2 (8.3%)	0	2 (6.1%)	0	1 (16.7%)	1 (5.6%)
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Bone related signs and symptoms (cont)						
Spinal pain (cont)						
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0
Metatarsalgia	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 1	0	0	0	1 (3.2%)	0	1 (1.8%)
Muscle related signs and symptoms NEC	1 (2.4%)	1 (3.3%)	2 (2.8%)	2 (6.5%)	0	2 (3.6%)
Grade 1	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Grade 2	0	1 (3.3%)	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Muscle spasms	1 (2.4%)	1 (3.3%)	2 (2.8%)	2 (6.5%)	0	2 (3.6%)
Grade 1	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Grade 2	0	1 (3.3%)	1 (1.4%)	1 (3.2%)	0	1 (1.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Muscle pains	2 (8.3%)	0	2 (6.1%)	0	0	0
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 2	1 (4.2%)	0	1 (3.0%)	0	0	0
Myalgia	2 (8.3%)	0	2 (6.1%)	0	0	0
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 2	1 (4.2%)	0	1 (3.0%)	0	0	0
Crystal arthropathic disorders	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 3	1 (4.2%)	0	1 (3.0%)	0	0	0
Gouty arthritis	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 3	1 (4.2%)	0	1 (3.0%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Muscle pains	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 1	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 2	0	0	0	0	0	0
Myalgia	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 1	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 2	0	0	0	0	0	0
Crystal arthropathic disorders	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Gouty arthritis	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Soft tissue disorders NEC	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Groin pain	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Arthropathies NEC	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0
Arthritis	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0
Bone disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Soft tissue disorders NEC	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 3	1 (2.4%)	0	1 (1.4%)	0	0	0
Groin pain	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 3	1 (2.4%)	0	1 (1.4%)	0	0	0
Arthropathies NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Arthritis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Bone disorders NEC	0	1 (3.3%)	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Grade 1	0	1 (3.3%)	1 (1.4%)	1 (3.2%)	0	1 (1.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Bone disorders NEC (cont)						
Bone lesion	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Osteosis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Bursal disorders	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Bursitis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Metabolic bone disorders	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Bone disorders NEC (cont)						
Bone lesion	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 1	0	1 (3.3%)	1 (1.4%)	0	0	0
Osteosis	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 1	0	0	0	1 (3.2%)	0	1 (1.8%)
Bursal disorders	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 2	0	0	0	1 (3.2%)	0	1 (1.8%)
Bursitis	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 2	0	0	0	1 (3.2%)	0	1 (1.8%)
Metabolic bone disorders	0	1 (3.3%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Metabolic bone disorders (cont) (cont)						
Grade 1	0	0	0	0	0	0
Osteoporosis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Muscle weakness conditions	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Muscular weakness	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Osteoarthropathies	0	1 (11.1%)	1 (3.0%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Metabolic bone disorders (cont) (cont)						
Grade 1	0	1 (3.3%)	1 (1.4%)	0	0	0
Osteoporosis	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 1	0	1 (3.3%)	1 (1.4%)	0	0	0
Muscle weakness conditions	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 2	0	0	0	0	1 (4.2%)	1 (1.8%)
Muscular weakness	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 2	0	0	0	0	1 (4.2%)	1 (1.8%)
Osteoarthropathies	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Osteoarthropathies (cont) (cont)						
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0
Osteoarthritis	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0
Spine and neck deformities	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0
Scoliosis	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0
Tendon disorders	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Osteoarthropathies (cont)						
(cont)						
Grade 1	0	0	0	0	0	0
Osteoarthritis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Spine and neck deformities	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Scoliosis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Tendon disorders	0	0	0	1 (3.2%)	0	1 (1.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Tendon disorders (cont)						
(cont)						
Grade 1	0	0	0	0	0	0
Tendonitis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Investigations	8 (33.3%)	1 (11.1%)	9 (27.3%)	1 (8.3%)	2 (33.3%)	3 (16.7%)
Grade 1	3 (12.5%)	0	3 (9.1%)	0	1 (16.7%)	1 (5.6%)
Grade 2	3 (12.5%)	1 (11.1%)	4 (12.1%)	1 (8.3%)	1 (16.7%)	2 (11.1%)
Grade 3	2 (8.3%)	0	2 (6.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Tendon disorders (cont)						
(cont)						
Grade 1	0	0	0	1 (3.2%)	0	1 (1.8%)
Tendonitis	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 1	0	0	0	1 (3.2%)	0	1 (1.8%)
Investigations	9 (21.4%)	2 (6.7%)	11 (15.3%)	6 (19.4%)	4 (16.7%)	10 (18.2%)
Grade 1	9 (21.4%)	1 (3.3%)	10 (13.9%)	5 (16.1%)	1 (4.2%)	6 (10.9%)
Grade 2	0	1 (3.3%)	1 (1.4%)	1 (3.2%)	2 (8.3%)	3 (5.5%)
Grade 3	0	0	0	0	1 (4.2%)	1 (1.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Physical examination procedures and organ system status	5 (20.8%)	0	5 (15.2%)	0	2 (33.3%)	2 (11.1%)
Grade 1	3 (12.5%)	0	3 (9.1%)	0	1 (16.7%)	1 (5.6%)
Grade 2	2 (8.3%)	0	2 (6.1%)	0	1 (16.7%)	1 (5.6%)
Weight decreased	4 (16.7%)	0	4 (12.1%)	0	2 (33.3%)	2 (11.1%)
Grade 1	2 (8.3%)	0	2 (6.1%)	0	1 (16.7%)	1 (5.6%)
Grade 2	2 (8.3%)	0	2 (6.1%)	0	1 (16.7%)	1 (5.6%)
Body temperature increased	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Weight increased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Physical examination procedures and organ system status	4 (9.5%)	1 (3.3%)	5 (6.9%)	2 (6.5%)	1 (4.2%)	3 (5.5%)
Grade 1	4 (9.5%)	0	4 (5.6%)	2 (6.5%)	1 (4.2%)	3 (5.5%)
Grade 2	0	1 (3.3%)	1 (1.4%)	0	0	0
Weight decreased	3 (7.1%)	1 (3.3%)	4 (5.6%)	0	1 (4.2%)	1 (1.8%)
Grade 1	3 (7.1%)	0	3 (4.2%)	0	1 (4.2%)	1 (1.8%)
Grade 2	0	1 (3.3%)	1 (1.4%)	0	0	0
Body temperature increased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Weight increased	1 (2.4%)	0	1 (1.4%)	2 (6.5%)	0	2 (3.6%)
Grade 1	1 (2.4%)	0	1 (1.4%)	2 (6.5%)	0	2 (3.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Liver function analyses	4 (16.7%)	1 (11.1%)	5 (15.2%)	0	0	0
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 2	2 (8.3%)	1 (11.1%)	3 (9.1%)	0	0	0
Grade 3	1 (4.2%)	0	1 (3.0%)	0	0	0
Blood bilirubin increased	2 (8.3%)	1 (11.1%)	3 (9.1%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	2 (8.3%)	1 (11.1%)	3 (9.1%)	0	0	0
Alanine aminotransferase increased	2 (8.3%)	0	2 (6.1%)	0	0	0
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 3	1 (4.2%)	0	1 (3.0%)	0	0	0
Aspartate aminotransferase increased	2 (8.3%)	0	2 (6.1%)	0	0	0
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Liver function analyses	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 1	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	1 (4.2%)	1 (1.8%)
Blood bilirubin increased	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 2	0	0	0	0	0	0
Alanine aminotransferase increased	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 1	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 3	0	0	0	0	0	0
Aspartate aminotransferase increased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Liver function analyses (cont)						
Aspartate aminotransferase increased (cont)						
Grade 2	1 (4.2%)	0	1 (3.0%)	0	0	0
Gamma-glutamyltransferase increased	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	1 (4.2%)	0	1 (3.0%)	0	0	0
Liver function test increased	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Renal function analyses	1 (4.2%)	0	1 (3.0%)	1 (8.3%)	0	1 (5.6%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	1 (8.3%)	0	1 (5.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Liver function analyses (cont)						
Aspartate aminotransferase increased (cont)						
Grade 2	0	0	0	0	0	0
Gamma-glutamyltransferase increased	0	0	0	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 1	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 3	0	0	0	0	1 (4.2%)	1 (1.8%)
Liver function test increased	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 3	0	0	0	0	1 (4.2%)	1 (1.8%)
Renal function analyses	2 (4.8%)	0	2 (2.8%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 1	2 (4.8%)	0	2 (2.8%)	0	0	0
Grade 2	0	0	0	1 (3.2%)	1 (4.2%)	2 (3.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Renal function analyses (cont)						
(cont)						
Grade 3	1 (4.2%)	0	1 (3.0%)	0	0	0
Blood creatinine increased	1 (4.2%)	0	1 (3.0%)	1 (8.3%)	0	1 (5.6%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	1 (8.3%)	0	1 (5.6%)
Grade 3	1 (4.2%)	0	1 (3.0%)	0	0	0
Tissue enzyme analyses NEC	1 (4.2%)	1 (11.1%)	2 (6.1%)	0	0	0
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 2	1 (4.2%)	0	1 (3.0%)	0	0	0
Blood alkaline phosphatase increased	1 (4.2%)	1 (11.1%)	2 (6.1%)	0	0	0
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Renal function analyses (cont)						
(cont)						
Grade 3	0	0	0	0	0	0
Blood creatinine increased	2 (4.8%)	0	2 (2.8%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 1	2 (4.8%)	0	2 (2.8%)	0	0	0
Grade 2	0	0	0	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 3	0	0	0	0	0	0
Tissue enzyme analyses NEC	2 (4.8%)	0	2 (2.8%)	1 (3.2%)	0	1 (1.8%)
Grade 1	2 (4.8%)	0	2 (2.8%)	1 (3.2%)	0	1 (1.8%)
Grade 2	0	0	0	0	0	0
Blood alkaline phosphatase increased	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Grade 1	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	0	1 (1.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Tissue enzyme analyses NEC (cont)						
Blood alkaline phosphatase increased (cont)						
Grade 2	1 (4.2%)	0	1 (3.0%)	0	0	0
Blood lactate dehydrogenase increased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Cardiac auscultatory investigations	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Cardiac murmur	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Tissue enzyme analyses NEC (cont)						
Blood alkaline phosphatase increased (cont)						
Grade 2	0	0	0	0	0	0
Blood lactate dehydrogenase increased	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Cardiac auscultatory investigations	2 (4.8%)	0	2 (2.8%)	1 (3.2%)	0	1 (1.8%)
Grade 1	2 (4.8%)	0	2 (2.8%)	1 (3.2%)	0	1 (1.8%)
Cardiac murmur	2 (4.8%)	0	2 (2.8%)	1 (3.2%)	0	1 (1.8%)
Grade 1	2 (4.8%)	0	2 (2.8%)	1 (3.2%)	0	1 (1.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Coagulation and bleeding analyses	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 2	0	0	0	0	0	0
International normalised ratio increased	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 2	0	0	0	0	0	0
Cardiac function diagnostic procedures	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Ejection fraction decreased	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Coagulation and bleeding analyses	0	0	0	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 1	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 2	0	0	0	0	1 (4.2%)	1 (1.8%)
International normalised ratio increased	0	0	0	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 1	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 2	0	0	0	0	1 (4.2%)	1 (1.8%)
Cardiac function diagnostic procedures	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 2	0	0	0	0	1 (4.2%)	1 (1.8%)
Ejection fraction decreased	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 2	0	0	0	0	1 (4.2%)	1 (1.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Mineral and electrolyte analyses	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Blood bicarbonate decreased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Vascular tests NEC (incl blood pressure)	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Blood pressure increased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Mineral and electrolyte analyses	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 1	0	0	0	1 (3.2%)	0	1 (1.8%)
Blood bicarbonate decreased	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 1	0	0	0	1 (3.2%)	0	1 (1.8%)
Vascular tests NEC (incl blood pressure)	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 1	0	1 (3.3%)	1 (1.4%)	0	0	0
Blood pressure increased	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 1	0	1 (3.3%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders	5 (20.8%)	0	5 (15.2%)	2 (16.7%)	1 (16.7%)	3 (16.7%)
Grade 1	1 (4.2%)	0	1 (3.0%)	0	1 (16.7%)	1 (5.6%)
Grade 2	1 (4.2%)	0	1 (3.0%)	1 (8.3%)	0	1 (5.6%)
Grade 3	2 (8.3%)	0	2 (6.1%)	1 (8.3%)	0	1 (5.6%)
Grade 4	1 (4.2%)	0	1 (3.0%)	0	0	0
Vascular hypertensive disorders NEC	3 (12.5%)	0	3 (9.1%)	2 (16.7%)	0	2 (11.1%)
Grade 2	1 (4.2%)	0	1 (3.0%)	1 (8.3%)	0	1 (5.6%)
Grade 3	1 (4.2%)	0	1 (3.0%)	1 (8.3%)	0	1 (5.6%)
Grade 4	1 (4.2%)	0	1 (3.0%)	0	0	0
Hypertension	3 (12.5%)	0	3 (9.1%)	2 (16.7%)	0	2 (11.1%)
Grade 2	1 (4.2%)	0	1 (3.0%)	1 (8.3%)	0	1 (5.6%)
Grade 3	1 (4.2%)	0	1 (3.0%)	1 (8.3%)	0	1 (5.6%)
Grade 4	1 (4.2%)	0	1 (3.0%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders	4 (9.5%)	2 (6.7%)	6 (8.3%)	2 (6.5%)	5 (20.8%)	7 (12.7%)
Grade 1	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 2	3 (7.1%)	1 (3.3%)	4 (5.6%)	0	3 (12.5%)	3 (5.5%)
Grade 3	0	1 (3.3%)	1 (1.4%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 4	0	0	0	0	0	0
Vascular hypertensive disorders NEC	3 (7.1%)	0	3 (4.2%)	0	1 (4.2%)	1 (1.8%)
Grade 2	3 (7.1%)	0	3 (4.2%)	0	1 (4.2%)	1 (1.8%)
Grade 3	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Hypertension	3 (7.1%)	0	3 (4.2%)	0	1 (4.2%)	1 (1.8%)
Grade 2	3 (7.1%)	0	3 (4.2%)	0	1 (4.2%)	1 (1.8%)
Grade 3	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Vascular hypotensive disorders	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 2	0	0	0	0	0	0
Hypotension	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Orthostatic hypotension	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Aortic necrosis and vascular insufficiency	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 3	1 (4.2%)	0	1 (3.0%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Vascular hypotensive disorders	1 (2.4%)	0	1 (1.4%)	0	2 (8.3%)	2 (3.6%)
Grade 1	1 (2.4%)	0	1 (1.4%)	0	1 (4.2%)	1 (1.8%)
Grade 2	0	0	0	0	1 (4.2%)	1 (1.8%)
Hypotension	1 (2.4%)	0	1 (1.4%)	0	2 (8.3%)	2 (3.6%)
Grade 1	1 (2.4%)	0	1 (1.4%)	0	1 (4.2%)	1 (1.8%)
Grade 2	0	0	0	0	1 (4.2%)	1 (1.8%)
Orthostatic hypotension	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Aortic necrosis and vascular insufficiency	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Aortic necrosis and vascular insufficiency (cont)						
Aortic stenosis	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 3	1 (4.2%)	0	1 (3.0%)	0	0	0
Peripheral vascular disorders NEC	0	0	0	0	1 (16.7%)	1 (5.6%)
Grade 1	0	0	0	0	1 (16.7%)	1 (5.6%)
Hot flush	0	0	0	0	1 (16.7%)	1 (5.6%)
Grade 1	0	0	0	0	1 (16.7%)	1 (5.6%)
Haemorrhages NEC	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Haematoma	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Aortic necrosis and vascular insufficiency (cont)						
Aortic stenosis	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Peripheral vascular disorders NEC	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Hot flush	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Haemorrhages NEC	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 3	0	0	0	0	1 (4.2%)	1 (1.8%)
Haematoma	0	0	0	0	1 (4.2%)	1 (1.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Haemorrhages NEC (cont)						
Haematoma (cont)						
Grade 3	0	0	0	0	0	0
Non-site specific embolism and thrombosis	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Embolism	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Non-site specific necrosis and vascular insufficiency NEC	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Haemorrhages NEC (cont)						
Haematoma (cont)						
Grade 3	0	0	0	0	1 (4.2%)	1 (1.8%)
Non-site specific embolism and thrombosis	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 3	0	0	0	1 (3.2%)	0	1 (1.8%)
Embolism	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 3	0	0	0	1 (3.2%)	0	1 (1.8%)
Non-site specific necrosis and vascular insufficiency NEC	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 2	0	1 (3.3%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Non-site specific necrosis and vascular insufficiency NEC (cont)						
Peripheral venous disease	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Non-site specific vascular disorders NEC	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Arterial disorder	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Peripheral embolism and thrombosis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Non-site specific necrosis and vascular insufficiency NEC (cont)						
Peripheral venous disease	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 2	0	1 (3.3%)	1 (1.4%)	0	0	0
Non-site specific vascular disorders NEC	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 3	0	1 (3.3%)	1 (1.4%)	0	0	0
Arterial disorder	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 3	0	1 (3.3%)	1 (1.4%)	0	0	0
Peripheral embolism and thrombosis	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 2	0	0	0	0	1 (4.2%)	1 (1.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Peripheral embolism and thrombosis (cont)						
Thrombophlebitis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Peripheral vasoconstriction, necrosis and vascular insufficiency	0	0	0	0	1 (16.7%)	1 (5.6%)
Grade 1	0	0	0	0	1 (16.7%)	1 (5.6%)
Grade 3	0	0	0	0	0	0
Diabetic vascular disorder	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Peripheral coldness	0	0	0	0	1 (16.7%)	1 (5.6%)
Grade 1	0	0	0	0	1 (16.7%)	1 (5.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Peripheral embolism and thrombosis (cont)						
Thrombophlebitis	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 2	0	0	0	0	1 (4.2%)	1 (1.8%)
Peripheral vasoconstriction, necrosis and vascular insufficiency	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	1 (3.3%)	1 (1.4%)	0	0	0
Diabetic vascular disorder	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 3	0	1 (3.3%)	1 (1.4%)	0	0	0
Peripheral coldness	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Site specific vascular disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Jugular vein distension	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Cardiac disorders	3 (12.5%)	1 (11.1%)	4 (12.1%)	1 (8.3%)	0	1 (5.6%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	1 (8.3%)	0	1 (5.6%)
Grade 3	3 (12.5%)	1 (11.1%)	4 (12.1%)	0	0	0
Grade 4	0	0	0	0	0	0
Heart failures NEC	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	1 (4.2%)	0	1 (3.0%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Site specific vascular disorders NEC	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 1	0	0	0	1 (3.2%)	0	1 (1.8%)
Jugular vein distension	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 1	0	0	0	1 (3.2%)	0	1 (1.8%)
Cardiac disorders	5 (11.9%)	4 (13.3%)	9 (12.5%)	3 (9.7%)	4 (16.7%)	7 (12.7%)
Grade 1	1 (2.4%)	1 (3.3%)	2 (2.8%)	0	0	0
Grade 2	1 (2.4%)	2 (6.7%)	3 (4.2%)	1 (3.2%)	3 (12.5%)	4 (7.3%)
Grade 3	3 (7.1%)	1 (3.3%)	4 (5.6%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 4	0	0	0	1 (3.2%)	0	1 (1.8%)
Heart failures NEC	3 (7.1%)	1 (3.3%)	4 (5.6%)	2 (6.5%)	1 (4.2%)	3 (5.5%)
Grade 2	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 3	3 (7.1%)	0	3 (4.2%)	2 (6.5%)	1 (4.2%)	3 (5.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Heart failures NEC (cont)						
Cardiac failure	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 3	1 (4.2%)	0	1 (3.0%)	0	0	0
Cardiac failure congestive	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Supraventricular arrhythmias	3 (12.5%)	0	3 (9.1%)	1 (8.3%)	0	1 (5.6%)
Grade 2	0	0	0	1 (8.3%)	0	1 (5.6%)
Grade 3	3 (12.5%)	0	3 (9.1%)	0	0	0
Grade 4	0	0	0	0	0	0
Atrial fibrillation	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Heart failures NEC (cont)						
Cardiac failure	2 (4.8%)	0	2 (2.8%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 3	2 (4.8%)	0	2 (2.8%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Cardiac failure congestive	1 (2.4%)	1 (3.3%)	2 (2.8%)	1 (3.2%)	0	1 (1.8%)
Grade 2	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 3	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Supraventricular arrhythmias	1 (2.4%)	2 (6.7%)	3 (4.2%)	2 (6.5%)	1 (4.2%)	3 (5.5%)
Grade 2	1 (2.4%)	1 (3.3%)	2 (2.8%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 3	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 4	0	0	0	1 (3.2%)	0	1 (1.8%)
Atrial fibrillation	1 (2.4%)	2 (6.7%)	3 (4.2%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 2	1 (2.4%)	1 (3.3%)	2 (2.8%)	0	1 (4.2%)	1 (1.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Supraventricular arrhythmias (cont)						
Atrial fibrillation (cont)						
Grade 3	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 4	0	0	0	0	0	0
Sinus tachycardia	1 (4.2%)	0	1 (3.0%)	1 (8.3%)	0	1 (5.6%)
Grade 2	0	0	0	1 (8.3%)	0	1 (5.6%)
Grade 3	1 (4.2%)	0	1 (3.0%)	0	0	0
Supraventricular tachycardia	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 3	1 (4.2%)	0	1 (3.0%)	0	0	0
Cardiac signs and symptoms NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Supraventricular arrhythmias (cont)						
Atrial fibrillation (cont)						
Grade 3	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 4	0	0	0	1 (3.2%)	0	1 (1.8%)
Sinus tachycardia	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 2	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 3	0	0	0	0	0	0
Supraventricular tachycardia	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Cardiac signs and symptoms NEC	1 (2.4%)	1 (3.3%)	2 (2.8%)	0	0	0
Grade 1	1 (2.4%)	1 (3.3%)	2 (2.8%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Cardiac signs and symptoms NEC (cont)						
Palpitations	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Ischaemic coronary artery disorders	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Myocardial ischaemia	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Left ventricular failures	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Left ventricular failure	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Cardiac signs and symptoms NEC (cont)						
Palpitations	1 (2.4%)	1 (3.3%)	2 (2.8%)	0	0	0
Grade 1	1 (2.4%)	1 (3.3%)	2 (2.8%)	0	0	0
Ischaemic coronary artery disorders	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 2	0	0	0	0	1 (4.2%)	1 (1.8%)
Myocardial ischaemia	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 2	0	0	0	0	1 (4.2%)	1 (1.8%)
Left ventricular failures	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 2	0	0	0	1 (3.2%)	0	1 (1.8%)
Left ventricular failure	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 2	0	0	0	1 (3.2%)	0	1 (1.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Pericardial disorders NEC	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Pericardial effusion	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Rate and rhythm disorders NEC	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 3	0	1 (11.1%)	1 (3.0%)	0	0	0
Tachycardia	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 3	0	1 (11.1%)	1 (3.0%)	0	0	0
Psychiatric disorders	1 (4.2%)	2 (22.2%)	3 (9.1%)	0	1 (16.7%)	1 (5.6%)
Grade 1	1 (4.2%)	1 (11.1%)	2 (6.1%)	0	0	0
Grade 2	0	1 (11.1%)	1 (3.0%)	0	1 (16.7%)	1 (5.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Pericardial disorders NEC	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 2	0	0	0	0	1 (4.2%)	1 (1.8%)
Pericardial effusion	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 2	0	0	0	0	1 (4.2%)	1 (1.8%)
Rate and rhythm disorders NEC	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Tachycardia	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Psychiatric disorders	7 (16.7%)	3 (10.0%)	10 (13.9%)	3 (9.7%)	4 (16.7%)	7 (12.7%)
Grade 1	3 (7.1%)	3 (10.0%)	6 (8.3%)	1 (3.2%)	2 (8.3%)	3 (5.5%)
Grade 2	4 (9.5%)	0	4 (5.6%)	2 (6.5%)	2 (8.3%)	4 (7.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Anxiety symptoms	1 (4.2%)	1 (11.1%)	2 (6.1%)	0	0	0
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 2	0	1 (11.1%)	1 (3.0%)	0	0	0
Agitation	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Anxiety	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (11.1%)	1 (3.0%)	0	0	0
Depressive disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Anxiety symptoms	2 (4.8%)	0	2 (2.8%)	1 (3.2%)	0	1 (1.8%)
Grade 1	2 (4.8%)	0	2 (2.8%)	0	0	0
Grade 2	0	0	0	1 (3.2%)	0	1 (1.8%)
Agitation	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Anxiety	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 2	0	0	0	1 (3.2%)	0	1 (1.8%)
Depressive disorders	2 (4.8%)	1 (3.3%)	3 (4.2%)	0	0	0
Grade 1	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 2	2 (4.8%)	0	2 (2.8%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Depressive disorders (cont)						
Depression	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Disturbances in initiating and maintaining sleep	0	1 (11.1%)	1 (3.0%)	0	1 (16.7%)	1 (5.6%)
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 2	0	0	0	0	1 (16.7%)	1 (5.6%)
Insomnia	0	1 (11.1%)	1 (3.0%)	0	1 (16.7%)	1 (5.6%)
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 2	0	0	0	0	1 (16.7%)	1 (5.6%)
Confusion and disorientation	0	1 (11.1%)	1 (3.0%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Depressive disorders (cont)						
Depression	2 (4.8%)	1 (3.3%)	3 (4.2%)	0	0	0
Grade 1	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 2	2 (4.8%)	0	2 (2.8%)	0	0	0
Disturbances in initiating and maintaining sleep	2 (4.8%)	2 (6.7%)	4 (5.6%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 1	1 (2.4%)	2 (6.7%)	3 (4.2%)	0	1 (4.2%)	1 (1.8%)
Grade 2	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Insomnia	2 (4.8%)	2 (6.7%)	4 (5.6%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 1	1 (2.4%)	2 (6.7%)	3 (4.2%)	0	1 (4.2%)	1 (1.8%)
Grade 2	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Confusion and disorientation	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	2 (8.3%)	3 (5.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Confusion and disorientation (cont) (cont)						
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 2	0	0	0	0	0	0
Confusional state	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 2	0	0	0	0	0	0
Emotional and mood disturbances NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Irritability	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Confusion and disorientation (cont)						
(cont)						
Grade 1	0	0	0	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 2	1 (2.4%)	0	1 (1.4%)	0	1 (4.2%)	1 (1.8%)
Confusional state	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	2 (8.3%)	3 (5.5%)
Grade 1	0	0	0	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 2	1 (2.4%)	0	1 (1.4%)	0	1 (4.2%)	1 (1.8%)
Emotional and mood disturbances NEC	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Irritability	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Increased physical activity levels	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Restlessness	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Deliria	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Delirium	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Mood alterations with depressive symptoms	0	1 (11.1%)	1 (3.0%)	0	1 (16.7%)	1 (5.6%)
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Increased physical activity levels	1 (2.4%)	1 (3.3%)	2 (2.8%)	0	0	0
Grade 1	1 (2.4%)	1 (3.3%)	2 (2.8%)	0	0	0
Restlessness	1 (2.4%)	1 (3.3%)	2 (2.8%)	0	0	0
Grade 1	1 (2.4%)	1 (3.3%)	2 (2.8%)	0	0	0
Deliria	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 2	0	0	0	0	1 (4.2%)	1 (1.8%)
Delirium	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 2	0	0	0	0	1 (4.2%)	1 (1.8%)
Mood alterations with depressive symptoms	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Mood alterations with depressive symptoms (cont)						
(cont)						
Grade 2	0	0	0	0	1 (16.7%)	1 (5.6%)
Depressed mood	0	1 (11.1%)	1 (3.0%)	0	1 (16.7%)	1 (5.6%)
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 2	0	0	0	0	1 (16.7%)	1 (5.6%)
Eye disorders	2 (8.3%)	1 (11.1%)	3 (9.1%)	0	1 (16.7%)	1 (5.6%)
Grade 1	1 (4.2%)	1 (11.1%)	2 (6.1%)	0	1 (16.7%)	1 (5.6%)
Grade 2	1 (4.2%)	0	1 (3.0%)	0	0	0
Cataract conditions	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Mood alterations with depressive symptoms (cont) (cont)						
Grade 2	0	0	0	0	0	0
Depressed mood	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Eye disorders	5 (11.9%)	3 (10.0%)	8 (11.1%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 1	3 (7.1%)	3 (10.0%)	6 (8.3%)	1 (3.2%)	0	1 (1.8%)
Grade 2	2 (4.8%)	0	2 (2.8%)	0	1 (4.2%)	1 (1.8%)
Cataract conditions	2 (4.8%)	0	2 (2.8%)	0	0	0
Grade 1	2 (4.8%)	0	2 (2.8%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Cataract conditions (cont)						
(cont)						
Grade 2	1 (4.2%)	0	1 (3.0%)	0	0	0
Cataract	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 2	1 (4.2%)	0	1 (3.0%)	0	0	0
Cataract nuclear	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Cataract subcapsular	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Cataract conditions (cont)						
(cont)						
Grade 2	0	0	0	0	0	0
Cataract	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Cataract nuclear	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Cataract subcapsular	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Conjunctival and corneal bleeding and vascular disorders	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 2	0	0	0	0	0	0
Conjunctival haemorrhage	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Corneal bleeding	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0
Visual disorders NEC	1 (4.2%)	0	1 (3.0%)	0	1 (16.7%)	1 (5.6%)
Grade 1	1 (4.2%)	0	1 (3.0%)	0	1 (16.7%)	1 (5.6%)
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Conjunctival and corneal bleeding and vascular disorders	2 (4.8%)	1 (3.3%)	3 (4.2%)	0	0	0
Grade 1	1 (2.4%)	1 (3.3%)	2 (2.8%)	0	0	0
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0
Conjunctival haemorrhage	2 (4.8%)	1 (3.3%)	3 (4.2%)	0	0	0
Grade 1	1 (2.4%)	1 (3.3%)	2 (2.8%)	0	0	0
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0
Corneal bleeding	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Visual disorders NEC	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Grade 1	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Visual disorders NEC (cont)						
Vision blurred	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 2	0	0	0	0	0	0
Photopsia	0	0	0	0	1 (16.7%)	1 (5.6%)
Grade 1	0	0	0	0	1 (16.7%)	1 (5.6%)
Grade 2	0	0	0	0	0	0
Lacrimation disorders	0	0	0	0	1 (16.7%)	1 (5.6%)
Grade 1	0	0	0	0	1 (16.7%)	1 (5.6%)
Grade 2	0	0	0	0	0	0
Lacrimation increased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Visual disorders NEC (cont)						
Vision blurred	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Grade 1	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0
Photopsia	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0
Lacrimation disorders	1 (2.4%)	0	1 (1.4%)	0	1 (4.2%)	1 (1.8%)
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 2	0	0	0	0	1 (4.2%)	1 (1.8%)
Lacrimation increased	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Lacrimation disorders (cont)						
Dry eye	0	0	0	0	1 (16.7%)	1 (5.6%)
Grade 1	0	0	0	0	1 (16.7%)	1 (5.6%)
Grade 2	0	0	0	0	0	0
Ocular infections, inflammations and associated manifestations	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0
Ocular hyperaemia	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0
Retinal structural change, deposit and degeneration	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Lacrimation disorders (cont)						
Dry eye	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (4.2%)	1 (1.8%)
Ocular infections, inflammations and associated manifestations	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Ocular hyperaemia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Retinal structural change, deposit and degeneration	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 1	0	1 (3.3%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Retinal structural change, deposit and degeneration (cont)						
Myopic chorioretinal degeneration	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Visual impairment and blindness (excl colour blindness)	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Visual acuity reduced	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Retinal structural change, deposit and degeneration (cont)						
Myopic chorioretinal degeneration	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 1	0	1 (3.3%)	1 (1.4%)	0	0	0
Visual impairment and blindness (excl colour blindness)	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 1	0	1 (3.3%)	1 (1.4%)	0	0	0
Visual acuity reduced	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 1	0	1 (3.3%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications	0	1 (11.1%)	1 (3.0%)	0	1 (16.7%)	1 (5.6%)
Grade 1	0	0	0	0	1 (16.7%)	1 (5.6%)
Grade 2	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 3	0	0	0	0	0	0
Skin injuries NEC	0	1 (11.1%)	1 (3.0%)	0	1 (16.7%)	1 (5.6%)
Grade 1	0	0	0	0	1 (16.7%)	1 (5.6%)
Grade 2	0	1 (11.1%)	1 (3.0%)	0	0	0
Contusion	0	1 (11.1%)	1 (3.0%)	0	1 (16.7%)	1 (5.6%)
Grade 1	0	0	0	0	1 (16.7%)	1 (5.6%)
Grade 2	0	1 (11.1%)	1 (3.0%)	0	0	0
Limb fractures and dislocations	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications	7 (16.7%)	3 (10.0%)	10 (13.9%)	2 (6.5%)	1 (4.2%)	3 (5.5%)
Grade 1	5 (11.9%)	2 (6.7%)	7 (9.7%)	2 (6.5%)	0	2 (3.6%)
Grade 2	1 (2.4%)	1 (3.3%)	2 (2.8%)	0	1 (4.2%)	1 (1.8%)
Grade 3	1 (2.4%)	0	1 (1.4%)	0	0	0
Skin injuries NEC	5 (11.9%)	2 (6.7%)	7 (9.7%)	0	0	0
Grade 1	5 (11.9%)	2 (6.7%)	7 (9.7%)	0	0	0
Grade 2	0	0	0	0	0	0
Contusion	5 (11.9%)	2 (6.7%)	7 (9.7%)	0	0	0
Grade 1	5 (11.9%)	2 (6.7%)	7 (9.7%)	0	0	0
Grade 2	0	0	0	0	0	0
Limb fractures and dislocations	2 (4.8%)	0	2 (2.8%)	0	0	0
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Limb fractures and dislocations (cont) (cont)						
Grade 3	0	0	0	0	0	0
Femur fracture	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Radius fracture	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Non-site specific injuries NEC	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Limb fractures and dislocations (cont) (cont)						
Grade 3	1 (2.4%)	0	1 (1.4%)	0	0	0
Femur fracture	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 3	1 (2.4%)	0	1 (1.4%)	0	0	0
Radius fracture	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0
Non-site specific injuries NEC	1 (2.4%)	2 (6.7%)	3 (4.2%)	2 (6.5%)	0	2 (3.6%)
Grade 1	0	1 (3.3%)	1 (1.4%)	2 (6.5%)	0	2 (3.6%)
Grade 2	1 (2.4%)	1 (3.3%)	2 (2.8%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Non-site specific injuries NEC (cont)						
Fall	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 2	0	0	0	0	0	0
Post-traumatic pain	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Muscle, tendon and ligament injuries	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Muscle rupture	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Non-site specific injuries NEC (cont)						
Fall	1 (2.4%)	1 (3.3%)	2 (2.8%)	2 (6.5%)	0	2 (3.6%)
Grade 1	0	1 (3.3%)	1 (1.4%)	2 (6.5%)	0	2 (3.6%)
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0
Post-traumatic pain	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 2	0	1 (3.3%)	1 (1.4%)	0	0	0
Muscle, tendon and ligament injuries	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 2	0	0	0	0	1 (4.2%)	1 (1.8%)
Muscle rupture	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 2	0	0	0	0	1 (4.2%)	1 (1.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Non-site specific procedural complications	0	0	0	0	1 (16.7%)	1 (5.6%)
Grade 1	0	0	0	0	1 (16.7%)	1 (5.6%)
Procedural pain	0	0	0	0	1 (16.7%)	1 (5.6%)
Grade 1	0	0	0	0	1 (16.7%)	1 (5.6%)
Site specific injuries NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Limb injury	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Non-site specific procedural complications	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Procedural pain	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Site specific injuries NEC	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 1	0	1 (3.3%)	1 (1.4%)	0	0	0
Limb injury	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 1	0	1 (3.3%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (8.3%)	0	2 (6.1%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 3	0	0	0	0	0	0
Grade 4	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 5	0	0	0	0	0	0
Skin neoplasms malignant and unspecified (excl melanoma)	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Basal cell carcinoma	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Bowen's disease	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	5 (11.9%)	4 (13.3%)	9 (12.5%)	3 (9.7%)	0	3 (5.5%)
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 2	3 (7.1%)	1 (3.3%)	4 (5.6%)	2 (6.5%)	0	2 (3.6%)
Grade 3	0	1 (3.3%)	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Grade 4	0	0	0	0	0	0
Grade 5	1 (2.4%)	2 (6.7%)	3 (4.2%)	0	0	0
Skin neoplasms malignant and unspecified (excl melanoma)	2 (4.8%)	1 (3.3%)	3 (4.2%)	1 (3.2%)	0	1 (1.8%)
Grade 2	2 (4.8%)	1 (3.3%)	3 (4.2%)	1 (3.2%)	0	1 (1.8%)
Basal cell carcinoma	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0
Bowen's disease	1 (2.4%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Skin neoplasms malignant and unspecified (excl melanoma) (cont)						
Bowen's disease (cont)						
Grade 2	0	0	0	0	0	0
Carcinoma in situ of skin	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Squamous cell carcinoma of skin	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Bladder neoplasms malignant	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 2	1 (4.2%)	0	1 (3.0%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Skin neoplasms malignant and unspecified (excl melanoma) (cont)						
Bowen's disease (cont)						
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0
Carcinoma in situ of skin	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0
Squamous cell carcinoma of skin	1 (2.4%)	1 (3.3%)	2 (2.8%)	1 (3.2%)	0	1 (1.8%)
Grade 2	1 (2.4%)	1 (3.3%)	2 (2.8%)	1 (3.2%)	0	1 (1.8%)
Bladder neoplasms malignant	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Bladder neoplasms malignant (cont)						
Bladder cancer	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 2	1 (4.2%)	0	1 (3.0%)	0	0	0
Leukaemias NEC	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 3	0	0	0	0	0	0
Grade 4	1 (4.2%)	0	1 (3.0%)	0	0	0
Leukaemia	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 3	0	0	0	0	0	0
Grade 4	1 (4.2%)	0	1 (3.0%)	0	0	0
Leukaemias acute myeloid	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Bladder neoplasms malignant (cont)						
Bladder cancer	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Leukaemias NEC	0	1 (3.3%)	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Grade 3	0	1 (3.3%)	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Grade 4	0	0	0	0	0	0
Leukaemia	0	1 (3.3%)	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Grade 3	0	1 (3.3%)	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Grade 4	0	0	0	0	0	0
Leukaemias acute myeloid	1 (2.4%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Leukaemias acute myeloid (cont) (cont)						
Grade 5	0	0	0	0	0	0
Acute myeloid leukaemia	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Upper gastrointestinal neoplasms benign	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Oesophageal papilloma	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cts and polyps) (cont)						
Leukaemias acute myeloid (cont)						
(cont)						
Grade 5	1 (2.4%)	0	1 (1.4%)	0	0	0
Acute myeloid leukaemia	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 5	1 (2.4%)	0	1 (1.4%)	0	0	0
Upper gastrointestinal neoplasms benign	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Oesophageal papilloma	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cists and polyps) (cont)						
Urinary tract neoplasms malignant NEC	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Transitional cell carcinoma	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Myeloproliferative disorders (excl leukaemias)	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Myelofibrosis	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Urinary tract neoplasms malignant NEC	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0
Transitional cell carcinoma	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0
Myeloproliferative disorders (excl leukaemias)	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 5	0	1 (3.3%)	1 (1.4%)	0	0	0
Myelofibrosis	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 5	0	1 (3.3%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Non-small cell neoplasms malignant of the respiratory tract cell type specified	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Lung adenocarcinoma	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Urinary tract neoplasms unspecified malignancy NEC	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Bladder neoplasm	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Non-small cell neoplasms malignant of the respiratory tract cell type specified	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 5	0	1 (3.3%)	1 (1.4%)	0	0	0
Lung adenocarcinoma	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 5	0	1 (3.3%)	1 (1.4%)	0	0	0
Urinary tract neoplasms unspecified malignancy NEC	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 2	0	0	0	1 (3.2%)	0	1 (1.8%)
Bladder neoplasm	0	0	0	1 (3.2%)	0	1 (1.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Urinary tract neoplasms unspecified malignancy NEC (cont)						
Bladder neoplasm (cont)						
Grade 2	0	0	0	0	0	0
Renal and urinary disorders	3 (12.5%)	1 (11.1%)	4 (12.1%)	1 (8.3%)	1 (16.7%)	2 (11.1%)
Grade 1	2 (8.3%)	0	2 (6.1%)	0	1 (16.7%)	1 (5.6%)
Grade 2	1 (4.2%)	1 (11.1%)	2 (6.1%)	0	0	0
Grade 3	0	0	0	1 (8.3%)	0	1 (5.6%)
Renal failure and impairment	2 (8.3%)	1 (11.1%)	3 (9.1%)	0	0	0
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 2	1 (4.2%)	1 (11.1%)	2 (6.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Urinary tract neoplasms unspecified malignancy NEC (cont)						
Bladder neoplasm (cont)						
Grade 2	0	0	0	1 (3.2%)	0	1 (1.8%)
Renal and urinary disorders	2 (4.8%)	2 (6.7%)	4 (5.6%)	6 (19.4%)	4 (16.7%)	10 (18.2%)
Grade 1	0	1 (3.3%)	1 (1.4%)	1 (3.2%)	2 (8.3%)	3 (5.5%)
Grade 2	1 (2.4%)	0	1 (1.4%)	5 (16.1%)	1 (4.2%)	6 (10.9%)
Grade 3	1 (2.4%)	1 (3.3%)	2 (2.8%)	0	1 (4.2%)	1 (1.8%)
Renal failure and impairment	1 (2.4%)	1 (3.3%)	2 (2.8%)	3 (9.7%)	4 (16.7%)	7 (12.7%)
Grade 1	0	0	0	0	2 (8.3%)	2 (3.6%)
Grade 2	1 (2.4%)	0	1 (1.4%)	3 (9.7%)	1 (4.2%)	4 (7.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Renal failure and impairment (cont)						
(cont)						
Grade 3	0	0	0	0	0	0
Acute kidney injury	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Renal failure	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	1 (4.2%)	0	1 (3.0%)	0	0	0
Renal impairment	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Renal failure and impairment (cont)						
(cont)						
Grade 3	0	1 (3.3%)	1 (1.4%)	0	1 (4.2%)	1 (1.8%)
Acute kidney injury	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 1	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 2	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Renal failure	0	0	0	1 (3.2%)	2 (8.3%)	3 (5.5%)
Grade 1	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 2	0	0	0	1 (3.2%)	1 (4.2%)	2 (3.6%)
Renal impairment	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	1 (3.3%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Renal failure and impairment (cont)						
Chronic kidney disease	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 2	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 3	0	0	0	0	0	0
Bladder and urethral symptoms	1 (4.2%)	0	1 (3.0%)	0	1 (16.7%)	1 (5.6%)
Grade 1	1 (4.2%)	0	1 (3.0%)	0	1 (16.7%)	1 (5.6%)
Grade 2	0	0	0	0	0	0
Micturition urgency	1 (4.2%)	0	1 (3.0%)	0	0	0
Grade 1	1 (4.2%)	0	1 (3.0%)	0	0	0
Dysuria	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Renal failure and impairment (cont)						
Chronic kidney disease	0	0	0	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 2	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 3	0	0	0	0	1 (4.2%)	1 (1.8%)
Bladder and urethral symptoms	0	1 (3.3%)	1 (1.4%)	2 (6.5%)	0	2 (3.6%)
Grade 1	0	1 (3.3%)	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Grade 2	0	0	0	1 (3.2%)	0	1 (1.8%)
Micturition urgency	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dysuria	0	0	0	2 (6.5%)	0	2 (3.6%)
Grade 1	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 2	0	0	0	1 (3.2%)	0	1 (1.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Bladder and urethral symptoms (cont)						
Pollakiuria	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Urinary incontinence	0	0	0	0	1 (16.7%)	1 (5.6%)
Grade 1	0	0	0	0	1 (16.7%)	1 (5.6%)
Renal lithiasis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Nephrolithiasis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Bladder and urethral symptoms (cont)						
Pollakiuria	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 1	0	1 (3.3%)	1 (1.4%)	0	0	0
Urinary incontinence	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Renal lithiasis	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Grade 2	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 3	1 (2.4%)	0	1 (1.4%)	0	0	0
Nephrolithiasis	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Grade 2	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 3	1 (2.4%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Urinary abnormalities	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Haematuria	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Urinary tract signs and symptoms NEC	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Renal colic	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Renal neoplasms	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Urinary abnormalities	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Haematuria	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Urinary tract signs and symptoms NEC	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0
Renal colic	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0
Renal neoplasms	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 1	0	0	0	1 (3.2%)	0	1 (1.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Renal neoplasms (cont)						
Renal cyst	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Urinary tract lithiasis (excl renal)	0	0	0	1 (8.3%)	0	1 (5.6%)
Grade 3	0	0	0	1 (8.3%)	0	1 (5.6%)
Ureterolithiasis	0	0	0	1 (8.3%)	0	1 (5.6%)
Grade 3	0	0	0	1 (8.3%)	0	1 (5.6%)
Ear and labyrinth disorders	0	2 (22.2%)	2 (6.1%)	1 (8.3%)	0	1 (5.6%)
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 2	0	0	0	1 (8.3%)	0	1 (5.6%)
Grade 3	0	1 (11.1%)	1 (3.0%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Renal neoplasms (cont)						
Renal cyst	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 1	0	0	0	1 (3.2%)	0	1 (1.8%)
Urinary tract lithiasis (excl renal)	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Ureterolithiasis	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Ear and labyrinth disorders	3 (7.1%)	0	3 (4.2%)	1 (3.2%)	2 (8.3%)	3 (5.5%)
Grade 1	2 (4.8%)	0	2 (2.8%)	0	2 (8.3%)	2 (3.6%)
Grade 2	1 (2.4%)	0	1 (1.4%)	1 (3.2%)	0	1 (1.8%)
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Ear and labyrinth disorders (cont)						
Inner ear signs and symptoms	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	1 (11.1%)	1 (3.0%)	0	0	0
Tinnitus	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Vertigo	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	1 (11.1%)	1 (3.0%)	0	0	0
Ear disorders NEC	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Ear and labyrinth disorders (cont)						
Inner ear signs and symptoms	3 (7.1%)	0	3 (4.2%)	0	1 (4.2%)	1 (1.8%)
Grade 1	2 (4.8%)	0	2 (2.8%)	0	1 (4.2%)	1 (1.8%)
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 3	0	0	0	0	0	0
Tinnitus	2 (4.8%)	0	2 (2.8%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0
Vertigo	1 (2.4%)	0	1 (1.4%)	0	1 (4.2%)	1 (1.8%)
Grade 1	1 (2.4%)	0	1 (1.4%)	0	1 (4.2%)	1 (1.8%)
Grade 3	0	0	0	0	0	0
Ear disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Ear and labyrinth disorders (cont)						
Ear disorders NEC (cont)						
Ear discomfort	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0
Hearing losses	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Deafness bilateral	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hypoacusis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Inner ear disorders NEC	0	1 (11.1%)	1 (3.0%)	1 (8.3%)	0	1 (5.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Ear and labyrinth disorders (cont)						
Ear disorders NEC (cont)						
Ear discomfort	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hearing losses	0	0	0	1 (3.2%)	1 (4.2%)	2 (3.6%)
Grade 1	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 2	0	0	0	1 (3.2%)	0	1 (1.8%)
Deafness bilateral	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 1	0	0	0	0	1 (4.2%)	1 (1.8%)
Hypoacusis	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 2	0	0	0	1 (3.2%)	0	1 (1.8%)
Inner ear disorders NEC	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Ear and labyrinth disorders (cont)						
Inner ear disorders NEC (cont)						
(cont)						
Grade 2	0	0	0	1 (8.3%)	0	1 (5.6%)
Grade 3	0	1 (11.1%)	1 (3.0%)	0	0	0
Vestibular disorder	0	1 (11.1%)	1 (3.0%)	1 (8.3%)	0	1 (5.6%)
Grade 2	0	0	0	1 (8.3%)	0	1 (5.6%)
Grade 3	0	1 (11.1%)	1 (3.0%)	0	0	0
Reproductive system and breast disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Breast signs and symptoms	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Ear and labyrinth disorders (cont)						
Inner ear disorders NEC (cont)						
(cont)						
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Vestibular disorder	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Reproductive system and breast disorders	2 (4.8%)	1 (3.3%)	3 (4.2%)	0	0	0
Grade 1	1 (2.4%)	1 (3.3%)	2 (2.8%)	0	0	0
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0
Breast signs and symptoms	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Reproductive system and breast disorders (cont)						
Breast signs and symptoms (cont)						
Breast pain	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Prostatic neoplasms and hypertrophy	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Benign prostatic hyperplasia	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Vulvovaginal disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Vaginal haemorrhage	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Reproductive system and breast disorders (cont)						
Breast signs and symptoms (cont)						
Breast pain	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Prostatic neoplasms and hypertrophy	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0
Benign prostatic hyperplasia	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 2	1 (2.4%)	0	1 (1.4%)	0	0	0
Vulvovaginal disorders NEC	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 1	0	1 (3.3%)	1 (1.4%)	0	0	0
Vaginal haemorrhage	0	1 (3.3%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Reproductive system and breast disorders (cont)						
Vulvovaginal disorders NEC (cont)						
Vaginal haemorrhage (cont)						
Grade 1	0	0	0	0	0	0
Endocrine disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Thyroid hypofunction disorders	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Hypothyroidism	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Reproductive system and breast disorders (cont)						
Vulvovaginal disorders NEC (cont)						
Vaginal haemorrhage (cont)						
Grade 1	0	1 (3.3%)	1 (1.4%)	0	0	0
Endocrine disorders	1 (2.4%)	0	1 (1.4%)	2 (6.5%)	1 (4.2%)	3 (5.5%)
Grade 1	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 2	1 (2.4%)	0	1 (1.4%)	2 (6.5%)	0	2 (3.6%)
Thyroid hypofunction disorders	1 (2.4%)	0	1 (1.4%)	2 (6.5%)	0	2 (3.6%)
Grade 2	1 (2.4%)	0	1 (1.4%)	2 (6.5%)	0	2 (3.6%)
Hypothyroidism	1 (2.4%)	0	1 (1.4%)	2 (6.5%)	0	2 (3.6%)
Grade 2	1 (2.4%)	0	1 (1.4%)	2 (6.5%)	0	2 (3.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Endocrine disorders (cont)						
Thyroid disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Thyroid mass	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hepatobiliary disorders	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 5	0	0	0	0	0	0
Hepatic vascular disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Portal hypertension	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Endocrine disorders (cont)						
Thyroid disorders NEC	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 1	0	0	0	0	1 (4.2%)	1 (1.8%)
Thyroid mass	0	0	0	0	1 (4.2%)	1 (1.8%)
Grade 1	0	0	0	0	1 (4.2%)	1 (1.8%)
Hepatobiliary disorders	1 (2.4%)	1 (3.3%)	2 (2.8%)	1 (3.2%)	0	1 (1.8%)
Grade 1	1 (2.4%)	1 (3.3%)	2 (2.8%)	0	0	0
Grade 5	0	0	0	1 (3.2%)	0	1 (1.8%)
Hepatic vascular disorders	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0
Portal hypertension	1 (2.4%)	0	1 (1.4%)	0	0	0
Grade 1	1 (2.4%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Hepatobiliary disorders (cont)						
Cholestasis and jaundice	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0
Ocular icterus	0	1 (11.1%)	1 (3.0%)	0	0	0
Grade 1	0	1 (11.1%)	1 (3.0%)	0	0	0
Hepatic failure and associated disorders	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Hepatic failure	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Hepatobiliary signs and symptoms	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Hepatobiliary disorders (cont)						
Cholestasis and jaundice	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Ocular icterus	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hepatic failure and associated disorders	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 5	0	0	0	1 (3.2%)	0	1 (1.8%)
Hepatic failure	0	0	0	1 (3.2%)	0	1 (1.8%)
Grade 5	0	0	0	1 (3.2%)	0	1 (1.8%)
Hepatobiliary signs and symptoms	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 1	0	1 (3.3%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Hepatobiliary disorders (cont)						
Hepatobiliary signs and symptoms (cont)						
Hepatomegaly	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Immune system disorders	0	0	0	1 (8.3%)	1 (16.7%)	2 (11.1%)
Grade 1	0	0	0	1 (8.3%)	1 (16.7%)	2 (11.1%)
Allergic conditions NEC	0	0	0	1 (8.3%)	0	1 (5.6%)
Grade 1	0	0	0	1 (8.3%)	0	1 (5.6%)
Allergic oedema	0	0	0	1 (8.3%)	0	1 (5.6%)
Grade 1	0	0	0	1 (8.3%)	0	1 (5.6%)
Allergies to foods, food additives, drugs and other chemicals	0	0	0	0	1 (16.7%)	1 (5.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Hepatobiliary disorders (cont)						
Hepatobiliary signs and symptoms (cont)						
Hepatomegaly	0	1 (3.3%)	1 (1.4%)	0	0	0
Grade 1	0	1 (3.3%)	1 (1.4%)	0	0	0
Immune system disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Allergic conditions NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Allergic oedema	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Allergies to foods, food additives, drugs and other chemicals	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-age-rt.pdf 24AUG2023:15:00

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	<65 Years					
	RT Phase MMB (N=24)	RT Phase BAT (N=9)	RT Phase Total (N=33)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=12)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=6)	ET Phase (Week 24 - 48) Total (N=18)
Number of Subjects with Any Treatment-Emergent AE	24 (100.0%)	7 (77.8%)	31 (93.9%)	12 (100.0%)	6 (100.0%)	18 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Immune system disorders (cont)						
Allergies to foods, food additives, drugs and other chemicals (cont) (cont)						
Grade 1	0	0	0	0	1 (16.7%)	1 (5.6%)
Drug hypersensitivity	0	0	0	0	1 (16.7%)	1 (5.6%)
Grade 1	0	0	0	0	1 (16.7%)	1 (5.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0403: TEAEs by SOC, HLT, PT and Severity by Age Group
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	>=65 Years					
	RT Phase MMB (N=42)	RT Phase BAT (N=30)	RT Phase Total (N=72)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=31)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=24)	ET Phase (Week 24 - 48) Total (N=55)
Number of Subjects with Any Treatment-Emergent AE	42 (100.0%)	28 (93.3%)	70 (97.2%)	28 (90.3%)	24 (100.0%)	52 (94.5%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Immune system disorders (cont)						
Allergies to foods, food additives, drugs and other chemicals (cont) (cont)						
Grade 1	0	0	0	0	0	0
Drug hypersensitivity	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders	16 (43.2%)	16 (64.0%)	32 (51.6%)	55 (69.6%)
Grade 1	7 (18.9%)	7 (28.0%)	14 (22.6%)	23 (29.1%)
Grade 2	6 (16.2%)	4 (16.0%)	10 (16.1%)	21 (26.6%)
Grade 3	3 (8.1%)	4 (16.0%)	7 (11.3%)	10 (12.7%)
Grade 4	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Diarrhoea (excl infective)	11 (29.7%)	4 (16.0%)	15 (24.2%)	27 (34.2%)
Grade 1	9 (24.3%)	1 (4.0%)	10 (16.1%)	18 (22.8%)
Grade 2	1 (2.7%)	2 (8.0%)	3 (4.8%)	6 (7.6%)
Grade 3	1 (2.7%)	1 (4.0%)	2 (3.2%)	3 (3.8%)
Diarrhoea	11 (29.7%)	4 (16.0%)	15 (24.2%)	27 (34.2%)
Grade 1	9 (24.3%)	1 (4.0%)	10 (16.1%)	18 (22.8%)
Grade 2	1 (2.7%)	2 (8.0%)	3 (4.8%)	6 (7.6%)
Grade 3	1 (2.7%)	1 (4.0%)	2 (3.2%)	3 (3.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders	3 (50.0%)	5 (100.0%)	8 (72.7%)	14 (82.4%)
Grade 1	1 (16.7%)	2 (40.0%)	3 (27.3%)	5 (29.4%)
Grade 2	2 (33.3%)	2 (40.0%)	4 (36.4%)	7 (41.2%)
Grade 3	0	1 (20.0%)	1 (9.1%)	2 (11.8%)
Grade 4	0	0	0	0
Diarrhoea (excl infective)	2 (33.3%)	3 (60.0%)	5 (45.5%)	8 (47.1%)
Grade 1	1 (16.7%)	1 (20.0%)	2 (18.2%)	3 (17.6%)
Grade 2	1 (16.7%)	1 (20.0%)	2 (18.2%)	4 (23.5%)
Grade 3	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Diarrhoea	2 (33.3%)	3 (60.0%)	5 (45.5%)	8 (47.1%)
Grade 1	1 (16.7%)	1 (20.0%)	2 (18.2%)	3 (17.6%)
Grade 2	1 (16.7%)	1 (20.0%)	2 (18.2%)	4 (23.5%)
Grade 3	0	1 (20.0%)	1 (9.1%)	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal and abdominal pains (excl oral and throat)	4 (10.8%)	3 (12.0%)	7 (11.3%)	19 (24.1%)
Grade 1	1 (2.7%)	1 (4.0%)	2 (3.2%)	7 (8.9%)
Grade 2	2 (5.4%)	2 (8.0%)	4 (6.5%)	9 (11.4%)
Grade 3	1 (2.7%)	0	1 (1.6%)	3 (3.8%)
Abdominal pain	3 (8.1%)	2 (8.0%)	5 (8.1%)	12 (15.2%)
Grade 1	0	0	0	4 (5.1%)
Grade 2	2 (5.4%)	2 (8.0%)	4 (6.5%)	6 (7.6%)
Grade 3	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Abdominal pain upper	1 (2.7%)	1 (4.0%)	2 (3.2%)	6 (7.6%)
Grade 1	1 (2.7%)	1 (4.0%)	2 (3.2%)	2 (2.5%)
Grade 2	0	0	0	3 (3.8%)
Grade 3	0	0	0	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal and abdominal pains (excl oral and throat)	0	3 (60.0%)	3 (27.3%)	6 (35.3%)
Grade 1	0	3 (60.0%)	3 (27.3%)	5 (29.4%)
Grade 2	0	0	0	1 (5.9%)
Grade 3	0	0	0	0
Abdominal pain	0	1 (20.0%)	1 (9.1%)	3 (17.6%)
Grade 1	0	1 (20.0%)	1 (9.1%)	2 (11.8%)
Grade 2	0	0	0	1 (5.9%)
Grade 3	0	0	0	0
Abdominal pain upper	0	2 (40.0%)	2 (18.2%)	3 (17.6%)
Grade 1	0	2 (40.0%)	2 (18.2%)	3 (17.6%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal and abdominal pains (excl oral and throat) (cont)				
Abdominal pain lower	0	0	0	1 (1.3%)
Grade 1	0	0	0	1 (1.3%)
Nausea and vomiting symptoms	4 (10.8%)	5 (20.0%)	9 (14.5%)	19 (24.1%)
Grade 1	4 (10.8%)	2 (8.0%)	6 (9.7%)	15 (19.0%)
Grade 2	0	2 (8.0%)	2 (3.2%)	3 (3.8%)
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Nausea	4 (10.8%)	4 (16.0%)	8 (12.9%)	18 (22.8%)
Grade 1	4 (10.8%)	2 (8.0%)	6 (9.7%)	15 (19.0%)
Grade 2	0	2 (8.0%)	2 (3.2%)	3 (3.8%)
Vomiting	2 (5.4%)	3 (12.0%)	5 (8.1%)	6 (7.6%)
Grade 1	2 (5.4%)	1 (4.0%)	3 (4.8%)	4 (5.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal and abdominal pains (excl oral and throat) (cont)				
Abdominal pain lower	0	0	0	0
Grade 1	0	0	0	0
Nausea and vomiting symptoms	1 (16.7%)	1 (20.0%)	2 (18.2%)	3 (17.6%)
Grade 1	1 (16.7%)	0	1 (9.1%)	2 (11.8%)
Grade 2	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 3	0	0	0	0
Nausea	1 (16.7%)	1 (20.0%)	2 (18.2%)	3 (17.6%)
Grade 1	1 (16.7%)	0	1 (9.1%)	2 (11.8%)
Grade 2	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Vomiting	0	0	0	1 (5.9%)
Grade 1	0	0	0	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Nausea and vomiting symptoms (cont)				
Vomiting (cont)				
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Gastrointestinal atonic and hypomotility disorders NEC	4 (10.8%)	0	4 (6.5%)	13 (16.5%)
Grade 1	3 (8.1%)	0	3 (4.8%)	10 (12.7%)
Grade 2	1 (2.7%)	0	1 (1.6%)	3 (3.8%)
Constipation	3 (8.1%)	0	3 (4.8%)	9 (11.4%)
Grade 1	3 (8.1%)	0	3 (4.8%)	9 (11.4%)
Gastrooesophageal reflux disease	1 (2.7%)	0	1 (1.6%)	4 (5.1%)
Grade 1	0	0	0	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	3 (3.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Nausea and vomiting symptoms (cont)				
Vomiting (cont)				
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Gastrointestinal atonic and hypomotility disorders NEC	0	1 (20.0%)	1 (9.1%)	2 (11.8%)
Grade 1	0	1 (20.0%)	1 (9.1%)	2 (11.8%)
Grade 2	0	0	0	0
Constipation	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Gastrooesophageal reflux disease	0	0	0	1 (5.9%)
Grade 1	0	0	0	1 (5.9%)
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal atonic and hypomotility disorders NEC (cont)				
Impaired gastric emptying	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Dyspeptic signs and symptoms	1 (2.7%)	1 (4.0%)	2 (3.2%)	7 (8.9%)
Grade 1	1 (2.7%)	1 (4.0%)	2 (3.2%)	4 (5.1%)
Grade 2	0	0	0	3 (3.8%)
Dyspepsia	1 (2.7%)	1 (4.0%)	2 (3.2%)	6 (7.6%)
Grade 1	1 (2.7%)	1 (4.0%)	2 (3.2%)	3 (3.8%)
Grade 2	0	0	0	3 (3.8%)
Epigastric discomfort	0	0	0	1 (1.3%)
Grade 1	0	0	0	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal atonic and hypomotility disorders NEC (cont)				
Impaired gastric emptying	0	0	0	0
Grade 1	0	0	0	0
Dyspeptic signs and symptoms	0	0	0	2 (11.8%)
Grade 1	0	0	0	1 (5.9%)
Grade 2	0	0	0	1 (5.9%)
Dyspepsia	0	0	0	2 (11.8%)
Grade 1	0	0	0	1 (5.9%)
Grade 2	0	0	0	1 (5.9%)
Epigastric discomfort	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Non-site specific gastrointestinal haemorrhages	1 (2.7%)	3 (12.0%)	4 (6.5%)	5 (6.3%)
Grade 1	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 3	1 (2.7%)	1 (4.0%)	2 (3.2%)	3 (3.8%)
Melaena	0	2 (8.0%)	2 (3.2%)	3 (3.8%)
Grade 1	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 3	0	0	0	1 (1.3%)
Gastrointestinal haemorrhage	1 (2.7%)	1 (4.0%)	2 (3.2%)	2 (2.5%)
Grade 2	0	0	0	0
Grade 3	1 (2.7%)	1 (4.0%)	2 (3.2%)	2 (2.5%)
Haematemesis	0	0	0	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Non-site specific gastrointestinal haemorrhages	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 1	0	0	0	0
Grade 2	1 (16.7%)	0	1 (9.1%)	0
Grade 3	0	0	0	1 (5.9%)
Melaena	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 1	0	0	0	0
Grade 2	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 3	0	0	0	0
Gastrointestinal haemorrhage	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 2	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 3	0	0	0	0
Haematemesis	1 (16.7%)	0	1 (9.1%)	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
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Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Non-site specific gastrointestinal haemorrhages (cont)				
Haematemesis (cont)				
Grade 2	0	0	0	0
Grade 3	0	0	0	1 (1.3%)
Upper gastrointestinal haemorrhage	0	0	0	1 (1.3%)
Grade 3	0	0	0	1 (1.3%)
Peritoneal and retroperitoneal disorders	0	2 (8.0%)	2 (3.2%)	3 (3.8%)
Grade 1	0	0	0	1 (1.3%)
Grade 2	0	2 (8.0%)	2 (3.2%)	2 (2.5%)
Ascites	0	2 (8.0%)	2 (3.2%)	3 (3.8%)
Grade 1	0	0	0	1 (1.3%)
Grade 2	0	2 (8.0%)	2 (3.2%)	2 (2.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Non-site specific gastrointestinal haemorrhages (cont)				
Haematemesis (cont)				
Grade 2	1 (16.7%)	0	1 (9.1%)	0
Grade 3	0	0	0	1 (5.9%)
Upper gastrointestinal haemorrhage	0	0	0	1 (5.9%)
Grade 3	0	0	0	1 (5.9%)
Peritoneal and retroperitoneal disorders	1 (16.7%)	0	1 (9.1%)	2 (11.8%)
Grade 1	0	0	0	1 (5.9%)
Grade 2	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Ascites	1 (16.7%)	0	1 (9.1%)	2 (11.8%)
Grade 1	0	0	0	1 (5.9%)
Grade 2	1 (16.7%)	0	1 (9.1%)	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
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SAF-Anemic Analysis Set

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Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Flatulence, bloating and distension	1 (2.7%)	0	1 (1.6%)	3 (3.8%)
Grade 1	0	0	0	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Abdominal distension	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	0	0	0	0
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Flatulence	0	0	0	2 (2.5%)
Grade 1	0	0	0	1 (1.3%)
Grade 2	0	0	0	1 (1.3%)
Gastrointestinal signs and symptoms NEC	0	2 (8.0%)	2 (3.2%)	3 (3.8%)
Grade 1	0	2 (8.0%)	2 (3.2%)	3 (3.8%)
Abdominal discomfort	0	1 (4.0%)	1 (1.6%)	2 (2.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
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Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Flatulence, bloating and distension	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 2	0	0	0	0
Abdominal distension	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 2	0	0	0	0
Flatulence	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Gastrointestinal signs and symptoms NEC	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Abdominal discomfort	0	1 (20.0%)	1 (9.1%)	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
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SAF-Anemic Analysis Set

	White			
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal signs and symptoms NEC (cont)				
Abdominal discomfort (cont)				
Grade 1	0	1 (4.0%)	1 (1.6%)	2 (2.5%)
Dysphagia	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 1	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Stomatitis and ulceration	1 (2.7%)	1 (4.0%)	2 (3.2%)	3 (3.8%)
Grade 1	0	1 (4.0%)	1 (1.6%)	2 (2.5%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Mouth ulceration	1 (2.7%)	1 (4.0%)	2 (3.2%)	3 (3.8%)
Grade 1	0	1 (4.0%)	1 (1.6%)	2 (2.5%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal signs and symptoms NEC (cont)				
Abdominal discomfort (cont)				
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Dysphagia	0	0	0	0
Grade 1	0	0	0	0
Stomatitis and ulceration	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 1	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 2	0	0	0	0
Mouth ulceration	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Stomatitis and ulceration (cont)				
Palatal ulcer	0	0	0	0
Grade 1	0	0	0	0
Dental and periodontal infections and inflammations	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Grade 1	0	0	0	0
Grade 2	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Dental caries	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Grade 1	0	0	0	0
Grade 2	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Intestinal haemorrhages	1 (2.7%)	1 (4.0%)	2 (3.2%)	3 (3.8%)
Grade 1	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Stomatitis and ulceration (cont)				
Palatal ulcer	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 1	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Dental and periodontal infections and inflammations	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 2	0	0	0	0
Dental caries	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 2	0	0	0	0
Intestinal haemorrhages	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Intestinal haemorrhages (cont)				
Rectal haemorrhage	1 (2.7%)	1 (4.0%)	2 (3.2%)	2 (2.5%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Anal haemorrhage	0	0	0	1 (1.3%)
Grade 1	0	0	0	1 (1.3%)
Oral dryness and saliva altered	0	2 (8.0%)	2 (3.2%)	2 (2.5%)
Grade 1	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Dry mouth	0	2 (8.0%)	2 (3.2%)	2 (2.5%)
Grade 1	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Intestinal haemorrhages (cont)				
Rectal haemorrhage	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Anal haemorrhage	0	0	0	0
Grade 1	0	0	0	0
Oral dryness and saliva altered	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 1	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 2	0	0	0	0
Dry mouth	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 1	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
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	White			
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Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal spastic and hypermotility disorders	0	0	0	2 (2.5%)
Grade 1	0	0	0	2 (2.5%)
Defaecation urgency	0	0	0	1 (1.3%)
Grade 1	0	0	0	1 (1.3%)
Frequent bowel movements	0	0	0	1 (1.3%)
Grade 1	0	0	0	1 (1.3%)
Haemorrhoids and gastrointestinal varices (excl oesophageal)	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	0	0	0	0
Haemorrhoidal haemorrhage	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
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Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal spastic and hypermotility disorders	0	0	0	0
Grade 1	0	0	0	0
Defaecation urgency	0	0	0	0
Grade 1	0	0	0	0
Frequent bowel movements	0	0	0	0
Grade 1	0	0	0	0
Haemorrhoids and gastrointestinal varices (excl oesophageal)	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	0	0	0
Grade 2	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Haemorrhoidal haemorrhage	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Haemorrhoids and gastrointestinal varices (excl oesophageal) (cont)				
Haemorrhoidal haemorrhage (cont)				
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Haemorrhoids	0	0	0	0
Grade 2	0	0	0	0
Abdominal wall conditions NEC	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Abdominal wall haematoma	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Anal and rectal disorders NEC	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
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SAF-Anemic Analysis Set

(Continued)	Other Races			
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Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Haemorrhoids and gastrointestinal varices (excl oesophageal) (cont)				
Haemorrhoidal haemorrhage (cont)				
Grade 1	0	0	0	0
Haemorrhoids	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 2	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Abdominal wall conditions NEC	0	0	0	0
Grade 3	0	0	0	0
Abdominal wall haematoma	0	0	0	0
Grade 3	0	0	0	0
Anal and rectal disorders NEC	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Anal and rectal disorders NEC (cont)				
Anal fissure	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Anal and rectal signs and symptoms	0	0	0	0
Grade 1	0	0	0	0
Anorectal discomfort	0	0	0	0
Grade 1	0	0	0	0
Dental pain and sensation disorders	0	0	0	0
Grade 2	0	0	0	0
Toothache	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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(Continued)	Other Races			
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Anal and rectal disorders NEC (cont)				
Anal fissure	0	0	0	0
Grade 2	0	0	0	0
Anal and rectal signs and symptoms	0	0	0	1 (5.9%)
Grade 1	0	0	0	1 (5.9%)
Anorectal discomfort	0	0	0	1 (5.9%)
Grade 1	0	0	0	1 (5.9%)
Dental pain and sensation disorders	0	0	0	1 (5.9%)
Grade 2	0	0	0	1 (5.9%)
Toothache	0	0	0	1 (5.9%)
Grade 2	0	0	0	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Diaphragmatic hernias	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Hiatus hernia	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Gastric and oesophageal haemorrhages	0	0	0	1 (1.3%)
Grade 2	0	0	0	1 (1.3%)
Oesophageal haemorrhage	0	0	0	1 (1.3%)
Grade 2	0	0	0	1 (1.3%)
Gastric ulcers and perforation	0	0	0	1 (1.3%)
Grade 3	0	0	0	1 (1.3%)
Gastric ulcer	0	0	0	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Diaphragmatic hernias	0	0	0	0
Grade 2	0	0	0	0
Hiatus hernia	0	0	0	0
Grade 2	0	0	0	0
Gastric and oesophageal haemorrhages	0	0	0	0
Grade 2	0	0	0	0
Oesophageal haemorrhage	0	0	0	0
Grade 2	0	0	0	0
Gastric ulcers and perforation	0	0	0	0
Grade 3	0	0	0	0
Gastric ulcer	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastric ulcers and perforation (cont)				
Gastric ulcer (cont)				
Grade 3	0	0	0	1 (1.3%)
Gastritis (excl infective)	0	0	0	1 (1.3%)
Grade 1	0	0	0	1 (1.3%)
Gastritis	0	0	0	1 (1.3%)
Grade 1	0	0	0	1 (1.3%)
Gastrointestinal mucosal dystrophies and secretion disorders	0	0	0	1 (1.3%)
Grade 1	0	0	0	1 (1.3%)
Gastrointestinal melanosis	0	0	0	1 (1.3%)
Grade 1	0	0	0	1 (1.3%)

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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastric ulcers and perforation (cont)				
Gastric ulcer (cont)				
Grade 3	0	0	0	0
Gastritis (excl infective)	0	0	0	0
Grade 1	0	0	0	0
Gastritis	0	0	0	0
Grade 1	0	0	0	0
Gastrointestinal mucosal dystrophies and secretion disorders	0	0	0	0
Grade 1	0	0	0	0
Gastrointestinal melanosis	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal vascular occlusion and infarction	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 4	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Visceral venous thrombosis	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 4	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Oesophageal varices	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Varices oesophageal	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Oral soft tissue haemorrhages	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal vascular occlusion and infarction	0	0	0	0
Grade 4	0	0	0	0
Visceral venous thrombosis	0	0	0	0
Grade 4	0	0	0	0
Oesophageal varices	0	0	0	0
Grade 2	0	0	0	0
Varices oesophageal	0	0	0	0
Grade 2	0	0	0	0
Oral soft tissue haemorrhages	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Oral soft tissue haemorrhages (cont)				
Mouth haemorrhage	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Oral soft tissue pain and paraesthesia	0	0	0	0
Grade 1	0	0	0	0
Oral pain	0	0	0	0
Grade 1	0	0	0	0
Umbilical hernias	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Umbilical hernia	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Oral soft tissue haemorrhages (cont)				
Mouth haemorrhage	0	0	0	0
Grade 2	0	0	0	0
Oral soft tissue pain and paraesthesia	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Oral pain	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Umbilical hernias	0	0	0	0
Grade 1	0	0	0	0
Umbilical hernia	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions	20 (54.1%)	15 (60.0%)	35 (56.5%)	50 (63.3%)
Grade 1	6 (16.2%)	5 (20.0%)	11 (17.7%)	14 (17.7%)
Grade 2	10 (27.0%)	6 (24.0%)	16 (25.8%)	23 (29.1%)
Grade 3	4 (10.8%)	4 (16.0%)	8 (12.9%)	13 (16.5%)
Grade 5	0	0	0	0
Asthenic conditions	8 (21.6%)	9 (36.0%)	17 (27.4%)	31 (39.2%)
Grade 1	2 (5.4%)	2 (8.0%)	4 (6.5%)	9 (11.4%)
Grade 2	4 (10.8%)	4 (16.0%)	8 (12.9%)	14 (17.7%)
Grade 3	2 (5.4%)	3 (12.0%)	5 (8.1%)	8 (10.1%)
Asthenia	5 (13.5%)	6 (24.0%)	11 (17.7%)	17 (21.5%)
Grade 1	2 (5.4%)	1 (4.0%)	3 (4.8%)	5 (6.3%)
Grade 2	2 (5.4%)	2 (8.0%)	4 (6.5%)	5 (6.3%)
Grade 3	1 (2.7%)	3 (12.0%)	4 (6.5%)	7 (8.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions	5 (83.3%)	4 (80.0%)	9 (81.8%)	14 (82.4%)
Grade 1	3 (50.0%)	1 (20.0%)	4 (36.4%)	5 (29.4%)
Grade 2	1 (16.7%)	3 (60.0%)	4 (36.4%)	5 (29.4%)
Grade 3	0	0	0	3 (17.6%)
Grade 5	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Asthenic conditions	2 (33.3%)	4 (80.0%)	6 (54.5%)	10 (58.8%)
Grade 1	2 (33.3%)	1 (20.0%)	3 (27.3%)	3 (17.6%)
Grade 2	0	3 (60.0%)	3 (27.3%)	6 (35.3%)
Grade 3	0	0	0	1 (5.9%)
Asthenia	1 (16.7%)	3 (60.0%)	4 (36.4%)	8 (47.1%)
Grade 1	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 2	0	3 (60.0%)	3 (27.3%)	6 (35.3%)
Grade 3	0	0	0	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Asthenic conditions (cont)				
Fatigue	3 (8.1%)	4 (16.0%)	7 (11.3%)	16 (20.3%)
Grade 1	0	1 (4.0%)	1 (1.6%)	5 (6.3%)
Grade 2	2 (5.4%)	2 (8.0%)	4 (6.5%)	9 (11.4%)
Grade 3	1 (2.7%)	1 (4.0%)	2 (3.2%)	2 (2.5%)
Febrile disorders	10 (27.0%)	7 (28.0%)	17 (27.4%)	21 (26.6%)
Grade 1	6 (16.2%)	5 (20.0%)	11 (17.7%)	13 (16.5%)
Grade 2	3 (8.1%)	2 (8.0%)	5 (8.1%)	6 (7.6%)
Grade 3	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Pyrexia	10 (27.0%)	7 (28.0%)	17 (27.4%)	21 (26.6%)
Grade 1	6 (16.2%)	5 (20.0%)	11 (17.7%)	13 (16.5%)
Grade 2	3 (8.1%)	2 (8.0%)	5 (8.1%)	6 (7.6%)
Grade 3	1 (2.7%)	0	1 (1.6%)	2 (2.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Asthenic conditions (cont)				
Fatigue	1 (16.7%)	1 (20.0%)	2 (18.2%)	2 (11.8%)
Grade 1	1 (16.7%)	1 (20.0%)	2 (18.2%)	2 (11.8%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Febrile disorders	1 (16.7%)	2 (40.0%)	3 (27.3%)	5 (29.4%)
Grade 1	1 (16.7%)	1 (20.0%)	2 (18.2%)	3 (17.6%)
Grade 2	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 3	0	0	0	1 (5.9%)
Pyrexia	1 (16.7%)	2 (40.0%)	3 (27.3%)	5 (29.4%)
Grade 1	1 (16.7%)	1 (20.0%)	2 (18.2%)	3 (17.6%)
Grade 2	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 3	0	0	0	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-et.pdf 24AUG2023:15:00

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Oedema NEC	9 (24.3%)	2 (8.0%)	11 (17.7%)	16 (20.3%)
Grade 1	3 (8.1%)	0	3 (4.8%)	6 (7.6%)
Grade 2	5 (13.5%)	1 (4.0%)	6 (9.7%)	8 (10.1%)
Grade 3	1 (2.7%)	1 (4.0%)	2 (3.2%)	2 (2.5%)
Oedema peripheral	8 (21.6%)	2 (8.0%)	10 (16.1%)	15 (19.0%)
Grade 1	2 (5.4%)	0	2 (3.2%)	5 (6.3%)
Grade 2	5 (13.5%)	1 (4.0%)	6 (9.7%)	8 (10.1%)
Grade 3	1 (2.7%)	1 (4.0%)	2 (3.2%)	2 (2.5%)
Generalised oedema	0	0	0	0
Grade 2	0	0	0	0
Oedema	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Oedema NEC	1 (16.7%)	1 (20.0%)	2 (18.2%)	5 (29.4%)
Grade 1	0	1 (20.0%)	1 (9.1%)	2 (11.8%)
Grade 2	1 (16.7%)	0	1 (9.1%)	3 (17.6%)
Grade 3	0	0	0	0
Oedema peripheral	0	1 (20.0%)	1 (9.1%)	4 (23.5%)
Grade 1	0	1 (20.0%)	1 (9.1%)	2 (11.8%)
Grade 2	0	0	0	2 (11.8%)
Grade 3	0	0	0	0
Generalised oedema	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 2	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Oedema	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Feelings and sensations NEC	3 (8.1%)	1 (4.0%)	4 (6.5%)	6 (7.6%)
Grade 1	2 (5.4%)	0	2 (3.2%)	4 (5.1%)
Grade 2	1 (2.7%)	1 (4.0%)	2 (3.2%)	2 (2.5%)
Early satiety	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Grade 1	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Grade 2	0	0	0	0
Chills	2 (5.4%)	1 (4.0%)	3 (4.8%)	3 (3.8%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	1 (4.0%)	2 (3.2%)	2 (2.5%)
Feeling hot	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Grade 1	1 (2.7%)	0	1 (1.6%)	2 (2.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Feelings and sensations NEC	0	1 (20.0%)	1 (9.1%)	2 (11.8%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 2	0	0	0	1 (5.9%)
Early satiety	0	1 (20.0%)	1 (9.1%)	2 (11.8%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 2	0	0	0	1 (5.9%)
Chills	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Feeling hot	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Pain and discomfort NEC	3 (8.1%)	0	3 (4.8%)	6 (7.6%)
Grade 1	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Grade 2	1 (2.7%)	0	1 (1.6%)	4 (5.1%)
Chest pain	2 (5.4%)	0	2 (3.2%)	3 (3.8%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Chest discomfort	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Facial pain	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Non-cardiac chest pain	0	0	0	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Pain and discomfort NEC	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Chest pain	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Chest discomfort	0	0	0	0
Grade 1	0	0	0	0
Facial pain	0	0	0	0
Grade 1	0	0	0	0
Non-cardiac chest pain	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Pain and discomfort NEC (cont)				
Non-cardiac chest pain (cont)				
Grade 2	0	0	0	1 (1.3%)
Pain	0	0	0	1 (1.3%)
Grade 2	0	0	0	1 (1.3%)
General signs and symptoms NEC	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 3	0	0	0	1 (1.3%)
Grade 5	0	0	0	0
Disease progression	0	0	0	1 (1.3%)
Grade 3	0	0	0	1 (1.3%)
Grade 5	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Pain and discomfort NEC (cont)				
Non-cardiac chest pain (cont)				
Grade 2	0	0	0	0
Pain	0	0	0	0
Grade 2	0	0	0	0
General signs and symptoms NEC	1 (16.7%)	0	1 (9.1%)	2 (11.8%)
Grade 1	0	0	0	0
Grade 3	0	0	0	1 (5.9%)
Grade 5	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Disease progression	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 3	0	0	0	0
Grade 5	1 (16.7%)	0	1 (9.1%)	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
General signs and symptoms NEC (cont)				
General physical health deterioration	0	0	0	0
Grade 3	0	0	0	0
Peripheral swelling	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Gait disturbances	2 (5.4%)	0	2 (3.2%)	3 (3.8%)
Grade 1	2 (5.4%)	0	2 (3.2%)	1 (1.3%)
Grade 2	0	0	0	2 (2.5%)
Gait disturbance	2 (5.4%)	0	2 (3.2%)	3 (3.8%)
Grade 1	2 (5.4%)	0	2 (3.2%)	1 (1.3%)
Grade 2	0	0	0	2 (2.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-et.pdf 24AUG2023:15:00

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
General signs and symptoms NEC (cont)				
General physical health deterioration	0	0	0	1 (5.9%)
Grade 3	0	0	0	1 (5.9%)
Peripheral swelling	0	0	0	0
Grade 1	0	0	0	0
Gait disturbances	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Gait disturbance	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Inflammations	0	0	0	0
Grade 2	0	0	0	0
Inflammation	0	0	0	0
Grade 2	0	0	0	0
Injection site reactions	0	0	0	0
Grade 1	0	0	0	0
Injection site pain	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Inflammations	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 2	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Inflammation	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 2	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Injection site reactions	0	0	0	1 (5.9%)
Grade 1	0	0	0	1 (5.9%)
Injection site pain	0	0	0	1 (5.9%)
Grade 1	0	0	0	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations	22 (59.5%)	13 (52.0%)	35 (56.5%)	49 (62.0%)
Grade 1	2 (5.4%)	5 (20.0%)	7 (11.3%)	9 (11.4%)
Grade 2	10 (27.0%)	5 (20.0%)	15 (24.2%)	23 (29.1%)
Grade 3	6 (16.2%)	1 (4.0%)	7 (11.3%)	10 (12.7%)
Grade 4	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Grade 5	2 (5.4%)	2 (8.0%)	4 (6.5%)	5 (6.3%)
Lower respiratory tract and lung infections	11 (29.7%)	3 (12.0%)	14 (22.6%)	17 (21.5%)
Grade 1	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Grade 2	4 (10.8%)	1 (4.0%)	5 (8.1%)	8 (10.1%)
Grade 3	4 (10.8%)	1 (4.0%)	5 (8.1%)	5 (6.3%)
Grade 4	0	0	0	0
Grade 5	1 (2.7%)	1 (4.0%)	2 (3.2%)	2 (2.5%)
Pneumonia	7 (18.9%)	3 (12.0%)	10 (16.1%)	10 (12.7%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	1 (4.0%)	2 (3.2%)	2 (2.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations	5 (83.3%)	5 (100.0%)	10 (90.9%)	15 (88.2%)
Grade 1	1 (16.7%)	1 (20.0%)	2 (18.2%)	1 (5.9%)
Grade 2	2 (33.3%)	3 (60.0%)	5 (45.5%)	7 (41.2%)
Grade 3	0	1 (20.0%)	1 (9.1%)	4 (23.5%)
Grade 4	1 (16.7%)	0	1 (9.1%)	2 (11.8%)
Grade 5	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Lower respiratory tract and lung infections	3 (50.0%)	4 (80.0%)	7 (63.6%)	11 (64.7%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 2	2 (33.3%)	2 (40.0%)	4 (36.4%)	6 (35.3%)
Grade 3	1 (16.7%)	1 (20.0%)	2 (18.2%)	3 (17.6%)
Grade 4	0	0	0	1 (5.9%)
Grade 5	0	0	0	0
Pneumonia	0	0	0	3 (17.6%)
Grade 1	0	0	0	0
Grade 2	0	0	0	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Lower respiratory tract and lung infections (cont)				
Pneumonia (cont)				
Grade 3	4 (10.8%)	1 (4.0%)	5 (8.1%)	5 (6.3%)
Grade 4	0	0	0	0
Grade 5	1 (2.7%)	1 (4.0%)	2 (3.2%)	2 (2.5%)
Bronchitis	5 (13.5%)	0	5 (8.1%)	7 (8.9%)
Grade 1	0	0	0	0
Grade 2	5 (13.5%)	0	5 (8.1%)	7 (8.9%)
Lung infection	0	1 (4.0%)	1 (1.6%)	2 (2.5%)
Grade 2	0	1 (4.0%)	1 (1.6%)	2 (2.5%)
Grade 3	0	0	0	0
Atypical pneumonia	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Lower respiratory tract and lung infections (cont)				
Pneumonia (cont)				
Grade 3	0	0	0	1 (5.9%)
Grade 4	0	0	0	1 (5.9%)
Grade 5	0	0	0	0
Bronchitis	1 (16.7%)	3 (60.0%)	4 (36.4%)	4 (23.5%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 2	1 (16.7%)	2 (40.0%)	3 (27.3%)	3 (17.6%)
Lung infection	1 (16.7%)	1 (20.0%)	2 (18.2%)	3 (17.6%)
Grade 2	0	0	0	1 (5.9%)
Grade 3	1 (16.7%)	1 (20.0%)	2 (18.2%)	2 (11.8%)
Atypical pneumonia	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Lower respiratory tract and lung infections (cont)				
Atypical pneumonia (cont)				
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Lower respiratory tract infection	0	0	0	0
Grade 2	0	0	0	0
Upper respiratory tract infections	11 (29.7%)	6 (24.0%)	17 (27.4%)	24 (30.4%)
Grade 1	3 (8.1%)	5 (20.0%)	8 (12.9%)	11 (13.9%)
Grade 2	7 (18.9%)	1 (4.0%)	8 (12.9%)	12 (15.2%)
Grade 3	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 4	0	0	0	0
Upper respiratory tract infection	7 (18.9%)	5 (20.0%)	12 (19.4%)	17 (21.5%)
Grade 1	2 (5.4%)	4 (16.0%)	6 (9.7%)	8 (10.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Lower respiratory tract and lung infections (cont)				
Atypical pneumonia (cont)				
Grade 1	0	0	0	0
Lower respiratory tract infection	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 2	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Upper respiratory tract infections	1 (16.7%)	1 (20.0%)	2 (18.2%)	4 (23.5%)
Grade 1	0	0	0	0
Grade 2	1 (16.7%)	1 (20.0%)	2 (18.2%)	3 (17.6%)
Grade 3	0	0	0	0
Grade 4	0	0	0	1 (5.9%)
Upper respiratory tract infection	1 (16.7%)	0	1 (9.1%)	2 (11.8%)
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Upper respiratory tract infections (cont)				
Upper respiratory tract infection (cont)				
Grade 2	4 (10.8%)	1 (4.0%)	5 (8.1%)	8 (10.1%)
Grade 3	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 4	0	0	0	0
Nasopharyngitis	2 (5.4%)	2 (8.0%)	4 (6.5%)	6 (7.6%)
Grade 1	1 (2.7%)	2 (8.0%)	3 (4.8%)	5 (6.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Sinusitis	2 (5.4%)	0	2 (3.2%)	3 (3.8%)
Grade 2	2 (5.4%)	0	2 (3.2%)	3 (3.8%)
Tracheitis	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Upper respiratory tract infections (cont)				
Upper respiratory tract infection (cont)				
Grade 2	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 3	0	0	0	0
Grade 4	0	0	0	1 (5.9%)
Nasopharyngitis	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 1	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 2	0	0	0	0
Sinusitis	1 (16.7%)	0	1 (9.1%)	2 (11.8%)
Grade 2	1 (16.7%)	0	1 (9.1%)	2 (11.8%)
Tracheitis	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 2	0	1 (20.0%)	1 (9.1%)	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Urinary tract infections	7 (18.9%)	4 (16.0%)	11 (17.7%)	14 (17.7%)
Grade 1	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Grade 2	3 (8.1%)	4 (16.0%)	7 (11.3%)	9 (11.4%)
Grade 3	2 (5.4%)	0	2 (3.2%)	3 (3.8%)
Urinary tract infection	5 (13.5%)	4 (16.0%)	9 (14.5%)	11 (13.9%)
Grade 1	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Grade 2	2 (5.4%)	4 (16.0%)	6 (9.7%)	7 (8.9%)
Grade 3	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Cystitis	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Grade 2	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Kidney infection	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 3	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Urinary tract infections	1 (16.7%)	2 (40.0%)	3 (27.3%)	4 (23.5%)
Grade 1	0	0	0	0
Grade 2	0	2 (40.0%)	2 (18.2%)	3 (17.6%)
Grade 3	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Urinary tract infection	1 (16.7%)	2 (40.0%)	3 (27.3%)	4 (23.5%)
Grade 1	0	0	0	0
Grade 2	0	2 (40.0%)	2 (18.2%)	3 (17.6%)
Grade 3	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Cystitis	0	0	0	0
Grade 2	0	0	0	0
Kidney infection	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Herpes viral infections	2 (5.4%)	1 (4.0%)	3 (4.8%)	6 (7.6%)
Grade 1	0	0	0	3 (3.8%)
Grade 2	2 (5.4%)	1 (4.0%)	3 (4.8%)	3 (3.8%)
Grade 3	0	0	0	0
Oral herpes	0	1 (4.0%)	1 (1.6%)	4 (5.1%)
Grade 1	0	0	0	3 (3.8%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Herpes zoster	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	0	0	0	0
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Herpes simplex	1 (2.7%)	1 (4.0%)	2 (3.2%)	2 (2.5%)
Grade 2	1 (2.7%)	1 (4.0%)	2 (3.2%)	2 (2.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Herpes viral infections	2 (33.3%)	1 (20.0%)	3 (27.3%)	4 (23.5%)
Grade 1	2 (33.3%)	0	2 (18.2%)	1 (5.9%)
Grade 2	0	1 (20.0%)	1 (9.1%)	2 (11.8%)
Grade 3	0	0	0	1 (5.9%)
Oral herpes	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 1	1 (16.7%)	0	1 (9.1%)	0
Grade 2	0	0	0	1 (5.9%)
Herpes zoster	1 (16.7%)	1 (20.0%)	2 (18.2%)	3 (17.6%)
Grade 1	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 2	0	1 (20.0%)	1 (9.1%)	2 (11.8%)
Herpes simplex	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-et.pdf 24AUG2023:15:00

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Herpes viral infections (cont)				
Ophthalmic herpes zoster	0	0	0	0
Grade 3	0	0	0	0
Bacterial infections NEC	4 (10.8%)	0	4 (6.5%)	8 (10.1%)
Grade 2	2 (5.4%)	0	2 (3.2%)	3 (3.8%)
Grade 3	2 (5.4%)	0	2 (3.2%)	4 (5.1%)
Grade 5	0	0	0	1 (1.3%)
Cellulitis	2 (5.4%)	0	2 (3.2%)	3 (3.8%)
Grade 3	2 (5.4%)	0	2 (3.2%)	3 (3.8%)
Urinary tract infection bacterial	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Bacterial rhinitis	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Herpes viral infections (cont)				
Ophthalmic herpes zoster	0	0	0	1 (5.9%)
Grade 3	0	0	0	1 (5.9%)
Bacterial infections NEC	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 2	0	0	0	0
Grade 3	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 5	0	0	0	0
Cellulitis	0	0	0	0
Grade 3	0	0	0	0
Urinary tract infection bacterial	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 2	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Bacterial rhinitis	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Bacterial infections NEC (cont)				
Bacterial rhinitis (cont)				
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Bacterial sepsis	0	0	0	1 (1.3%)
Grade 5	0	0	0	1 (1.3%)
Citrobacter infection	0	0	0	0
Grade 3	0	0	0	0
Peritonitis bacterial	0	0	0	1 (1.3%)
Grade 3	0	0	0	1 (1.3%)
Propionibacterium infection	0	0	0	1 (1.3%)
Grade 2	0	0	0	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Bacterial infections NEC (cont)				
Bacterial rhinitis (cont)				
Grade 2	0	0	0	0
Bacterial sepsis	0	0	0	0
Grade 5	0	0	0	0
Citrobacter infection	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 3	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Peritonitis bacterial	0	0	0	0
Grade 3	0	0	0	0
Propionibacterium infection	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Sepsis, bacteraemia, viraemia and fungaemia NEC	3 (8.1%)	1 (4.0%)	4 (6.5%)	4 (5.1%)
Grade 3	0	0	0	0
Grade 4	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Grade 5	1 (2.7%)	1 (4.0%)	2 (3.2%)	2 (2.5%)
Sepsis	2 (5.4%)	1 (4.0%)	3 (4.8%)	3 (3.8%)
Grade 3	0	0	0	0
Grade 4	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Grade 5	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Bacteraemia	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 5	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Urosepsis	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 4	0	1 (4.0%)	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Sepsis, bacteraemia, viraemia and fungaemia NEC	2 (33.3%)	0	2 (18.2%)	4 (23.5%)
Grade 3	0	0	0	1 (5.9%)
Grade 4	1 (16.7%)	0	1 (9.1%)	2 (11.8%)
Grade 5	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Sepsis	2 (33.3%)	0	2 (18.2%)	4 (23.5%)
Grade 3	0	0	0	1 (5.9%)
Grade 4	1 (16.7%)	0	1 (9.1%)	2 (11.8%)
Grade 5	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Bacteraemia	0	0	0	0
Grade 5	0	0	0	0
Urosepsis	0	0	0	0
Grade 4	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Infections NEC	3 (8.1%)	2 (8.0%)	5 (8.1%)	6 (7.6%)
Grade 1	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Grade 2	2 (5.4%)	2 (8.0%)	4 (6.5%)	4 (5.1%)
Respiratory tract infection	1 (2.7%)	1 (4.0%)	2 (3.2%)	3 (3.8%)
Grade 1	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Infection	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Localised infection	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Wound infection	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Infections NEC	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Respiratory tract infection	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Infection	0	0	0	0
Grade 2	0	0	0	0
Localised infection	0	0	0	0
Grade 2	0	0	0	0
Wound infection	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Candida infections	0	1 (4.0%)	1 (1.6%)	4 (5.1%)
Grade 1	0	0	0	2 (2.5%)
Grade 2	0	0	0	1 (1.3%)
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Oral candidiasis	0	1 (4.0%)	1 (1.6%)	3 (3.8%)
Grade 1	0	0	0	1 (1.3%)
Grade 2	0	0	0	1 (1.3%)
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Oropharyngeal candidiasis	0	0	0	1 (1.3%)
Grade 1	0	0	0	1 (1.3%)
Abdominal and gastrointestinal infections	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Candida infections	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Oral candidiasis	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Oropharyngeal candidiasis	0	0	0	0
Grade 1	0	0	0	0
Abdominal and gastrointestinal infections	1 (16.7%)	0	1 (9.1%)	2 (11.8%)
Grade 1	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 3	0	0	0	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
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SAF-Anemic Analysis Set

	White			
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Abdominal and gastrointestinal infections (cont)				
Gastroenteritis	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Diverticulitis	0	0	0	0
Grade 3	0	0	0	0
Ear infections	3 (8.1%)	0	3 (4.8%)	3 (3.8%)
Grade 2	3 (8.1%)	0	3 (4.8%)	3 (3.8%)
Ear infection	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Grade 2	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Otitis media	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

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Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Abdominal and gastrointestinal infections (cont)				
Gastroenteritis	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 1	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Diverticulitis	0	0	0	1 (5.9%)
Grade 3	0	0	0	1 (5.9%)
Ear infections	0	0	0	0
Grade 2	0	0	0	0
Ear infection	0	0	0	0
Grade 2	0	0	0	0
Otitis media	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Fungal infections NEC	1 (2.7%)	1 (4.0%)	2 (3.2%)	2 (2.5%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Oral fungal infection	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 1	0	0	0	0
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Fungal skin infection	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Dental and oral soft tissue infections	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Grade 2	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Dental fistula	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Fungal infections NEC	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 1	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 3	0	0	0	0
Oral fungal infection	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 1	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 3	0	0	0	0
Fungal skin infection	0	0	0	0
Grade 1	0	0	0	0
Dental and oral soft tissue infections	0	0	0	0
Grade 2	0	0	0	0
Dental fistula	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Dental and oral soft tissue infections (cont)				
Tooth abscess	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Escherichia infections	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 2	0	0	0	0
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Escherichia bacteraemia	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Escherichia infection	0	0	0	0
Grade 1	0	0	0	0
Escherichia urinary tract infection	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
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SAF-Anemic Analysis Set

(Continued)	Other Races			
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Dental and oral soft tissue infections (cont)				
Tooth abscess	0	0	0	0
Grade 2	0	0	0	0
Escherichia infections	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 2	1 (16.7%)	0	1 (9.1%)	0
Grade 3	0	0	0	1 (5.9%)
Escherichia bacteraemia	0	0	0	0
Grade 3	0	0	0	0
Escherichia infection	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 1	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Escherichia urinary tract infection	1 (16.7%)	0	1 (9.1%)	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Escherichia infections (cont)				
Escherichia urinary tract infection (cont)				
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Eye and eyelid infections	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Conjunctivitis	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Influenza viral infections	0	1 (4.0%)	1 (1.6%)	2 (2.5%)
Grade 1	0	0	0	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Escherichia infections (cont)				
Escherichia urinary tract infection (cont)				
Grade 2	1 (16.7%)	0	1 (9.1%)	0
Grade 3	0	0	0	1 (5.9%)
Eye and eyelid infections	1 (16.7%)	0	1 (9.1%)	2 (11.8%)
Grade 1	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 2	0	0	0	1 (5.9%)
Conjunctivitis	1 (16.7%)	0	1 (9.1%)	2 (11.8%)
Grade 1	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 2	0	0	0	1 (5.9%)
Influenza viral infections	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Influenza viral infections (cont)				
(cont)				
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Influenza	0	1 (4.0%)	1 (1.6%)	2 (2.5%)
Grade 1	0	0	0	1 (1.3%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Skin structures and soft tissue infections	0	0	0	2 (2.5%)
Grade 1	0	0	0	1 (1.3%)
Grade 2	0	0	0	1 (1.3%)
Folliculitis	0	0	0	1 (1.3%)
Grade 1	0	0	0	1 (1.3%)
Skin infection	0	0	0	1 (1.3%)

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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Influenza viral infections (cont)				
(cont)				
Grade 2	0	0	0	0
Influenza	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Skin structures and soft tissue infections	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Folliculitis	0	0	0	0
Grade 1	0	0	0	0
Skin infection	0	0	0	0

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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Skin structures and soft tissue infections (cont)				
Skin infection (cont)				
Grade 2	0	0	0	1 (1.3%)
Viral infections NEC	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	0	0	0	0
Grade 3	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Pneumonia viral	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 3	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Viral rash	0	0	0	0
Grade 1	0	0	0	0
Clostridia infections	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Skin structures and soft tissue infections (cont)				
Skin infection (cont)				
Grade 2	0	0	0	0
Viral infections NEC	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 3	0	0	0	0
Pneumonia viral	0	0	0	0
Grade 3	0	0	0	0
Viral rash	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Clostridia infections	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Clostridia infections (cont)				
(cont)				
Grade 3	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Clostridium difficile infection	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 3	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Enterococcal infections	0	0	0	0
Grade 2	0	0	0	0
Urinary tract infection enterococcal	0	0	0	0
Grade 2	0	0	0	0
Muscle and soft tissue infections	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Clostridia infections (cont)				
(cont)				
Grade 3	0	0	0	0
Clostridium difficile infection	0	0	0	0
Grade 3	0	0	0	0
Enterococcal infections	0	0	0	1 (5.9%)
Grade 2	0	0	0	1 (5.9%)
Urinary tract infection enterococcal	0	0	0	1 (5.9%)
Grade 2	0	0	0	1 (5.9%)
Muscle and soft tissue infections	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Muscle and soft tissue infections (cont)				
Soft tissue infection	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Staphylococcal infections	0	0	0	1 (1.3%)
Grade 2	0	0	0	1 (1.3%)
Staphylococcal infection	0	0	0	1 (1.3%)
Grade 2	0	0	0	1 (1.3%)
Streptococcal infections	0	0	0	0
Grade 2	0	0	0	0
Erysipelas	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Muscle and soft tissue infections (cont)				
Soft tissue infection	0	0	0	0
Grade 3	0	0	0	0
Staphylococcal infections	0	0	0	0
Grade 2	0	0	0	0
Staphylococcal infection	0	0	0	0
Grade 2	0	0	0	0
Streptococcal infections	0	0	0	1 (5.9%)
Grade 2	0	0	0	1 (5.9%)
Erysipelas	0	0	0	1 (5.9%)
Grade 2	0	0	0	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Vascular infections	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Haematoma infection	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Nervous system disorders	15 (40.5%)	14 (56.0%)	29 (46.8%)	47 (59.5%)
Grade 1	8 (21.6%)	8 (32.0%)	16 (25.8%)	28 (35.4%)
Grade 2	3 (8.1%)	4 (16.0%)	7 (11.3%)	12 (15.2%)
Grade 3	2 (5.4%)	2 (8.0%)	4 (6.5%)	5 (6.3%)
Grade 4	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Neurological signs and symptoms NEC	4 (10.8%)	3 (12.0%)	7 (11.3%)	16 (20.3%)
Grade 1	3 (8.1%)	3 (12.0%)	6 (9.7%)	13 (16.5%)
Grade 2	1 (2.7%)	0	1 (1.6%)	3 (3.8%)
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Vascular infections	0	0	0	0
Grade 2	0	0	0	0
Haematoma infection	0	0	0	0
Grade 2	0	0	0	0
Nervous system disorders	3 (50.0%)	3 (60.0%)	6 (54.5%)	10 (58.8%)
Grade 1	1 (16.7%)	2 (40.0%)	3 (27.3%)	5 (29.4%)
Grade 2	1 (16.7%)	1 (20.0%)	2 (18.2%)	3 (17.6%)
Grade 3	1 (16.7%)	0	1 (9.1%)	2 (11.8%)
Grade 4	0	0	0	0
Neurological signs and symptoms NEC	3 (50.0%)	0	3 (27.3%)	5 (29.4%)
Grade 1	2 (33.3%)	0	2 (18.2%)	2 (11.8%)
Grade 2	0	0	0	1 (5.9%)
Grade 3	1 (16.7%)	0	1 (9.1%)	2 (11.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Neurological signs and symptoms NEC (cont)				
Dizziness	3 (8.1%)	3 (12.0%)	6 (9.7%)	12 (15.2%)
Grade 1	3 (8.1%)	3 (12.0%)	6 (9.7%)	11 (13.9%)
Grade 2	0	0	0	1 (1.3%)
Grade 3	0	0	0	0
Presyncope	1 (2.7%)	0	1 (1.6%)	3 (3.8%)
Grade 1	0	0	0	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Grade 3	0	0	0	0
Dizziness exertional	0	0	0	1 (1.3%)
Grade 1	0	0	0	1 (1.3%)
Dizziness postural	0	0	0	1 (1.3%)
Grade 1	0	0	0	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Neurological signs and symptoms NEC (cont)				
Dizziness	3 (50.0%)	0	3 (27.3%)	5 (29.4%)
Grade 1	2 (33.3%)	0	2 (18.2%)	3 (17.6%)
Grade 2	0	0	0	1 (5.9%)
Grade 3	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Presyncope	0	0	0	1 (5.9%)
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	1 (5.9%)
Dizziness exertional	0	0	0	0
Grade 1	0	0	0	0
Dizziness postural	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Peripheral neuropathies NEC	4 (10.8%)	7 (28.0%)	11 (17.7%)	17 (21.5%)
Grade 1	2 (5.4%)	5 (20.0%)	7 (11.3%)	12 (15.2%)
Grade 2	2 (5.4%)	1 (4.0%)	3 (4.8%)	4 (5.1%)
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Peripheral sensory neuropathy	3 (8.1%)	6 (24.0%)	9 (14.5%)	14 (17.7%)
Grade 1	2 (5.4%)	5 (20.0%)	7 (11.3%)	11 (13.9%)
Grade 2	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Neuropathy peripheral	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Peripheral motor neuropathy	0	0	0	1 (1.3%)
Grade 1	0	0	0	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Peripheral neuropathies NEC	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 1	0	0	0	0
Grade 2	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 3	0	0	0	0
Peripheral sensory neuropathy	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 1	0	0	0	0
Grade 2	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 3	0	0	0	0
Neuropathy peripheral	0	0	0	0
Grade 2	0	0	0	0
Peripheral motor neuropathy	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Peripheral neuropathies NEC (cont)				
Peripheral sensorimotor neuropathy	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Headaches NEC	0	4 (16.0%)	4 (6.5%)	12 (15.2%)
Grade 1	0	1 (4.0%)	1 (1.6%)	7 (8.9%)
Grade 2	0	2 (8.0%)	2 (3.2%)	4 (5.1%)
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Headache	0	4 (16.0%)	4 (6.5%)	12 (15.2%)
Grade 1	0	1 (4.0%)	1 (1.6%)	7 (8.9%)
Grade 2	0	2 (8.0%)	2 (3.2%)	4 (5.1%)
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Paraesthesias and dysaesthesias	2 (5.4%)	2 (8.0%)	4 (6.5%)	6 (7.6%)
Grade 1	2 (5.4%)	2 (8.0%)	4 (6.5%)	5 (6.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Peripheral neuropathies NEC (cont)				
Peripheral sensorimotor neuropathy	0	0	0	0
Grade 2	0	0	0	0
Headaches NEC	0	2 (40.0%)	2 (18.2%)	2 (11.8%)
Grade 1	0	2 (40.0%)	2 (18.2%)	2 (11.8%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Headache	0	2 (40.0%)	2 (18.2%)	2 (11.8%)
Grade 1	0	2 (40.0%)	2 (18.2%)	2 (11.8%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Paraesthesias and dysaesthesias	0	1 (20.0%)	1 (9.1%)	2 (11.8%)
Grade 1	0	1 (20.0%)	1 (9.1%)	2 (11.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Paraesthesias and dysaesthesias (cont)				
(cont)				
Grade 2	0	0	0	1 (1.3%)
Paraesthesia	1 (2.7%)	2 (8.0%)	3 (4.8%)	6 (7.6%)
Grade 1	1 (2.7%)	2 (8.0%)	3 (4.8%)	5 (6.3%)
Grade 2	0	0	0	1 (1.3%)
Hypoaesthesia	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Disturbances in consciousness NEC	2 (5.4%)	1 (4.0%)	3 (4.8%)	5 (6.3%)
Grade 1	0	1 (4.0%)	1 (1.6%)	2 (2.5%)
Grade 3	2 (5.4%)	0	2 (3.2%)	3 (3.8%)
Somnolence	0	1 (4.0%)	1 (1.6%)	2 (2.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Paraesthesias and dysaesthesias (cont)				
(cont)				
Grade 2	0	0	0	0
Paraesthesia	0	1 (20.0%)	1 (9.1%)	2 (11.8%)
Grade 1	0	1 (20.0%)	1 (9.1%)	2 (11.8%)
Grade 2	0	0	0	0
Hypoaesthesia	0	0	0	0
Grade 1	0	0	0	0
Disturbances in consciousness NEC	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 3	0	0	0	0
Somnolence	0	1 (20.0%)	1 (9.1%)	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Disturbances in consciousness NEC (cont)				
Somnolence (cont)				
Grade 1	0	1 (4.0%)	1 (1.6%)	2 (2.5%)
Syncope	2 (5.4%)	0	2 (3.2%)	3 (3.8%)
Grade 3	2 (5.4%)	0	2 (3.2%)	3 (3.8%)
Loss of consciousness	0	0	0	1 (1.3%)
Grade 3	0	0	0	1 (1.3%)
Sensory abnormalities NEC	2 (5.4%)	0	2 (3.2%)	4 (5.1%)
Grade 1	2 (5.4%)	0	2 (3.2%)	3 (3.8%)
Grade 2	0	0	0	1 (1.3%)
Restless legs syndrome	1 (2.7%)	0	1 (1.6%)	3 (3.8%)
Grade 1	1 (2.7%)	0	1 (1.6%)	2 (2.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Disturbances in consciousness NEC (cont)				
Somnolence (cont)				
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Syncope	0	0	0	0
Grade 3	0	0	0	0
Loss of consciousness	0	0	0	0
Grade 3	0	0	0	0
Sensory abnormalities NEC	0	1 (20.0%)	1 (9.1%)	2 (11.8%)
Grade 1	0	0	0	1 (5.9%)
Grade 2	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Restless legs syndrome	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Sensory abnormalities NEC (cont)				
Restless legs syndrome (cont)				
Grade 2	0	0	0	1 (1.3%)
Allodynia	0	0	0	0
Grade 2	0	0	0	0
Hypogeusia	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Neuralgia	0	0	0	1 (1.3%)
Grade 1	0	0	0	1 (1.3%)
Post herpetic neuralgia	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
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Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Sensory abnormalities NEC (cont)				
Restless legs syndrome (cont)				
Grade 2	0	0	0	0
Allodynia	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 2	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Hypogeusia	0	0	0	0
Grade 1	0	0	0	0
Neuralgia	0	0	0	0
Grade 1	0	0	0	0
Post herpetic neuralgia	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 2	0	1 (20.0%)	1 (9.1%)	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
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SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
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Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Sensory abnormalities NEC (cont)				
Taste disorder	0	0	0	0
Grade 1	0	0	0	0
Mental impairment (excl dementia and memory loss)	2 (5.4%)	0	2 (3.2%)	3 (3.8%)
Grade 1	2 (5.4%)	0	2 (3.2%)	3 (3.8%)
Disturbance in attention	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Grade 1	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Cognitive disorder	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Sensory abnormalities NEC (cont)				
Taste disorder	0	0	0	1 (5.9%)
Grade 1	0	0	0	1 (5.9%)
Mental impairment (excl dementia and memory loss)	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Disturbance in attention	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Cognitive disorder	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
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Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Central nervous system haemorrhages and cerebrovascular accidents	2 (5.4%)	1 (4.0%)	3 (4.8%)	3 (3.8%)
Grade 1	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 4	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Cerebrovascular accident	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 4	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Cerebral infarction	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 1	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Subarachnoid haemorrhage	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 4	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Tremor (excl congenital)	1 (2.7%)	0	1 (1.6%)	2 (2.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Central nervous system haemorrhages and cerebrovascular accidents	0	0	0	0
Grade 1	0	0	0	0
Grade 4	0	0	0	0
Cerebrovascular accident	0	0	0	0
Grade 2	0	0	0	0
Grade 4	0	0	0	0
Cerebral infarction	0	0	0	0
Grade 1	0	0	0	0
Subarachnoid haemorrhage	0	0	0	0
Grade 4	0	0	0	0
Tremor (excl congenital)	0	0	0	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Tremor (excl congenital) (cont)				
(cont)				
Grade 1	0	0	0	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Tremor	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Grade 1	0	0	0	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Coordination and balance disturbances	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Grade 1	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Balance disorder	0	0	0	1 (1.3%)
Grade 1	0	0	0	1 (1.3%)
Coordination abnormal	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

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(Continued)	Other Races			
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Tremor (excl congenital) (cont)				
(cont)				
Grade 1	0	0	0	1 (5.9%)
Grade 2	0	0	0	0
Tremor	0	0	0	1 (5.9%)
Grade 1	0	0	0	1 (5.9%)
Grade 2	0	0	0	0
Coordination and balance disturbances	0	0	0	0
Grade 1	0	0	0	0
Balance disorder	0	0	0	0
Grade 1	0	0	0	0
Coordination abnormal	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Coordination and balance disturbances (cont)				
Coordination abnormal (cont)				
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Memory loss (excl dementia)	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Grade 1	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Amnesia	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Memory impairment	0	0	0	1 (1.3%)
Grade 1	0	0	0	1 (1.3%)
Central nervous system aneurysms and dissections	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 3	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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SAF-Anemic Analysis Set

(Continued)	Other Races			
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Coordination and balance disturbances (cont)				
Coordination abnormal (cont)				
Grade 1	0	0	0	0
Memory loss (excl dementia)	0	0	0	0
Grade 1	0	0	0	0
Amnesia	0	0	0	0
Grade 1	0	0	0	0
Memory impairment	0	0	0	0
Grade 1	0	0	0	0
Central nervous system aneurysms and dissections	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Central nervous system aneurysms and dissections (cont)				
Carotid artery aneurysm	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 3	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Cervical spinal cord and nerve root disorders	0	0	0	1 (1.3%)
Grade 1	0	0	0	1 (1.3%)
Cervical radiculopathy	0	0	0	1 (1.3%)
Grade 1	0	0	0	1 (1.3%)
Dementia (excl Alzheimer's type)	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 1	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Dementia	0	1 (4.0%)	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Central nervous system aneurysms and dissections (cont)				
Carotid artery aneurysm	0	0	0	0
Grade 3	0	0	0	0
Cervical spinal cord and nerve root disorders	0	0	0	0
Grade 1	0	0	0	0
Cervical radiculopathy	0	0	0	0
Grade 1	0	0	0	0
Dementia (excl Alzheimer's type)	0	0	0	0
Grade 1	0	0	0	0
Dementia	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Dementia (excl Alzheimer's type) (cont)				
Dementia (cont)				
Grade 1	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Hypoglossal nerve disorders	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Tongue paralysis	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Lumbar spinal cord and nerve root disorders	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Sciatica	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Dementia (excl Alzheimer's type) (cont)				
Dementia (cont)				
Grade 1	0	0	0	0
Hypoglossal nerve disorders	0	0	0	0
Grade 2	0	0	0	0
Tongue paralysis	0	0	0	0
Grade 2	0	0	0	0
Lumbar spinal cord and nerve root disorders	0	0	0	0
Grade 2	0	0	0	0
Sciatica	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Mononeuropathies	0	0	0	1 (1.3%)
Grade 1	0	0	0	1 (1.3%)
Nerve compression	0	0	0	1 (1.3%)
Grade 1	0	0	0	1 (1.3%)
Nervous system cysts and polyps	0	0	0	0
Grade 1	0	0	0	0
Arachnoid cyst	0	0	0	0
Grade 1	0	0	0	0
Neurologic visual problems NEC	0	0	0	0
Grade 2	0	0	0	0
Visual field defect	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Mononeuropathies	0	0	0	0
Grade 1	0	0	0	0
Nerve compression	0	0	0	0
Grade 1	0	0	0	0
Nervous system cysts and polyps	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Arachnoid cyst	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Neurologic visual problems NEC	0	0	0	1 (5.9%)
Grade 2	0	0	0	1 (5.9%)
Visual field defect	0	0	0	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Neurologic visual problems NEC (cont)				
Visual field defect (cont)				
Grade 2	0	0	0	0
Neuromuscular disorders NEC	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Muscle contractions involuntary	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Olfactory nerve disorders	0	0	0	0
Grade 1	0	0	0	0
Parosmia	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Neurologic visual problems NEC (cont)				
Visual field defect (cont)				
Grade 2	0	0	0	1 (5.9%)
Neuromuscular disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Muscle contractions involuntary	0	0	0	0
Grade 1	0	0	0	0
Olfactory nerve disorders	0	0	0	1 (5.9%)
Grade 1	0	0	0	1 (5.9%)
Parosmia	0	0	0	1 (5.9%)
Grade 1	0	0	0	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
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SAF-Anemic Analysis Set

	White			
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Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Speech and language abnormalities	0	0	0	0
Grade 1	0	0	0	0
Speech disorder	0	0	0	0
Grade 1	0	0	0	0
Blood and lymphatic system disorders	17 (45.9%)	17 (68.0%)	34 (54.8%)	46 (58.2%)
Grade 1	2 (5.4%)	1 (4.0%)	3 (4.8%)	3 (3.8%)
Grade 2	1 (2.7%)	5 (20.0%)	6 (9.7%)	9 (11.4%)
Grade 3	10 (27.0%)	8 (32.0%)	18 (29.0%)	24 (30.4%)
Grade 4	4 (10.8%)	3 (12.0%)	7 (11.3%)	10 (12.7%)
Anaemias NEC	10 (27.0%)	8 (32.0%)	18 (29.0%)	24 (30.4%)
Grade 2	0	1 (4.0%)	1 (1.6%)	2 (2.5%)
Grade 3	10 (27.0%)	7 (28.0%)	17 (27.4%)	21 (26.6%)
Grade 4	0	0	0	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Speech and language abnormalities	0	0	0	1 (5.9%)
Grade 1	0	0	0	1 (5.9%)
Speech disorder	0	0	0	1 (5.9%)
Grade 1	0	0	0	1 (5.9%)
Blood and lymphatic system disorders	0	3 (60.0%)	3 (27.3%)	8 (47.1%)
Grade 1	0	0	0	1 (5.9%)
Grade 2	0	0	0	0
Grade 3	0	2 (40.0%)	2 (18.2%)	5 (29.4%)
Grade 4	0	1 (20.0%)	1 (9.1%)	2 (11.8%)
Anaemias NEC	0	1 (20.0%)	1 (9.1%)	5 (29.4%)
Grade 2	0	0	0	0
Grade 3	0	1 (20.0%)	1 (9.1%)	5 (29.4%)
Grade 4	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
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SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Anaemias NEC (cont)				
Anaemia	10 (27.0%)	8 (32.0%)	18 (29.0%)	24 (30.4%)
Grade 2	0	1 (4.0%)	1 (1.6%)	2 (2.5%)
Grade 3	10 (27.0%)	7 (28.0%)	17 (27.4%)	21 (26.6%)
Grade 4	0	0	0	1 (1.3%)
Thrombocytopenias	6 (16.2%)	6 (24.0%)	12 (19.4%)	20 (25.3%)
Grade 1	0	0	0	1 (1.3%)
Grade 2	2 (5.4%)	3 (12.0%)	5 (8.1%)	8 (10.1%)
Grade 3	2 (5.4%)	1 (4.0%)	3 (4.8%)	5 (6.3%)
Grade 4	2 (5.4%)	2 (8.0%)	4 (6.5%)	6 (7.6%)
Thrombocytopenia	6 (16.2%)	6 (24.0%)	12 (19.4%)	20 (25.3%)
Grade 1	0	0	0	1 (1.3%)
Grade 2	2 (5.4%)	3 (12.0%)	5 (8.1%)	8 (10.1%)
Grade 3	2 (5.4%)	1 (4.0%)	3 (4.8%)	5 (6.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Anaemias NEC (cont)				
Anaemia	0	1 (20.0%)	1 (9.1%)	5 (29.4%)
Grade 2	0	0	0	0
Grade 3	0	1 (20.0%)	1 (9.1%)	5 (29.4%)
Grade 4	0	0	0	0
Thrombocytopenias	0	2 (40.0%)	2 (18.2%)	3 (17.6%)
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 4	0	1 (20.0%)	1 (9.1%)	2 (11.8%)
Thrombocytopenia	0	2 (40.0%)	2 (18.2%)	3 (17.6%)
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	1 (20.0%)	1 (9.1%)	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Thrombocytopenias (cont)				
Thrombocytopenia (cont)				
Grade 4	2 (5.4%)	2 (8.0%)	4 (6.5%)	6 (7.6%)
Neutropenias	2 (5.4%)	2 (8.0%)	4 (6.5%)	9 (11.4%)
Grade 1	0	0	0	0
Grade 2	0	0	0	1 (1.3%)
Grade 3	0	2 (8.0%)	2 (3.2%)	3 (3.8%)
Grade 4	2 (5.4%)	0	2 (3.2%)	5 (6.3%)
Neutropenia	2 (5.4%)	2 (8.0%)	4 (6.5%)	9 (11.4%)
Grade 1	0	0	0	0
Grade 2	0	0	0	1 (1.3%)
Grade 3	0	2 (8.0%)	2 (3.2%)	3 (3.8%)
Grade 4	2 (5.4%)	0	2 (3.2%)	5 (6.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
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Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Thrombocytopenias (cont)				
Thrombocytopenia (cont)				
Grade 4	0	1 (20.0%)	1 (9.1%)	2 (11.8%)
Neutropenias	0	0	0	1 (5.9%)
Grade 1	0	0	0	1 (5.9%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Neutropenia	0	0	0	1 (5.9%)
Grade 1	0	0	0	1 (5.9%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Grade 4	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
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SAF-Anemic Analysis Set

	White			
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Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Spleen disorders	0	4 (16.0%)	4 (6.5%)	6 (7.6%)
Grade 2	0	2 (8.0%)	2 (3.2%)	3 (3.8%)
Grade 3	0	1 (4.0%)	1 (1.6%)	2 (2.5%)
Grade 4	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Splenic infarction	0	3 (12.0%)	3 (4.8%)	4 (5.1%)
Grade 2	0	1 (4.0%)	1 (1.6%)	2 (2.5%)
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 4	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Splenomegaly	0	1 (4.0%)	1 (1.6%)	2 (2.5%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 3	0	0	0	1 (1.3%)
Leukocytoses NEC	4 (10.8%)	0	4 (6.5%)	5 (6.3%)
Grade 1	3 (8.1%)	0	3 (4.8%)	4 (5.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Spleen disorders	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Splenic infarction	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Splenomegaly	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Leukocytoses NEC	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Leukocytoses NEC (cont)				
(cont)				
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Leukocytosis	4 (10.8%)	0	4 (6.5%)	4 (5.1%)
Grade 1	3 (8.1%)	0	3 (4.8%)	3 (3.8%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Neutrophilia	0	0	0	1 (1.3%)
Grade 1	0	0	0	1 (1.3%)
Leukopenias NEC	1 (2.7%)	1 (4.0%)	2 (3.2%)	3 (3.8%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 3	0	1 (4.0%)	1 (1.6%)	2 (2.5%)
Leukopenia	1 (2.7%)	1 (4.0%)	2 (3.2%)	3 (3.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Leukocytoses NEC (cont)				
(cont)				
Grade 2	0	0	0	0
Leukocytosis	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Neutrophilia	0	0	0	0
Grade 1	0	0	0	0
Leukopenias NEC	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Leukopenia	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Leukopenias NEC (cont)				
Leukopenia (cont)				
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 3	0	1 (4.0%)	1 (1.6%)	2 (2.5%)
Bleeding tendencies	0	1 (4.0%)	1 (1.6%)	2 (2.5%)
Grade 1	0	1 (4.0%)	1 (1.6%)	2 (2.5%)
Increased tendency to bruise	0	1 (4.0%)	1 (1.6%)	2 (2.5%)
Grade 1	0	1 (4.0%)	1 (1.6%)	2 (2.5%)
Anaemias haemolytic NEC	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Haemolytic anaemia	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Leukopenias NEC (cont)				
Leukopenia (cont)				
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Bleeding tendencies	0	0	0	0
Grade 1	0	0	0	0
Increased tendency to bruise	0	0	0	0
Grade 1	0	0	0	0
Anaemias haemolytic NEC	0	0	0	0
Grade 3	0	0	0	0
Haemolytic anaemia	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Coagulopathies	0	0	0	0
Grade 1	0	0	0	0
Hyperfibrinogenaemia	0	0	0	0
Grade 1	0	0	0	0
Lymphatic system disorders NEC	0	0	0	1 (1.3%)
Grade 1	0	0	0	1 (1.3%)
Lymphadenopathy	0	0	0	1 (1.3%)
Grade 1	0	0	0	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Coagulopathies	0	0	0	1 (5.9%)
Grade 1	0	0	0	1 (5.9%)
Hyperfibrinogenaemia	0	0	0	1 (5.9%)
Grade 1	0	0	0	1 (5.9%)
Lymphatic system disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Lymphadenopathy	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders	19 (51.4%)	11 (44.0%)	30 (48.4%)	42 (53.2%)
Grade 1	7 (18.9%)	3 (12.0%)	10 (16.1%)	15 (19.0%)
Grade 2	5 (13.5%)	2 (8.0%)	7 (11.3%)	11 (13.9%)
Grade 3	5 (13.5%)	5 (20.0%)	10 (16.1%)	12 (15.2%)
Grade 4	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 5	2 (5.4%)	0	2 (3.2%)	3 (3.8%)
Coughing and associated symptoms	12 (32.4%)	4 (16.0%)	16 (25.8%)	24 (30.4%)
Grade 1	4 (10.8%)	2 (8.0%)	6 (9.7%)	12 (15.2%)
Grade 2	6 (16.2%)	1 (4.0%)	7 (11.3%)	9 (11.4%)
Grade 3	2 (5.4%)	1 (4.0%)	3 (4.8%)	3 (3.8%)
Cough	12 (32.4%)	4 (16.0%)	16 (25.8%)	22 (27.8%)
Grade 1	4 (10.8%)	2 (8.0%)	6 (9.7%)	11 (13.9%)
Grade 2	6 (16.2%)	1 (4.0%)	7 (11.3%)	8 (10.1%)
Grade 3	2 (5.4%)	1 (4.0%)	3 (4.8%)	3 (3.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders	5 (83.3%)	4 (80.0%)	9 (81.8%)	12 (70.6%)
Grade 1	1 (16.7%)	1 (20.0%)	2 (18.2%)	2 (11.8%)
Grade 2	1 (16.7%)	3 (60.0%)	4 (36.4%)	5 (29.4%)
Grade 3	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 4	2 (33.3%)	0	2 (18.2%)	3 (17.6%)
Grade 5	0	0	0	1 (5.9%)
Coughing and associated symptoms	1 (16.7%)	2 (40.0%)	3 (27.3%)	3 (17.6%)
Grade 1	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 2	0	2 (40.0%)	2 (18.2%)	2 (11.8%)
Grade 3	0	0	0	0
Cough	1 (16.7%)	2 (40.0%)	3 (27.3%)	3 (17.6%)
Grade 1	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 2	0	2 (40.0%)	2 (18.2%)	2 (11.8%)
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Coughing and associated symptoms (cont)				
Haemoptysis	0	0	0	2 (2.5%)
Grade 1	0	0	0	1 (1.3%)
Grade 2	0	0	0	1 (1.3%)
Productive cough	0	0	0	1 (1.3%)
Grade 1	0	0	0	1 (1.3%)
Sputum discoloured	0	0	0	0
Grade 2	0	0	0	0
Breathing abnormalities	6 (16.2%)	4 (16.0%)	10 (16.1%)	15 (19.0%)
Grade 1	3 (8.1%)	2 (8.0%)	5 (8.1%)	7 (8.9%)
Grade 2	2 (5.4%)	1 (4.0%)	3 (4.8%)	4 (5.1%)
Grade 3	0	1 (4.0%)	1 (1.6%)	3 (3.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Coughing and associated symptoms (cont)				
Haemoptysis	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Productive cough	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Sputum discoloured	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 2	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Breathing abnormalities	1 (16.7%)	3 (60.0%)	4 (36.4%)	5 (29.4%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 2	0	2 (40.0%)	2 (18.2%)	3 (17.6%)
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Breathing abnormalities (cont) (cont)				
Grade 4	0	0	0	0
Grade 5	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Dyspnoea	4 (10.8%)	3 (12.0%)	7 (11.3%)	13 (16.5%)
Grade 1	2 (5.4%)	2 (8.0%)	4 (6.5%)	6 (7.6%)
Grade 2	2 (5.4%)	1 (4.0%)	3 (4.8%)	5 (6.3%)
Grade 3	0	0	0	2 (2.5%)
Dyspnoea exertional	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Grade 1	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Respiratory distress	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 4	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Breathing abnormalities (cont)				
(cont)				
Grade 4	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 5	0	0	0	0
Dyspnoea	0	3 (60.0%)	3 (27.3%)	4 (23.5%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 2	0	2 (40.0%)	2 (18.2%)	3 (17.6%)
Grade 3	0	0	0	0
Dyspnoea exertional	0	0	0	0
Grade 1	0	0	0	0
Respiratory distress	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 4	1 (16.7%)	0	1 (9.1%)	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Breathing abnormalities (cont)				
Respiratory distress (cont)				
Grade 5	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Sleep apnoea syndrome	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Nasal disorders NEC	2 (5.4%)	1 (4.0%)	3 (4.8%)	9 (11.4%)
Grade 1	2 (5.4%)	1 (4.0%)	3 (4.8%)	7 (8.9%)
Grade 2	0	0	0	2 (2.5%)
Epistaxis	1 (2.7%)	1 (4.0%)	2 (3.2%)	8 (10.1%)
Grade 1	1 (2.7%)	1 (4.0%)	2 (3.2%)	6 (7.6%)
Grade 2	0	0	0	2 (2.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Breathing abnormalities (cont)				
Respiratory distress (cont)				
Grade 5	0	0	0	0
Sleep apnoea syndrome	0	0	0	0
Grade 3	0	0	0	0
Nasal disorders NEC	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	0	0	0
Grade 2	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Epistaxis	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	0	0	0
Grade 2	0	1 (20.0%)	1 (9.1%)	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Nasal disorders NEC (cont)				
Nasal septum ulceration	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Upper respiratory tract signs and symptoms	4 (10.8%)	0	4 (6.5%)	6 (7.6%)
Grade 1	4 (10.8%)	0	4 (6.5%)	6 (7.6%)
Oropharyngeal pain	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Grade 1	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Rhinorrhoea	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Grade 1	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Dysphonia	0	0	0	1 (1.3%)
Grade 1	0	0	0	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-et.pdf 24AUG2023:15:00

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Nasal disorders NEC (cont)				
Nasal septum ulceration	0	0	0	0
Grade 1	0	0	0	0
Upper respiratory tract signs and symptoms	0	1 (20.0%)	1 (9.1%)	2 (11.8%)
Grade 1	0	1 (20.0%)	1 (9.1%)	2 (11.8%)
Oropharyngeal pain	0	0	0	1 (5.9%)
Grade 1	0	0	0	1 (5.9%)
Rhinorrhoea	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Dysphonia	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Upper respiratory tract signs and symptoms (cont)				
Upper-airway cough syndrome	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Lower respiratory tract inflammatory and immunologic conditions	4 (10.8%)	1 (4.0%)	5 (8.1%)	5 (6.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 3	2 (5.4%)	1 (4.0%)	3 (4.8%)	3 (3.8%)
Grade 4	0	0	0	0
Grade 5	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Pneumonitis	3 (8.1%)	1 (4.0%)	4 (6.5%)	4 (5.1%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 3	2 (5.4%)	1 (4.0%)	3 (4.8%)	3 (3.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Upper respiratory tract signs and symptoms (cont)				
Upper-airway cough syndrome	0	0	0	0
Grade 1	0	0	0	0
Lower respiratory tract inflammatory and immunologic conditions	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Grade 4	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 5	0	0	0	0
Pneumonitis	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Lower respiratory tract inflammatory and immunologic conditions (cont)				
Pneumonia aspiration	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 4	0	0	0	0
Grade 5	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Pulmonary oedemas	0	3 (12.0%)	3 (4.8%)	3 (3.8%)
Grade 3	0	3 (12.0%)	3 (4.8%)	3 (3.8%)
Grade 4	0	0	0	0
Pulmonary oedema	0	2 (8.0%)	2 (3.2%)	2 (2.5%)
Grade 3	0	2 (8.0%)	2 (3.2%)	2 (2.5%)
Acute respiratory distress syndrome	0	0	0	0
Grade 4	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Lower respiratory tract inflammatory and immunologic conditions (cont)				
Pneumonia aspiration	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 4	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 5	0	0	0	0
Pulmonary oedemas	0	0	0	1 (5.9%)
Grade 3	0	0	0	0
Grade 4	0	0	0	1 (5.9%)
Pulmonary oedema	0	0	0	0
Grade 3	0	0	0	0
Acute respiratory distress syndrome	0	0	0	1 (5.9%)
Grade 4	0	0	0	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Pulmonary oedemas (cont)				
Pulmonary congestion	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Parenchymal lung disorders NEC	1 (2.7%)	1 (4.0%)	2 (3.2%)	3 (3.8%)
Grade 2	0	0	0	1 (1.3%)
Grade 3	1 (2.7%)	1 (4.0%)	2 (3.2%)	2 (2.5%)
Atelectasis	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Grade 2	0	0	0	1 (1.3%)
Grade 3	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Interstitial lung disease	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Pulmonary oedemas (cont)				
Pulmonary congestion	0	0	0	0
Grade 3	0	0	0	0
Parenchymal lung disorders NEC	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Atelectasis	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Interstitial lung disease	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Respiratory failures (excl neonatal)	0	0	0	1 (1.3%)
Grade 3	0	0	0	0
Grade 5	0	0	0	1 (1.3%)
Respiratory failure	0	0	0	1 (1.3%)
Grade 3	0	0	0	0
Grade 5	0	0	0	1 (1.3%)
Bronchospasm and obstruction	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	0	0	0	0
Asthma	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
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Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Respiratory failures (excl neonatal)	1 (16.7%)	0	1 (9.1%)	2 (11.8%)
Grade 3	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 5	0	0	0	1 (5.9%)
Respiratory failure	1 (16.7%)	0	1 (9.1%)	2 (11.8%)
Grade 3	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 5	0	0	0	1 (5.9%)
Bronchospasm and obstruction	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 1	0	0	0	0
Grade 2	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Asthma	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 2	1 (16.7%)	0	1 (9.1%)	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
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Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Bronchospasm and obstruction (cont)				
Bronchial hyperreactivity	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Pneumothorax and pleural effusions NEC	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Pleural effusion	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Pulmonary hypertensions	0	0	0	2 (2.5%)
Grade 2	0	0	0	1 (1.3%)
Grade 3	0	0	0	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Bronchospasm and obstruction (cont)				
Bronchial hyperreactivity	0	0	0	0
Grade 1	0	0	0	0
Pneumothorax and pleural effusions NEC	1 (16.7%)	0	1 (9.1%)	2 (11.8%)
Grade 1	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 3	0	0	0	1 (5.9%)
Pleural effusion	1 (16.7%)	0	1 (9.1%)	2 (11.8%)
Grade 1	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 3	0	0	0	1 (5.9%)
Pulmonary hypertensions	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Pulmonary hypertensions (cont)				
Pulmonary hypertension	0	0	0	2 (2.5%)
Grade 2	0	0	0	1 (1.3%)
Grade 3	0	0	0	1 (1.3%)
Respiratory tract disorders NEC	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Lung disorder	0	0	0	0
Grade 2	0	0	0	0
Respiratory tract inflammation	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Bronchial conditions NEC	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Pulmonary hypertensions (cont)				
Pulmonary hypertension	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Respiratory tract disorders NEC	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 2	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Lung disorder	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 2	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Respiratory tract inflammation	0	0	0	0
Grade 2	0	0	0	0
Bronchial conditions NEC	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Bronchial conditions NEC (cont) (cont)				
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Bronchial wall thickening	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Conditions associated with abnormal gas exchange	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 4	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Hypoxia	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 4	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Pulmonary thrombotic and embolic conditions	0	1 (4.0%)	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Bronchial conditions NEC (cont) (cont)				
Grade 1	0	0	0	0
Bronchial wall thickening	0	0	0	0
Grade 1	0	0	0	0
Conditions associated with abnormal gas exchange	0	0	0	0
Grade 4	0	0	0	0
Hypoxia	0	0	0	0
Grade 4	0	0	0	0
Pulmonary thrombotic and embolic conditions	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Pulmonary thrombotic and embolic conditions (cont)				
(cont)				
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Pulmonary embolism	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Metabolism and nutrition disorders	16 (43.2%)	7 (28.0%)	23 (37.1%)	36 (45.6%)
Grade 1	7 (18.9%)	2 (8.0%)	9 (14.5%)	19 (24.1%)
Grade 2	6 (16.2%)	2 (8.0%)	8 (12.9%)	8 (10.1%)
Grade 3	2 (5.4%)	3 (12.0%)	5 (8.1%)	8 (10.1%)
Grade 4	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Pulmonary thrombotic and embolic conditions (cont) (cont)				
Grade 3	0	0	0	0
Pulmonary embolism	0	0	0	0
Grade 3	0	0	0	0
Metabolism and nutrition disorders	4 (66.7%)	2 (40.0%)	6 (54.5%)	11 (64.7%)
Grade 1	2 (33.3%)	0	2 (18.2%)	3 (17.6%)
Grade 2	1 (16.7%)	2 (40.0%)	3 (27.3%)	5 (29.4%)
Grade 3	1 (16.7%)	0	1 (9.1%)	3 (17.6%)
Grade 4	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Potassium imbalance	4 (10.8%)	4 (16.0%)	8 (12.9%)	11 (13.9%)
Grade 1	1 (2.7%)	0	1 (1.6%)	3 (3.8%)
Grade 2	1 (2.7%)	2 (8.0%)	3 (4.8%)	3 (3.8%)
Grade 3	2 (5.4%)	2 (8.0%)	4 (6.5%)	5 (6.3%)
Hyperkalaemia	3 (8.1%)	2 (8.0%)	5 (8.1%)	8 (10.1%)
Grade 1	1 (2.7%)	0	1 (1.6%)	3 (3.8%)
Grade 2	2 (5.4%)	1 (4.0%)	3 (4.8%)	4 (5.1%)
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Hypokalaemia	3 (8.1%)	2 (8.0%)	5 (8.1%)	6 (7.6%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 3	2 (5.4%)	1 (4.0%)	3 (4.8%)	4 (5.1%)
Water soluble vitamin deficiencies	6 (16.2%)	1 (4.0%)	7 (11.3%)	12 (15.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Potassium imbalance	1 (16.7%)	1 (20.0%)	2 (18.2%)	4 (23.5%)
Grade 1	0	0	0	1 (5.9%)
Grade 2	1 (16.7%)	1 (20.0%)	2 (18.2%)	3 (17.6%)
Grade 3	0	0	0	0
Hyperkalaemia	1 (16.7%)	0	1 (9.1%)	3 (17.6%)
Grade 1	0	0	0	2 (11.8%)
Grade 2	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 3	0	0	0	0
Hypokalaemia	0	1 (20.0%)	1 (9.1%)	2 (11.8%)
Grade 1	0	0	0	0
Grade 2	0	1 (20.0%)	1 (9.1%)	2 (11.8%)
Grade 3	0	0	0	0
Water soluble vitamin deficiencies	0	0	0	2 (11.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Water soluble vitamin deficiencies (cont)				
(cont)				
Grade 1	3 (8.1%)	1 (4.0%)	4 (6.5%)	8 (10.1%)
Grade 2	3 (8.1%)	0	3 (4.8%)	4 (5.1%)
Vitamin B1 deficiency	5 (13.5%)	1 (4.0%)	6 (9.7%)	9 (11.4%)
Grade 1	3 (8.1%)	1 (4.0%)	4 (6.5%)	6 (7.6%)
Grade 2	2 (5.4%)	0	2 (3.2%)	3 (3.8%)
Vitamin B complex deficiency	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Grade 1	0	0	0	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Vitamin B6 deficiency	0	0	0	1 (1.3%)
Grade 1	0	0	0	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Water soluble vitamin deficiencies (cont) (cont)				
Grade 1	0	0	0	1 (5.9%)
Grade 2	0	0	0	1 (5.9%)
Vitamin B1 deficiency	0	0	0	2 (11.8%)
Grade 1	0	0	0	1 (5.9%)
Grade 2	0	0	0	1 (5.9%)
Vitamin B complex deficiency	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Vitamin B6 deficiency	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Disorders of purine metabolism	3 (8.1%)	1 (4.0%)	4 (6.5%)	6 (7.6%)
Grade 1	2 (5.4%)	0	2 (3.2%)	3 (3.8%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 3	0	0	0	1 (1.3%)
Grade 4	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Hyperuricaemia	3 (8.1%)	1 (4.0%)	4 (6.5%)	6 (7.6%)
Grade 1	2 (5.4%)	0	2 (3.2%)	3 (3.8%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 3	0	0	0	1 (1.3%)
Grade 4	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Gout	0	0	0	0
Grade 3	0	0	0	0
Appetite disorders	2 (5.4%)	1 (4.0%)	3 (4.8%)	6 (7.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Disorders of purine metabolism	2 (33.3%)	0	2 (18.2%)	4 (23.5%)
Grade 1	1 (16.7%)	0	1 (9.1%)	3 (17.6%)
Grade 2	0	0	0	0
Grade 3	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 4	0	0	0	0
Hyperuricaemia	1 (16.7%)	0	1 (9.1%)	3 (17.6%)
Grade 1	1 (16.7%)	0	1 (9.1%)	3 (17.6%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Gout	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 3	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Appetite disorders	0	1 (20.0%)	1 (9.1%)	3 (17.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Appetite disorders (cont)				
(cont)				
Grade 1	1 (2.7%)	1 (4.0%)	2 (3.2%)	5 (6.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Decreased appetite	2 (5.4%)	1 (4.0%)	3 (4.8%)	6 (7.6%)
Grade 1	1 (2.7%)	1 (4.0%)	2 (3.2%)	5 (6.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Appetite disorder	0	0	0	0
Grade 1	0	0	0	0
Calcium metabolism disorders	2 (5.4%)	2 (8.0%)	4 (6.5%)	6 (7.6%)
Grade 1	2 (5.4%)	1 (4.0%)	3 (4.8%)	5 (6.3%)
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Appetite disorders (cont)				
(cont)				
Grade 1	0	0	0	1 (5.9%)
Grade 2	0	1 (20.0%)	1 (9.1%)	2 (11.8%)
Decreased appetite	0	1 (20.0%)	1 (9.1%)	2 (11.8%)
Grade 1	0	0	0	0
Grade 2	0	1 (20.0%)	1 (9.1%)	2 (11.8%)
Appetite disorder	0	0	0	1 (5.9%)
Grade 1	0	0	0	1 (5.9%)
Calcium metabolism disorders	0	0	0	1 (5.9%)
Grade 1	0	0	0	1 (5.9%)
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Calcium metabolism disorders (cont)				
Hypocalcaemia	2 (5.4%)	2 (8.0%)	4 (6.5%)	6 (7.6%)
Grade 1	2 (5.4%)	1 (4.0%)	3 (4.8%)	5 (6.3%)
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Sodium imbalance	2 (5.4%)	3 (12.0%)	5 (8.1%)	6 (7.6%)
Grade 1	2 (5.4%)	1 (4.0%)	3 (4.8%)	4 (5.1%)
Grade 3	0	2 (8.0%)	2 (3.2%)	2 (2.5%)
Hyponatraemia	2 (5.4%)	3 (12.0%)	5 (8.1%)	6 (7.6%)
Grade 1	2 (5.4%)	1 (4.0%)	3 (4.8%)	4 (5.1%)
Grade 3	0	2 (8.0%)	2 (3.2%)	2 (2.5%)
Hypernatraemia	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Calcium metabolism disorders (cont)				
Hypocalcaemia	0	0	0	1 (5.9%)
Grade 1	0	0	0	1 (5.9%)
Grade 3	0	0	0	0
Sodium imbalance	0	0	0	1 (5.9%)
Grade 1	0	0	0	1 (5.9%)
Grade 3	0	0	0	0
Hyponatraemia	0	0	0	1 (5.9%)
Grade 1	0	0	0	1 (5.9%)
Grade 3	0	0	0	0
Hypernatraemia	0	0	0	1 (5.9%)
Grade 1	0	0	0	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Phosphorus metabolism disorders	1 (2.7%)	2 (8.0%)	3 (4.8%)	4 (5.1%)
Grade 1	0	0	0	1 (1.3%)
Grade 2	1 (2.7%)	1 (4.0%)	2 (3.2%)	2 (2.5%)
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Hypophosphataemia	1 (2.7%)	2 (8.0%)	3 (4.8%)	3 (3.8%)
Grade 2	1 (2.7%)	1 (4.0%)	2 (3.2%)	2 (2.5%)
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Hyperphosphataemia	0	0	0	1 (1.3%)
Grade 1	0	0	0	1 (1.3%)
Hyperglycaemic conditions NEC	0	1 (4.0%)	1 (1.6%)	3 (3.8%)
Grade 1	0	0	0	1 (1.3%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 3	0	0	0	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Phosphorus metabolism disorders	0	0	0	1 (5.9%)
Grade 1	0	0	0	0
Grade 2	0	0	0	1 (5.9%)
Grade 3	0	0	0	0
Hypophosphataemia	0	0	0	1 (5.9%)
Grade 2	0	0	0	1 (5.9%)
Grade 3	0	0	0	0
Hyperphosphataemia	0	0	0	0
Grade 1	0	0	0	0
Hyperglycaemic conditions NEC	0	0	0	1 (5.9%)
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Hyperglycaemic conditions NEC (cont)				
Hyperglycaemia	0	1 (4.0%)	1 (1.6%)	3 (3.8%)
Grade 1	0	0	0	1 (1.3%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 3	0	0	0	1 (1.3%)
Magnesium metabolism disorders	2 (5.4%)	1 (4.0%)	3 (4.8%)	3 (3.8%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Hypomagnesaemia	2 (5.4%)	1 (4.0%)	3 (4.8%)	3 (3.8%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Hyperglycaemic conditions NEC (cont)				
Hyperglycaemia	0	0	0	1 (5.9%)
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	1 (5.9%)
Magnesium metabolism disorders	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Hypomagnesaemia	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Protein metabolism disorders NEC	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Hypoalbuminaemia	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Total fluid volume decreased	0	0	0	2 (2.5%)
Grade 1	0	0	0	2 (2.5%)
Dehydration	0	0	0	1 (1.3%)
Grade 1	0	0	0	1 (1.3%)
Hypovolaemia	0	0	0	1 (1.3%)
Grade 1	0	0	0	1 (1.3%)
Diabetes mellitus (incl subtypes)	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Protein metabolism disorders NEC	0	0	0	1 (5.9%)
Grade 2	0	0	0	1 (5.9%)
Hypoalbuminaemia	0	0	0	1 (5.9%)
Grade 2	0	0	0	1 (5.9%)
Total fluid volume decreased	0	0	0	0
Grade 1	0	0	0	0
Dehydration	0	0	0	0
Grade 1	0	0	0	0
Hypovolaemia	0	0	0	0
Grade 1	0	0	0	0
Diabetes mellitus (incl subtypes)	0	1 (20.0%)	1 (9.1%)	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Diabetes mellitus (incl subtypes) (cont)				
(cont)				
Grade 2	0	0	0	0
Diabetes mellitus	0	0	0	0
Grade 2	0	0	0	0
Electrolyte imbalance NEC	0	0	0	0
Grade 3	0	0	0	0
Tumour lysis syndrome	0	0	0	0
Grade 3	0	0	0	0
Elevated cholesterol	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Diabetes mellitus (incl subtypes) (cont) (cont)				
Grade 2	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Diabetes mellitus	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 2	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Electrolyte imbalance NEC	0	0	0	1 (5.9%)
Grade 3	0	0	0	1 (5.9%)
Tumour lysis syndrome	0	0	0	1 (5.9%)
Grade 3	0	0	0	1 (5.9%)
Elevated cholesterol	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 1	1 (16.7%)	0	1 (9.1%)	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Elevated cholesterol (cont)				
Hypercholesterolaemia	0	0	0	0
Grade 1	0	0	0	0
Total fluid volume increased	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Fluid overload	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Musculoskeletal and connective tissue disorders	13 (35.1%)	8 (32.0%)	21 (33.9%)	34 (43.0%)
Grade 1	6 (16.2%)	5 (20.0%)	11 (17.7%)	18 (22.8%)
Grade 2	7 (18.9%)	3 (12.0%)	10 (16.1%)	14 (17.7%)
Grade 3	0	0	0	2 (2.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Elevated cholesterol (cont)				
Hypercholesterolaemia	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 1	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Total fluid volume increased	0	0	0	0
Grade 2	0	0	0	0
Fluid overload	0	0	0	0
Grade 2	0	0	0	0
Musculoskeletal and connective tissue disorders	5 (83.3%)	3 (60.0%)	8 (72.7%)	9 (52.9%)
Grade 1	3 (50.0%)	2 (40.0%)	5 (45.5%)	6 (35.3%)
Grade 2	2 (33.3%)	1 (20.0%)	3 (27.3%)	3 (17.6%)
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
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Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Musculoskeletal and connective tissue pain and discomfort	9 (24.3%)	3 (12.0%)	12 (19.4%)	15 (19.0%)
Grade 1	4 (10.8%)	2 (8.0%)	6 (9.7%)	9 (11.4%)
Grade 2	5 (13.5%)	1 (4.0%)	6 (9.7%)	6 (7.6%)
Pain in extremity	4 (10.8%)	0	4 (6.5%)	7 (8.9%)
Grade 1	2 (5.4%)	0	2 (3.2%)	5 (6.3%)
Grade 2	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Back pain	5 (13.5%)	1 (4.0%)	6 (9.7%)	6 (7.6%)
Grade 1	2 (5.4%)	1 (4.0%)	3 (4.8%)	3 (3.8%)
Grade 2	3 (8.1%)	0	3 (4.8%)	3 (3.8%)
Limb discomfort	0	1 (4.0%)	1 (1.6%)	2 (2.5%)
Grade 1	0	1 (4.0%)	1 (1.6%)	2 (2.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Musculoskeletal and connective tissue pain and discomfort	2 (33.3%)	1 (20.0%)	3 (27.3%)	4 (23.5%)
Grade 1	2 (33.3%)	1 (20.0%)	3 (27.3%)	4 (23.5%)
Grade 2	0	0	0	0
Pain in extremity	2 (33.3%)	1 (20.0%)	3 (27.3%)	3 (17.6%)
Grade 1	2 (33.3%)	1 (20.0%)	3 (27.3%)	3 (17.6%)
Grade 2	0	0	0	0
Back pain	0	0	0	1 (5.9%)
Grade 1	0	0	0	1 (5.9%)
Grade 2	0	0	0	0
Limb discomfort	0	0	0	1 (5.9%)
Grade 1	0	0	0	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Musculoskeletal and connective tissue pain and discomfort (cont)				
Flank pain	0	0	0	1 (1.3%)
Grade 1	0	0	0	1 (1.3%)
Musculoskeletal chest pain	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Musculoskeletal pain	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Neck pain	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Joint related signs and symptoms	1 (2.7%)	0	1 (1.6%)	7 (8.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Musculoskeletal and connective tissue pain and discomfort (cont)				
Flank pain	0	0	0	0
Grade 1	0	0	0	0
Musculoskeletal chest pain	0	0	0	0
Grade 1	0	0	0	0
Musculoskeletal pain	0	0	0	0
Grade 2	0	0	0	0
Neck pain	0	0	0	0
Grade 2	0	0	0	0
Joint related signs and symptoms	2 (33.3%)	0	2 (18.2%)	2 (11.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
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Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Joint related signs and symptoms (cont) (cont)				
Grade 1	1 (2.7%)	0	1 (1.6%)	6 (7.6%)
Grade 2	0	0	0	1 (1.3%)
Arthralgia	1 (2.7%)	0	1 (1.6%)	7 (8.9%)
Grade 1	1 (2.7%)	0	1 (1.6%)	6 (7.6%)
Grade 2	0	0	0	1 (1.3%)
Bone related signs and symptoms	0	3 (12.0%)	3 (4.8%)	6 (7.6%)
Grade 1	0	3 (12.0%)	3 (4.8%)	3 (3.8%)
Grade 2	0	0	0	3 (3.8%)
Bone pain	0	3 (12.0%)	3 (4.8%)	5 (6.3%)
Grade 1	0	3 (12.0%)	3 (4.8%)	3 (3.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Joint related signs and symptoms (cont) (cont)				
Grade 1	2 (33.3%)	0	2 (18.2%)	2 (11.8%)
Grade 2	0	0	0	0
Arthralgia	2 (33.3%)	0	2 (18.2%)	2 (11.8%)
Grade 1	2 (33.3%)	0	2 (18.2%)	2 (11.8%)
Grade 2	0	0	0	0
Bone related signs and symptoms	2 (33.3%)	0	2 (18.2%)	2 (11.8%)
Grade 1	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 2	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Bone pain	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Bone related signs and symptoms (cont)				
Bone pain (cont)				
Grade 2	0	0	0	2 (2.5%)
Metatarsalgia	0	0	0	0
Grade 1	0	0	0	0
Spinal pain	0	0	0	1 (1.3%)
Grade 2	0	0	0	1 (1.3%)
Muscle related signs and symptoms NEC	3 (8.1%)	1 (4.0%)	4 (6.5%)	7 (8.9%)
Grade 1	2 (5.4%)	1 (4.0%)	3 (4.8%)	6 (7.6%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Muscle spasms	3 (8.1%)	1 (4.0%)	4 (6.5%)	7 (8.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Bone related signs and symptoms (cont)				
Bone pain (cont)				
Grade 2	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Metatarsalgia	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 1	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Spinal pain	0	0	0	0
Grade 2	0	0	0	0
Muscle related signs and symptoms NEC	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 2	0	0	0	0
Muscle spasms	0	1 (20.0%)	1 (9.1%)	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-et.pdf 24AUG2023:15:00

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Muscle related signs and symptoms NEC (cont)				
Muscle spasms (cont)				
Grade 1	2 (5.4%)	1 (4.0%)	3 (4.8%)	6 (7.6%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Muscle pains	2 (5.4%)	1 (4.0%)	3 (4.8%)	5 (6.3%)
Grade 1	2 (5.4%)	1 (4.0%)	3 (4.8%)	4 (5.1%)
Grade 2	0	0	0	1 (1.3%)
Myalgia	2 (5.4%)	1 (4.0%)	3 (4.8%)	5 (6.3%)
Grade 1	2 (5.4%)	1 (4.0%)	3 (4.8%)	4 (5.1%)
Grade 2	0	0	0	1 (1.3%)
Bone disorders NEC	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Muscle related signs and symptoms NEC (cont)				
Muscle spasms (cont)				
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 2	0	0	0	0
Muscle pains	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Myalgia	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Bone disorders NEC	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 1	1 (16.7%)	0	1 (9.1%)	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

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Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
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Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Bone disorders NEC (cont)				
(cont)				
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Osteonecrosis	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Osteosis	0	0	0	0
Grade 1	0	0	0	0
Crystal arthropathic disorders	0	1 (4.0%)	1 (1.6%)	2 (2.5%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 3	0	0	0	1 (1.3%)
Chondrocalcinosis pyrophosphate	0	1 (4.0%)	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
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Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Bone disorders NEC (cont) (cont)				
Grade 2	0	0	0	0
Osteonecrosis	0	0	0	0
Grade 2	0	0	0	0
Osteosis	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 1	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Crystal arthropathic disorders	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Chondrocalcinosis pyrophosphate	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
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SAF-Anemic Analysis Set

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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Crystal arthropathic disorders (cont)				
Chondrocalcinosis pyrophosphate (cont)				
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Gouty arthritis	0	0	0	1 (1.3%)
Grade 3	0	0	0	1 (1.3%)
Muscle weakness conditions	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Muscular weakness	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Bursal disorders	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Crystal arthropathic disorders (cont)				
Chondrocalcinosis pyrophosphate (cont)				
Grade 2	0	0	0	0
Gouty arthritis	0	0	0	0
Grade 3	0	0	0	0
Muscle weakness conditions	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 2	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Muscular weakness	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 2	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Bursal disorders	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Bursal disorders (cont)				
Bursitis	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Extremity deformities	0	0	0	0
Grade 2	0	0	0	0
Foot deformity	0	0	0	0
Grade 2	0	0	0	0
Musculoskeletal and connective tissue conditions NEC	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Muscle contracture	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
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Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Bursal disorders (cont)				
Bursitis	0	0	0	0
Grade 2	0	0	0	0
Extremity deformities	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 2	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Foot deformity	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 2	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Musculoskeletal and connective tissue conditions NEC	0	0	0	0
Grade 1	0	0	0	0
Muscle contracture	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Musculoskeletal and connective tissue conditions NEC (cont)				
Muscle contracture (cont)				
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Soft tissue disorders NEC	0	0	0	1 (1.3%)
Grade 3	0	0	0	1 (1.3%)
Groin pain	0	0	0	1 (1.3%)
Grade 3	0	0	0	1 (1.3%)
Spine and neck deformities	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Spinal stenosis	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Musculoskeletal and connective tissue conditions NEC (cont)				
Muscle contracture (cont)				
Grade 1	0	0	0	0
Soft tissue disorders NEC	0	0	0	0
Grade 3	0	0	0	0
Groin pain	0	0	0	0
Grade 3	0	0	0	0
Spine and neck deformities	0	0	0	0
Grade 2	0	0	0	0
Spinal stenosis	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Spine and neck deformities (cont)				
Spinal stenosis (cont)				
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Tendon disorders	0	0	0	0
Grade 1	0	0	0	0
Tendonitis	0	0	0	0
Grade 1	0	0	0	0
Investigations	16 (43.2%)	7 (28.0%)	23 (37.1%)	34 (43.0%)
Grade 1	6 (16.2%)	2 (8.0%)	8 (12.9%)	16 (20.3%)
Grade 2	6 (16.2%)	4 (16.0%)	10 (16.1%)	12 (15.2%)
Grade 3	4 (10.8%)	1 (4.0%)	5 (8.1%)	6 (7.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Spine and neck deformities (cont)				
Spinal stenosis (cont)				
Grade 2	0	0	0	0
Tendon disorders	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 1	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Tendonitis	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 1	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Investigations	2 (33.3%)	2 (40.0%)	4 (36.4%)	6 (35.3%)
Grade 1	1 (16.7%)	1 (20.0%)	2 (18.2%)	2 (11.8%)
Grade 2	1 (16.7%)	0	1 (9.1%)	2 (11.8%)
Grade 3	0	1 (20.0%)	1 (9.1%)	2 (11.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Physical examination procedures and organ system status	7 (18.9%)	4 (16.0%)	11 (17.7%)	18 (22.8%)
Grade 1	5 (13.5%)	2 (8.0%)	7 (11.3%)	12 (15.2%)
Grade 2	1 (2.7%)	2 (8.0%)	3 (4.8%)	5 (6.3%)
Grade 3	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Weight decreased	2 (5.4%)	3 (12.0%)	5 (8.1%)	10 (12.7%)
Grade 1	1 (2.7%)	2 (8.0%)	3 (4.8%)	6 (7.6%)
Grade 2	1 (2.7%)	1 (4.0%)	2 (3.2%)	4 (5.1%)
Weight increased	2 (5.4%)	0	2 (3.2%)	3 (3.8%)
Grade 1	2 (5.4%)	0	2 (3.2%)	3 (3.8%)
Eastern Cooperative Oncology Group performance status worsened	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Physical examination procedures and organ system status	2 (33.3%)	1 (20.0%)	3 (27.3%)	4 (23.5%)
Grade 1	1 (16.7%)	1 (20.0%)	2 (18.2%)	3 (17.6%)
Grade 2	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 3	0	0	0	0
Weight decreased	2 (33.3%)	1 (20.0%)	3 (27.3%)	4 (23.5%)
Grade 1	1 (16.7%)	1 (20.0%)	2 (18.2%)	3 (17.6%)
Grade 2	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Weight increased	0	0	0	0
Grade 1	0	0	0	0
Eastern Cooperative Oncology Group performance status worsened	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Physical examination procedures and organ system status (cont)				
Eastern Cooperative Oncology Group performance status worsened (cont)				
Grade 3	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Body temperature increased	0	0	0	1 (1.3%)
Grade 1	0	0	0	1 (1.3%)
Breath sounds abnormal	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
General physical condition abnormal	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Physical examination procedures and organ system status (cont)				
Eastern Cooperative Oncology Group performance status worsened (cont)				
Grade 3	0	0	0	0
Body temperature increased	0	0	0	0
Grade 1	0	0	0	0
Breath sounds abnormal	0	0	0	0
Grade 1	0	0	0	0
General physical condition abnormal	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

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Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
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Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Liver function analyses	5 (13.5%)	1 (4.0%)	6 (9.7%)	9 (11.4%)
Grade 1	3 (8.1%)	0	3 (4.8%)	5 (6.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 3	1 (2.7%)	1 (4.0%)	2 (3.2%)	3 (3.8%)
Alanine aminotransferase increased	2 (5.4%)	0	2 (3.2%)	4 (5.1%)
Grade 1	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Grade 3	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Blood bilirubin increased	2 (5.4%)	0	2 (3.2%)	3 (3.8%)
Grade 1	2 (5.4%)	0	2 (3.2%)	3 (3.8%)
Grade 2	0	0	0	0
Aspartate aminotransferase increased	0	0	0	2 (2.5%)
Grade 1	0	0	0	1 (1.3%)
Grade 2	0	0	0	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Liver function analyses	0	1 (20.0%)	1 (9.1%)	3 (17.6%)
Grade 1	0	0	0	0
Grade 2	0	0	0	2 (11.8%)
Grade 3	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Alanine aminotransferase increased	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	0	0	0
Grade 3	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Blood bilirubin increased	0	0	0	2 (11.8%)
Grade 1	0	0	0	0
Grade 2	0	0	0	2 (11.8%)
Aspartate aminotransferase increased	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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SAF-Anemic Analysis Set

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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Liver function analyses (cont)				
Aspartate aminotransferase increased (cont)				
Grade 3	0	0	0	0
Gamma-glutamyltransferase increased	1 (2.7%)	1 (4.0%)	2 (3.2%)	3 (3.8%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 3	0	1 (4.0%)	1 (1.6%)	2 (2.5%)
Hepatic enzyme increased	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Liver function test increased	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
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Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Liver function analyses (cont)				
Aspartate aminotransferase increased (cont)				
Grade 3	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Gamma-glutamyltransferase increased	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Hepatic enzyme increased	0	0	0	0
Grade 2	0	0	0	0
Liver function test increased	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Renal function analyses	5 (13.5%)	1 (4.0%)	6 (9.7%)	8 (10.1%)
Grade 1	1 (2.7%)	0	1 (1.6%)	3 (3.8%)
Grade 2	4 (10.8%)	1 (4.0%)	5 (8.1%)	5 (6.3%)
Grade 3	0	0	0	0
Blood creatinine increased	4 (10.8%)	1 (4.0%)	5 (8.1%)	7 (8.9%)
Grade 1	1 (2.7%)	0	1 (1.6%)	3 (3.8%)
Grade 2	3 (8.1%)	1 (4.0%)	4 (6.5%)	4 (5.1%)
Grade 3	0	0	0	0
Creatinine renal clearance decreased	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Tissue enzyme analyses NEC	3 (8.1%)	0	3 (4.8%)	6 (7.6%)
Grade 1	1 (2.7%)	0	1 (1.6%)	3 (3.8%)
Grade 2	1 (2.7%)	0	1 (1.6%)	2 (2.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Renal function analyses	0	0	0	1 (5.9%)
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	1 (5.9%)
Blood creatinine increased	0	0	0	1 (5.9%)
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	1 (5.9%)
Creatinine renal clearance decreased	0	0	0	0
Grade 2	0	0	0	0
Tissue enzyme analyses NEC	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Tissue enzyme analyses NEC (cont)				
(cont)				
Grade 3	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Blood alkaline phosphatase increased	2 (5.4%)	0	2 (3.2%)	4 (5.1%)
Grade 1	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Grade 2	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Blood lactate dehydrogenase increased	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Grade 1	0	0	0	1 (1.3%)
Grade 3	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Cardiac auscultatory investigations	2 (5.4%)	0	2 (3.2%)	4 (5.1%)
Grade 1	2 (5.4%)	0	2 (3.2%)	4 (5.1%)
Cardiac murmur	2 (5.4%)	0	2 (3.2%)	4 (5.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Tissue enzyme analyses NEC (cont)				
(cont)				
Grade 3	0	0	0	0
Blood alkaline phosphatase increased	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Blood lactate dehydrogenase increased	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Cardiac auscultatory investigations	0	0	0	0
Grade 1	0	0	0	0
Cardiac murmur	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Cardiac auscultatory investigations (cont)				
Cardiac murmur (cont)				
Grade 1	2 (5.4%)	0	2 (3.2%)	4 (5.1%)
Coagulation and bleeding analyses	2 (5.4%)	1 (4.0%)	3 (4.8%)	3 (3.8%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	1 (4.0%)	2 (3.2%)	2 (2.5%)
International normalised ratio increased	2 (5.4%)	1 (4.0%)	3 (4.8%)	3 (3.8%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	1 (4.0%)	2 (3.2%)	2 (2.5%)
Mineral and electrolyte analyses	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Grade 1	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Blood bicarbonate decreased	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Cardiac auscultatory investigations (cont)				
Cardiac murmur (cont)				
Grade 1	0	0	0	0
Coagulation and bleeding analyses	0	0	0	1 (5.9%)
Grade 1	0	0	0	1 (5.9%)
Grade 2	0	0	0	0
International normalised ratio increased	0	0	0	1 (5.9%)
Grade 1	0	0	0	1 (5.9%)
Grade 2	0	0	0	0
Mineral and electrolyte analyses	0	0	0	0
Grade 1	0	0	0	0
Blood bicarbonate decreased	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Mineral and electrolyte analyses (cont)				
Blood bicarbonate decreased (cont)				
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Blood chloride increased	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Cardiac function diagnostic procedures	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Ejection fraction decreased	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Haematological analyses NEC	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Mineral and electrolyte analyses (cont)				
Blood bicarbonate decreased (cont)				
Grade 1	0	0	0	0
Blood chloride increased	0	0	0	0
Grade 1	0	0	0	0
Cardiac function diagnostic procedures	0	0	0	0
Grade 2	0	0	0	0
Ejection fraction decreased	0	0	0	0
Grade 2	0	0	0	0
Haematological analyses NEC	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Haematological analyses NEC (cont)				
Blast cell count increased	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Skeletal and cardiac muscle analyses	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Troponin increased	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
White blood cell analyses	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 3	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Neutrophil count decreased	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 3	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Haematological analyses NEC (cont)				
Blast cell count increased	0	0	0	0
Grade 2	0	0	0	0
Skeletal and cardiac muscle analyses	0	0	0	0
Grade 1	0	0	0	0
Troponin increased	0	0	0	0
Grade 1	0	0	0	0
White blood cell analyses	0	0	0	0
Grade 3	0	0	0	0
Neutrophil count decreased	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders	12 (32.4%)	7 (28.0%)	19 (30.6%)	29 (36.7%)
Grade 1	7 (18.9%)	2 (8.0%)	9 (14.5%)	17 (21.5%)
Grade 2	4 (10.8%)	3 (12.0%)	7 (11.3%)	9 (11.4%)
Grade 3	1 (2.7%)	2 (8.0%)	3 (4.8%)	3 (3.8%)
Pruritus NEC	5 (13.5%)	2 (8.0%)	7 (11.3%)	15 (19.0%)
Grade 1	4 (10.8%)	0	4 (6.5%)	9 (11.4%)
Grade 2	1 (2.7%)	1 (4.0%)	2 (3.2%)	5 (6.3%)
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Pruritus	4 (10.8%)	1 (4.0%)	5 (8.1%)	11 (13.9%)
Grade 1	3 (8.1%)	0	3 (4.8%)	7 (8.9%)
Grade 2	1 (2.7%)	0	1 (1.6%)	3 (3.8%)
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Pruritus generalised	1 (2.7%)	1 (4.0%)	2 (3.2%)	4 (5.1%)
Grade 1	1 (2.7%)	0	1 (1.6%)	2 (2.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders	1 (16.7%)	3 (60.0%)	4 (36.4%)	11 (64.7%)
Grade 1	1 (16.7%)	2 (40.0%)	3 (27.3%)	9 (52.9%)
Grade 2	0	1 (20.0%)	1 (9.1%)	2 (11.8%)
Grade 3	0	0	0	0
Pruritus NEC	0	1 (20.0%)	1 (9.1%)	4 (23.5%)
Grade 1	0	1 (20.0%)	1 (9.1%)	3 (17.6%)
Grade 2	0	0	0	1 (5.9%)
Grade 3	0	0	0	0
Pruritus	0	1 (20.0%)	1 (9.1%)	4 (23.5%)
Grade 1	0	1 (20.0%)	1 (9.1%)	3 (17.6%)
Grade 2	0	0	0	1 (5.9%)
Grade 3	0	0	0	0
Pruritus generalised	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Pruritus NEC (cont)				
Pruritus generalised (cont)				
Grade 2	0	1 (4.0%)	1 (1.6%)	2 (2.5%)
Aquagenic pruritus	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Apocrine and eccrine gland disorders	3 (8.1%)	5 (20.0%)	8 (12.9%)	14 (17.7%)
Grade 1	1 (2.7%)	2 (8.0%)	3 (4.8%)	8 (10.1%)
Grade 2	1 (2.7%)	1 (4.0%)	2 (3.2%)	3 (3.8%)
Grade 3	1 (2.7%)	2 (8.0%)	3 (4.8%)	3 (3.8%)
Night sweats	2 (5.4%)	3 (12.0%)	5 (8.1%)	10 (12.7%)
Grade 1	0	1 (4.0%)	1 (1.6%)	5 (6.3%)
Grade 2	1 (2.7%)	1 (4.0%)	2 (3.2%)	3 (3.8%)
Grade 3	1 (2.7%)	1 (4.0%)	2 (3.2%)	2 (2.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Pruritus NEC (cont)				
Pruritus generalised (cont)				
Grade 2	0	0	0	0
Aquagenic pruritus	0	0	0	0
Grade 1	0	0	0	0
Apocrine and eccrine gland disorders	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Night sweats	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Apocrine and eccrine gland disorders (cont)				
Hyperhidrosis	1 (2.7%)	2 (8.0%)	3 (4.8%)	5 (6.3%)
Grade 1	1 (2.7%)	1 (4.0%)	2 (3.2%)	4 (5.1%)
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Rashes, eruptions and exanthems NEC	2 (5.4%)	1 (4.0%)	3 (4.8%)	6 (7.6%)
Grade 1	2 (5.4%)	0	2 (3.2%)	5 (6.3%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Rash	1 (2.7%)	1 (4.0%)	2 (3.2%)	3 (3.8%)
Grade 1	1 (2.7%)	1 (4.0%)	2 (3.2%)	3 (3.8%)
Rash maculo-papular	1 (2.7%)	1 (4.0%)	2 (3.2%)	3 (3.8%)
Grade 1	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Apocrine and eccrine gland disorders (cont)				
Hyperhidrosis	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Rashes, eruptions and exanthems NEC	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 2	0	0	0	0
Rash	0	0	0	0
Grade 1	0	0	0	0
Rash maculo-papular	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Rashes, eruptions and exanthems NEC (cont)				
Rash generalised	0	0	0	1 (1.3%)
Grade 1	0	0	0	1 (1.3%)
Rash macular	0	0	0	0
Grade 1	0	0	0	0
Dermal and epidermal conditions NEC	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Dry skin	0	0	0	0
Grade 1	0	0	0	0
Skin lesion	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Rashes, eruptions and exanthems NEC (cont)				
Rash generalised	0	0	0	0
Grade 1	0	0	0	0
Rash macular	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Dermal and epidermal conditions NEC	1 (16.7%)	2 (40.0%)	3 (27.3%)	4 (23.5%)
Grade 1	1 (16.7%)	2 (40.0%)	3 (27.3%)	4 (23.5%)
Dry skin	1 (16.7%)	2 (40.0%)	3 (27.3%)	4 (23.5%)
Grade 1	1 (16.7%)	2 (40.0%)	3 (27.3%)	4 (23.5%)
Skin lesion	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Purpura and related conditions	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	0	0	0	0
Petechiae	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Ecchymosis	0	0	0	0
Grade 1	0	0	0	0
Purpura	0	0	0	0
Grade 2	0	0	0	0
Purpura senile	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Purpura and related conditions	0	2 (40.0%)	2 (18.2%)	4 (23.5%)
Grade 1	0	1 (20.0%)	1 (9.1%)	3 (17.6%)
Grade 2	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Petechiae	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Ecchymosis	0	0	0	1 (5.9%)
Grade 1	0	0	0	1 (5.9%)
Purpura	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 2	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Purpura senile	0	0	0	1 (5.9%)
Grade 1	0	0	0	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Erythemas	2 (5.4%)	1 (4.0%)	3 (4.8%)	3 (3.8%)
Grade 1	2 (5.4%)	1 (4.0%)	3 (4.8%)	3 (3.8%)
Erythema	2 (5.4%)	1 (4.0%)	3 (4.8%)	3 (3.8%)
Grade 1	2 (5.4%)	1 (4.0%)	3 (4.8%)	3 (3.8%)
Alopecias	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Alopecia	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Angioedemas	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Swelling face	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Erythemas	0	0	0	0
Grade 1	0	0	0	0
Erythema	0	0	0	0
Grade 1	0	0	0	0
Alopecias	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Alopecia	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Angioedemas	0	0	0	0
Grade 1	0	0	0	0
Swelling face	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Angioedemas (cont)				
Swelling face (cont)				
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Bullous conditions	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Erythema multiforme	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Dermatitis and eczema	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Dermatitis contact	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-et.pdf 24AUG2023:15:00

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Angioedemas (cont)				
Swelling face (cont)				
Grade 1	0	0	0	0
Bullous conditions	0	0	0	0
Grade 2	0	0	0	0
Erythema multiforme	0	0	0	0
Grade 2	0	0	0	0
Dermatitis and eczema	0	0	0	0
Grade 2	0	0	0	0
Dermatitis contact	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Dermatitis ascribed to specific agent	0	0	0	0
Grade 1	0	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	0	0	0	0
Grade 1	0	0	0	0
Rosaceas	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 1	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Rosacea	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 1	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Skin and subcutaneous tissue ulcerations	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Dermatitis ascribed to specific agent	0	0	0	1 (5.9%)
Grade 1	0	0	0	1 (5.9%)
Palmar-plantar erythrodysaesthesia syndrome	0	0	0	1 (5.9%)
Grade 1	0	0	0	1 (5.9%)
Rosaceas	0	0	0	0
Grade 1	0	0	0	0
Rosacea	0	0	0	0
Grade 1	0	0	0	0
Skin and subcutaneous tissue ulcerations	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Skin and subcutaneous tissue ulcerations (cont)				
Skin ulcer	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Skin preneoplastic conditions NEC	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Actinic keratosis	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Renal and urinary disorders	12 (32.4%)	8 (32.0%)	20 (32.3%)	22 (27.8%)
Grade 1	4 (10.8%)	4 (16.0%)	8 (12.9%)	9 (11.4%)
Grade 2	5 (13.5%)	2 (8.0%)	7 (11.3%)	8 (10.1%)
Grade 3	3 (8.1%)	2 (8.0%)	5 (8.1%)	5 (6.3%)
Grade 5	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Skin and subcutaneous tissue ulcerations (cont)				
Skin ulcer	0	0	0	0
Grade 2	0	0	0	0
Skin preneoplastic conditions NEC	0	0	0	0
Grade 2	0	0	0	0
Actinic keratosis	0	0	0	0
Grade 2	0	0	0	0
Renal and urinary disorders	3 (50.0%)	3 (60.0%)	6 (54.5%)	7 (41.2%)
Grade 1	0	2 (40.0%)	2 (18.2%)	2 (11.8%)
Grade 2	1 (16.7%)	1 (20.0%)	2 (18.2%)	3 (17.6%)
Grade 3	0	0	0	0
Grade 5	2 (33.3%)	0	2 (18.2%)	2 (11.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal failure and impairment	7 (18.9%)	5 (20.0%)	12 (19.4%)	14 (17.7%)
Grade 1	2 (5.4%)	2 (8.0%)	4 (6.5%)	5 (6.3%)
Grade 2	3 (8.1%)	1 (4.0%)	4 (6.5%)	5 (6.3%)
Grade 3	2 (5.4%)	2 (8.0%)	4 (6.5%)	4 (5.1%)
Grade 5	0	0	0	0
Acute kidney injury	3 (8.1%)	4 (16.0%)	7 (11.3%)	7 (8.9%)
Grade 1	2 (5.4%)	2 (8.0%)	4 (6.5%)	4 (5.1%)
Grade 2	1 (2.7%)	1 (4.0%)	2 (3.2%)	2 (2.5%)
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Renal failure	1 (2.7%)	1 (4.0%)	2 (3.2%)	3 (3.8%)
Grade 1	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 2	0	0	0	1 (1.3%)
Grade 3	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 5	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal failure and impairment	3 (50.0%)	1 (20.0%)	4 (36.4%)	5 (29.4%)
Grade 1	0	0	0	0
Grade 2	2 (33.3%)	1 (20.0%)	3 (27.3%)	4 (23.5%)
Grade 3	0	0	0	0
Grade 5	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Acute kidney injury	1 (16.7%)	0	1 (9.1%)	2 (11.8%)
Grade 1	0	0	0	0
Grade 2	1 (16.7%)	0	1 (9.1%)	2 (11.8%)
Grade 3	0	0	0	0
Renal failure	2 (33.3%)	1 (20.0%)	3 (27.3%)	3 (17.6%)
Grade 1	0	0	0	0
Grade 2	1 (16.7%)	1 (20.0%)	2 (18.2%)	2 (11.8%)
Grade 3	0	0	0	0
Grade 5	1 (16.7%)	0	1 (9.1%)	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-et.pdf 24AUG2023:15:00

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal failure and impairment (cont)				
Chronic kidney disease	2 (5.4%)	1 (4.0%)	3 (4.8%)	3 (3.8%)
Grade 2	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Renal impairment	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Grade 1	0	0	0	1 (1.3%)
Grade 3	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Bladder and urethral symptoms	3 (8.1%)	2 (8.0%)	5 (8.1%)	5 (6.3%)
Grade 1	2 (5.4%)	2 (8.0%)	4 (6.5%)	4 (5.1%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Dysuria	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal failure and impairment (cont)				
Chronic kidney disease	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Renal impairment	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Bladder and urethral symptoms	0	2 (40.0%)	2 (18.2%)	2 (11.8%)
Grade 1	0	2 (40.0%)	2 (18.2%)	2 (11.8%)
Grade 2	0	0	0	0
Dysuria	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Bladder and urethral symptoms (cont)				
Urinary incontinence	1 (2.7%)	1 (4.0%)	2 (3.2%)	2 (2.5%)
Grade 1	1 (2.7%)	1 (4.0%)	2 (3.2%)	2 (2.5%)
Bladder spasm	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 1	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Micturition urgency	0	0	0	1 (1.3%)
Grade 1	0	0	0	1 (1.3%)
Renal lithiasis	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 3	0	0	0	0
Nephrolithiasis	2 (5.4%)	0	2 (3.2%)	2 (2.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Bladder and urethral symptoms (cont)				
Urinary incontinence	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Bladder spasm	0	0	0	0
Grade 1	0	0	0	0
Micturition urgency	0	0	0	0
Grade 1	0	0	0	0
Renal lithiasis	0	0	0	1 (5.9%)
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	1 (5.9%)
Nephrolithiasis	0	0	0	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal lithiasis (cont)				
Nephrolithiasis (cont)				
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 3	0	0	0	0
Urinary abnormalities	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	0	0	0	0
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Proteinuria	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	0	0	0	0
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Haematuria	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal lithiasis (cont)				
Nephrolithiasis (cont)				
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	1 (5.9%)
Urinary abnormalities	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 1	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 2	0	0	0	0
Proteinuria	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 1	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 2	0	0	0	0
Haematuria	0	0	0	1 (5.9%)
Grade 1	0	0	0	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Bladder disorders NEC	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Urinary bladder haemorrhage	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Myoneurogenic bladder disorders	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Hypertonic bladder	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Nephritis NEC	0	0	0	0
Grade 5	0	0	0	0
Nephritis	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Bladder disorders NEC	0	0	0	0
Grade 2	0	0	0	0
Urinary bladder haemorrhage	0	0	0	0
Grade 2	0	0	0	0
Myoneurogenic bladder disorders	0	0	0	0
Grade 2	0	0	0	0
Hypertonic bladder	0	0	0	0
Grade 2	0	0	0	0
Nephritis NEC	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 5	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Nephritis	1 (16.7%)	0	1 (9.1%)	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Nephritis NEC (cont)				
Nephritis (cont)				
Grade 5	0	0	0	0
Renal neoplasms	0	0	0	0
Grade 1	0	0	0	0
Renal cyst	0	0	0	0
Grade 1	0	0	0	0
Urinary tract lithiasis (excl renal)	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 3	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Ureterolithiasis	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 3	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Nephritis NEC (cont)				
Nephritis (cont)				
Grade 5	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Renal neoplasms	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 1	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Renal cyst	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 1	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Urinary tract lithiasis (excl renal)	0	0	0	0
Grade 3	0	0	0	0
Ureterolithiasis	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Urinary tract signs and symptoms NEC	0	0	0	0
Grade 2	0	0	0	0
Renal colic	0	0	0	0
Grade 2	0	0	0	0
Vascular disorders	9 (24.3%)	6 (24.0%)	15 (24.2%)	19 (24.1%)
Grade 1	2 (5.4%)	3 (12.0%)	5 (8.1%)	6 (7.6%)
Grade 2	5 (13.5%)	3 (12.0%)	8 (12.9%)	9 (11.4%)
Grade 3	2 (5.4%)	0	2 (3.2%)	4 (5.1%)
Grade 4	0	0	0	0
Vascular hypertensive disorders NEC	2 (5.4%)	1 (4.0%)	3 (4.8%)	6 (7.6%)
Grade 2	1 (2.7%)	1 (4.0%)	2 (3.2%)	4 (5.1%)
Grade 3	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Grade 4	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Urinary tract signs and symptoms NEC	0	0	0	1 (5.9%)
Grade 2	0	0	0	1 (5.9%)
Renal colic	0	0	0	1 (5.9%)
Grade 2	0	0	0	1 (5.9%)
Vascular disorders	1 (16.7%)	1 (20.0%)	2 (18.2%)	5 (29.4%)
Grade 1	0	0	0	1 (5.9%)
Grade 2	0	0	0	1 (5.9%)
Grade 3	1 (16.7%)	1 (20.0%)	2 (18.2%)	2 (11.8%)
Grade 4	0	0	0	1 (5.9%)
Vascular hypertensive disorders NEC	0	0	0	2 (11.8%)
Grade 2	0	0	0	1 (5.9%)
Grade 3	0	0	0	0
Grade 4	0	0	0	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Vascular hypertensive disorders NEC (cont)				
Hypertension	2 (5.4%)	1 (4.0%)	3 (4.8%)	6 (7.6%)
Grade 2	1 (2.7%)	1 (4.0%)	2 (3.2%)	4 (5.1%)
Grade 3	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Grade 4	0	0	0	0
Vascular hypotensive disorders	2 (5.4%)	2 (8.0%)	4 (6.5%)	5 (6.3%)
Grade 1	1 (2.7%)	1 (4.0%)	2 (3.2%)	3 (3.8%)
Grade 2	1 (2.7%)	1 (4.0%)	2 (3.2%)	2 (2.5%)
Hypotension	2 (5.4%)	2 (8.0%)	4 (6.5%)	5 (6.3%)
Grade 1	1 (2.7%)	1 (4.0%)	2 (3.2%)	3 (3.8%)
Grade 2	1 (2.7%)	1 (4.0%)	2 (3.2%)	2 (2.5%)
Orthostatic hypotension	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Vascular hypertensive disorders NEC (cont)				
Hypertension	0	0	0	2 (11.8%)
Grade 2	0	0	0	1 (5.9%)
Grade 3	0	0	0	0
Grade 4	0	0	0	1 (5.9%)
Vascular hypotensive disorders	0	0	0	1 (5.9%)
Grade 1	0	0	0	1 (5.9%)
Grade 2	0	0	0	0
Hypotension	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Orthostatic hypotension	0	0	0	1 (5.9%)
Grade 1	0	0	0	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Haemorrhages NEC	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 1	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 3	0	0	0	0
Haematoma	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 1	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 3	0	0	0	0
Peripheral embolism and thrombosis	2 (5.4%)	1 (4.0%)	3 (4.8%)	3 (3.8%)
Grade 2	2 (5.4%)	1 (4.0%)	3 (4.8%)	3 (3.8%)
Deep vein thrombosis	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Grade 2	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Thrombophlebitis	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Haemorrhages NEC	1 (16.7%)	1 (20.0%)	2 (18.2%)	2 (11.8%)
Grade 1	0	0	0	0
Grade 3	1 (16.7%)	1 (20.0%)	2 (18.2%)	2 (11.8%)
Haematoma	1 (16.7%)	1 (20.0%)	2 (18.2%)	2 (11.8%)
Grade 1	0	0	0	0
Grade 3	1 (16.7%)	1 (20.0%)	2 (18.2%)	2 (11.8%)
Peripheral embolism and thrombosis	0	0	0	0
Grade 2	0	0	0	0
Deep vein thrombosis	0	0	0	0
Grade 2	0	0	0	0
Thrombophlebitis	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Peripheral vascular disorders NEC	0	1 (4.0%)	1 (1.6%)	2 (2.5%)
Grade 1	0	1 (4.0%)	1 (1.6%)	2 (2.5%)
Hot flush	0	1 (4.0%)	1 (1.6%)	2 (2.5%)
Grade 1	0	1 (4.0%)	1 (1.6%)	2 (2.5%)
Non-site specific embolism and thrombosis	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 3	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Embolism	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 3	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Site specific vascular disorders NEC	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Grade 1	2 (5.4%)	0	2 (3.2%)	2 (2.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Peripheral vascular disorders NEC	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 1	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Hot flush	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 1	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Non-site specific embolism and thrombosis	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Embolism	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Site specific vascular disorders NEC	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Site specific vascular disorders NEC (cont)				
Jugular vein distension	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Pallor	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Aortic necrosis and vascular insufficiency	0	0	0	1 (1.3%)
Grade 3	0	0	0	1 (1.3%)
Aortic stenosis	0	0	0	1 (1.3%)
Grade 3	0	0	0	1 (1.3%)
Peripheral vasoconstriction, necrosis and vascular insufficiency	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 1	0	1 (4.0%)	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Site specific vascular disorders NEC (cont)				
Jugular vein distension	0	0	0	0
Grade 1	0	0	0	0
Pallor	0	0	0	0
Grade 1	0	0	0	0
Aortic necrosis and vascular insufficiency	0	0	0	0
Grade 3	0	0	0	0
Aortic stenosis	0	0	0	0
Grade 3	0	0	0	0
Peripheral vasoconstriction, necrosis and vascular insufficiency	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Peripheral vasoconstriction, necrosis and vascular insufficiency (cont)				
Peripheral coldness	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 1	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Psychiatric disorders	9 (24.3%)	5 (20.0%)	14 (22.6%)	20 (25.3%)
Grade 1	5 (13.5%)	2 (8.0%)	7 (11.3%)	10 (12.7%)
Grade 2	4 (10.8%)	3 (12.0%)	7 (11.3%)	10 (12.7%)
Disturbances in initiating and maintaining sleep	4 (10.8%)	2 (8.0%)	6 (9.7%)	8 (10.1%)
Grade 1	3 (8.1%)	1 (4.0%)	4 (6.5%)	5 (6.3%)
Grade 2	1 (2.7%)	1 (4.0%)	2 (3.2%)	3 (3.8%)
Insomnia	4 (10.8%)	2 (8.0%)	6 (9.7%)	8 (10.1%)
Grade 1	3 (8.1%)	1 (4.0%)	4 (6.5%)	5 (6.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-et.pdf 24AUG2023:15:00

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Peripheral vasoconstriction, necrosis and vascular insufficiency (cont)				
Peripheral coldness	0	0	0	0
Grade 1	0	0	0	0
Psychiatric disorders	1 (16.7%)	2 (40.0%)	3 (27.3%)	3 (17.6%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 2	1 (16.7%)	1 (20.0%)	2 (18.2%)	2 (11.8%)
Disturbances in initiating and maintaining sleep	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 2	0	0	0	0
Insomnia	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Disturbances in initiating and maintaining sleep (cont)				
Insomnia (cont)				
Grade 2	1 (2.7%)	1 (4.0%)	2 (3.2%)	3 (3.8%)
Confusion and disorientation	3 (8.1%)	2 (8.0%)	5 (8.1%)	6 (7.6%)
Grade 1	3 (8.1%)	1 (4.0%)	4 (6.5%)	4 (5.1%)
Grade 2	0	1 (4.0%)	1 (1.6%)	2 (2.5%)
Confusional state	3 (8.1%)	2 (8.0%)	5 (8.1%)	6 (7.6%)
Grade 1	3 (8.1%)	1 (4.0%)	4 (6.5%)	4 (5.1%)
Grade 2	0	1 (4.0%)	1 (1.6%)	2 (2.5%)
Anxiety symptoms	1 (2.7%)	0	1 (1.6%)	4 (5.1%)
Grade 1	0	0	0	3 (3.8%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Disturbances in initiating and maintaining sleep (cont)				
Insomnia (cont)				
Grade 2	0	0	0	0
Confusion and disorientation	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Confusional state	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Anxiety symptoms	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 1	0	0	0	0
Grade 2	1 (16.7%)	0	1 (9.1%)	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Anxiety symptoms (cont)				
Anxiety	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Grade 1	0	0	0	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Agitation	0	0	0	2 (2.5%)
Grade 1	0	0	0	2 (2.5%)
Depressive disorders	0	0	0	2 (2.5%)
Grade 2	0	0	0	2 (2.5%)
Depression	0	0	0	2 (2.5%)
Grade 2	0	0	0	2 (2.5%)
Increased physical activity levels	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Grade 1	1 (2.7%)	0	1 (1.6%)	2 (2.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Anxiety symptoms (cont)				
Anxiety	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 1	0	0	0	0
Grade 2	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Agitation	0	0	0	0
Grade 1	0	0	0	0
Depressive disorders	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 2	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Depression	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 2	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Increased physical activity levels	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Increased physical activity levels (cont)				
Restlessness	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Grade 1	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Mood alterations with depressive symptoms	1 (2.7%)	1 (4.0%)	2 (3.2%)	2 (2.5%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Depressed mood	1 (2.7%)	1 (4.0%)	2 (3.2%)	2 (2.5%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Deliria	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Delirium	0	1 (4.0%)	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Increased physical activity levels (cont)				
Restlessness	0	0	0	0
Grade 1	0	0	0	0
Mood alterations with depressive symptoms	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Depressed mood	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Deliria	0	0	0	0
Grade 2	0	0	0	0
Delirium	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Deliria (cont)				
Delirium (cont)				
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Emotional and mood disturbances NEC	0	0	0	1 (1.3%)
Grade 1	0	0	0	1 (1.3%)
Irritability	0	0	0	1 (1.3%)
Grade 1	0	0	0	1 (1.3%)
Sexual desire disorders	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Libido increased	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Deliria (cont)				
Delirium (cont)				
Grade 2	0	0	0	0
Emotional and mood disturbances NEC	0	0	0	0
Grade 1	0	0	0	0
Irritability	0	0	0	0
Grade 1	0	0	0	0
Sexual desire disorders	0	0	0	0
Grade 2	0	0	0	0
Libido increased	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Sleep disorders NEC	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Sleep disorder	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Cardiac disorders	8 (21.6%)	6 (24.0%)	14 (22.6%)	17 (21.5%)
Grade 1	1 (2.7%)	1 (4.0%)	2 (3.2%)	2 (2.5%)
Grade 2	2 (5.4%)	3 (12.0%)	5 (8.1%)	5 (6.3%)
Grade 3	3 (8.1%)	2 (8.0%)	5 (8.1%)	8 (10.1%)
Grade 4	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 5	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Heart failures NEC	4 (10.8%)	2 (8.0%)	6 (9.7%)	8 (10.1%)
Grade 3	3 (8.1%)	2 (8.0%)	5 (8.1%)	7 (8.9%)
Grade 5	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Sleep disorders NEC	0	0	0	0
Grade 2	0	0	0	0
Sleep disorder	0	0	0	0
Grade 2	0	0	0	0
Cardiac disorders	0	1 (20.0%)	1 (9.1%)	3 (17.6%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 2	0	0	0	0
Grade 3	0	0	0	2 (11.8%)
Grade 4	0	0	0	0
Grade 5	0	0	0	0
Heart failures NEC	0	0	0	1 (5.9%)
Grade 3	0	0	0	1 (5.9%)
Grade 5	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
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SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Heart failures NEC (cont)				
Cardiac failure	2 (5.4%)	1 (4.0%)	3 (4.8%)	4 (5.1%)
Grade 3	1 (2.7%)	1 (4.0%)	2 (3.2%)	3 (3.8%)
Grade 5	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Cardiac failure congestive	1 (2.7%)	1 (4.0%)	2 (3.2%)	3 (3.8%)
Grade 3	1 (2.7%)	1 (4.0%)	2 (3.2%)	3 (3.8%)
Cardiac failure acute	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 3	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Supraventricular arrhythmias	4 (10.8%)	1 (4.0%)	5 (8.1%)	7 (8.9%)
Grade 2	2 (5.4%)	1 (4.0%)	3 (4.8%)	3 (3.8%)
Grade 3	1 (2.7%)	0	1 (1.6%)	3 (3.8%)
Grade 4	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Heart failures NEC (cont)				
Cardiac failure	0	0	0	1 (5.9%)
Grade 3	0	0	0	1 (5.9%)
Grade 5	0	0	0	0
Cardiac failure congestive	0	0	0	0
Grade 3	0	0	0	0
Cardiac failure acute	0	0	0	0
Grade 3	0	0	0	0
Supraventricular arrhythmias	0	0	0	1 (5.9%)
Grade 2	0	0	0	0
Grade 3	0	0	0	1 (5.9%)
Grade 4	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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SAF-Anemic Analysis Set

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Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Supraventricular arrhythmias (cont)				
Atrial fibrillation	2 (5.4%)	1 (4.0%)	3 (4.8%)	4 (5.1%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 3	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Grade 4	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Sinus tachycardia	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Grade 2	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Grade 3	0	0	0	0
Supraventricular tachycardia	0	0	0	1 (1.3%)
Grade 3	0	0	0	1 (1.3%)
Cardiac signs and symptoms NEC	1 (2.7%)	1 (4.0%)	2 (3.2%)	3 (3.8%)
Grade 1	1 (2.7%)	1 (4.0%)	2 (3.2%)	3 (3.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
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Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Supraventricular arrhythmias (cont)				
Atrial fibrillation	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Sinus tachycardia	0	0	0	1 (5.9%)
Grade 2	0	0	0	0
Grade 3	0	0	0	1 (5.9%)
Supraventricular tachycardia	0	0	0	0
Grade 3	0	0	0	0
Cardiac signs and symptoms NEC	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Cardiac signs and symptoms NEC (cont)				
Palpitations	1 (2.7%)	1 (4.0%)	2 (3.2%)	3 (3.8%)
Grade 1	1 (2.7%)	1 (4.0%)	2 (3.2%)	3 (3.8%)
Left ventricular failures	2 (5.4%)	1 (4.0%)	3 (4.8%)	3 (3.8%)
Grade 2	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Left ventricular failure	2 (5.4%)	1 (4.0%)	3 (4.8%)	3 (3.8%)
Grade 2	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Ischaemic coronary artery disorders	1 (2.7%)	1 (4.0%)	2 (3.2%)	2 (2.5%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 3	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Cardiac signs and symptoms NEC (cont)				
Palpitations	0	0	0	0
Grade 1	0	0	0	0
Left ventricular failures	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Left ventricular failure	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Ischaemic coronary artery disorders	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
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Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Ischaemic coronary artery disorders (cont)				
Acute myocardial infarction	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 3	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Myocardial ischaemia	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Pericardial disorders NEC	1 (2.7%)	1 (4.0%)	2 (3.2%)	2 (2.5%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Pericardial effusion	1 (2.7%)	1 (4.0%)	2 (3.2%)	2 (2.5%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Rate and rhythm disorders NEC	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Ischaemic coronary artery disorders (cont)				
Acute myocardial infarction	0	0	0	0
Grade 3	0	0	0	0
Myocardial ischaemia	0	0	0	0
Grade 2	0	0	0	0
Pericardial disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Pericardial effusion	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Rate and rhythm disorders NEC	0	1 (20.0%)	1 (9.1%)	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Rate and rhythm disorders NEC (cont)				
(cont)				
Grade 1	0	0	0	0
Grade 3	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Extrasystoles	0	0	0	0
Grade 1	0	0	0	0
Tachycardia	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 3	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Aortic valvular disorders	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Aortic valve calcification	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Rate and rhythm disorders NEC (cont)				
(cont)				
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 3	0	0	0	0
Extrasystoles	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Tachycardia	0	0	0	0
Grade 3	0	0	0	0
Aortic valvular disorders	0	0	0	0
Grade 1	0	0	0	0
Aortic valve calcification	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
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SAF-Anemic Analysis Set

	White			
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Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Cardiomyopathies	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Cardiomyopathy	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Coronary artery disorders NEC	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Arteriosclerosis coronary artery	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Myocardial disorders NEC	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Cardiomegaly	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Cardiomyopathies	0	0	0	0
Grade 1	0	0	0	0
Cardiomyopathy	0	0	0	0
Grade 1	0	0	0	0
Coronary artery disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Arteriosclerosis coronary artery	0	0	0	0
Grade 1	0	0	0	0
Myocardial disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Cardiomegaly	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Myocardial disorders NEC (cont)				
Cardiomegaly (cont)				
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Injury, poisoning and procedural complications	4 (10.8%)	1 (4.0%)	5 (8.1%)	11 (13.9%)
Grade 1	2 (5.4%)	1 (4.0%)	3 (4.8%)	7 (8.9%)
Grade 2	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Grade 3	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Skin injuries NEC	0	1 (4.0%)	1 (1.6%)	6 (7.6%)
Grade 1	0	1 (4.0%)	1 (1.6%)	6 (7.6%)
Contusion	0	1 (4.0%)	1 (1.6%)	6 (7.6%)
Grade 1	0	1 (4.0%)	1 (1.6%)	6 (7.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Myocardial disorders NEC (cont)				
Cardiomegaly (cont)				
Grade 1	0	0	0	0
Injury, poisoning and procedural complications	3 (50.0%)	2 (40.0%)	5 (45.5%)	5 (29.4%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 2	1 (16.7%)	1 (20.0%)	2 (18.2%)	2 (11.8%)
Grade 3	2 (33.3%)	0	2 (18.2%)	2 (11.8%)
Skin injuries NEC	0	0	0	0
Grade 1	0	0	0	0
Contusion	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
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	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Non-site specific injuries NEC	2 (5.4%)	0	2 (3.2%)	3 (3.8%)
Grade 1	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Grade 2	0	0	0	1 (1.3%)
Grade 3	0	0	0	0
Fall	2 (5.4%)	0	2 (3.2%)	3 (3.8%)
Grade 1	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Grade 2	0	0	0	1 (1.3%)
Grade 3	0	0	0	0
Limb fractures and dislocations	0	0	0	2 (2.5%)
Grade 2	0	0	0	1 (1.3%)
Grade 3	0	0	0	1 (1.3%)
Femur fracture	0	0	0	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Non-site specific injuries NEC	1 (16.7%)	1 (20.0%)	2 (18.2%)	2 (11.8%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 2	0	0	0	0
Grade 3	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Fall	1 (16.7%)	1 (20.0%)	2 (18.2%)	2 (11.8%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 2	0	0	0	0
Grade 3	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Limb fractures and dislocations	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Femur fracture	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

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SAF-Anemic Analysis Set

	White			
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Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Limb fractures and dislocations (cont)				
Femur fracture (cont)				
Grade 3	0	0	0	1 (1.3%)
Radius fracture	0	0	0	1 (1.3%)
Grade 2	0	0	0	1 (1.3%)
Muscle, tendon and ligament injuries	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	0	0	0	0
Ligament sprain	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Muscle rupture	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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(Continued)	Other Races			
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Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Limb fractures and dislocations (cont)				
Femur fracture (cont)				
Grade 3	0	0	0	0
Radius fracture	0	0	0	0
Grade 2	0	0	0	0
Muscle, tendon and ligament injuries	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	0	0	0
Grade 2	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Ligament sprain	0	0	0	0
Grade 1	0	0	0	0
Muscle rupture	0	1 (20.0%)	1 (9.1%)	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
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Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Muscle, tendon and ligament injuries (cont)				
Muscle rupture (cont)				
Grade 2	0	0	0	0
Non-site specific procedural complications	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 1	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 3	0	0	0	0
Procedural pain	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 1	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 3	0	0	0	0
Cerebral injuries NEC	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 3	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
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(Continued)	Other Races			
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Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Muscle, tendon and ligament injuries (cont)				
Muscle rupture (cont)				
Grade 2	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Non-site specific procedural complications	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 1	0	0	0	0
Grade 3	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Procedural pain	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 1	0	0	0	0
Grade 3	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Cerebral injuries NEC	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
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SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
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Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Cerebral injuries NEC (cont)				
Subdural haematoma	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 3	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Fractures and dislocations NEC	0	0	0	0
Grade 2	0	0	0	0
Joint dislocation	0	0	0	0
Grade 2	0	0	0	0
Site specific injuries NEC	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Tooth fracture	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Cerebral injuries NEC (cont)				
Subdural haematoma	0	0	0	0
Grade 3	0	0	0	0
Fractures and dislocations NEC	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 2	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Joint dislocation	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 2	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Site specific injuries NEC	0	0	0	0
Grade 2	0	0	0	0
Tooth fracture	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders	4 (10.8%)	3 (12.0%)	7 (11.3%)	12 (15.2%)
Grade 1	3 (8.1%)	0	3 (4.8%)	6 (7.6%)
Grade 2	1 (2.7%)	2 (8.0%)	3 (4.8%)	5 (6.3%)
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Visual disorders NEC	2 (5.4%)	0	2 (3.2%)	3 (3.8%)
Grade 1	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Grade 2	0	0	0	1 (1.3%)
Vision blurred	2 (5.4%)	0	2 (3.2%)	3 (3.8%)
Grade 1	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Grade 2	0	0	0	1 (1.3%)
Photopsia	0	0	0	1 (1.3%)
Grade 1	0	0	0	0
Grade 2	0	0	0	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders	0	2 (40.0%)	2 (18.2%)	3 (17.6%)
Grade 1	0	2 (40.0%)	2 (18.2%)	3 (17.6%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Visual disorders NEC	0	1 (20.0%)	1 (9.1%)	2 (11.8%)
Grade 1	0	1 (20.0%)	1 (9.1%)	2 (11.8%)
Grade 2	0	0	0	0
Vision blurred	0	0	0	1 (5.9%)
Grade 1	0	0	0	1 (5.9%)
Grade 2	0	0	0	0
Photopsia	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Cataract conditions	1 (2.7%)	0	1 (1.6%)	4 (5.1%)
Grade 1	0	0	0	2 (2.5%)
Grade 2	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Cataract subcapsular	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Grade 1	0	0	0	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Cataract	0	0	0	1 (1.3%)
Grade 2	0	0	0	1 (1.3%)
Cataract nuclear	0	0	0	1 (1.3%)
Grade 1	0	0	0	1 (1.3%)
Lacrimation disorders	0	1 (4.0%)	1 (1.6%)	2 (2.5%)
Grade 1	0	0	0	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Cataract conditions	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Cataract subcapsular	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Cataract	0	0	0	0
Grade 2	0	0	0	0
Cataract nuclear	0	0	0	0
Grade 1	0	0	0	0
Lacrimation disorders	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Lacrimation disorders (cont) (cont)				
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Dry eye	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 1	0	0	0	0
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Lacrimation increased	0	0	0	1 (1.3%)
Grade 1	0	0	0	1 (1.3%)
Conjunctival and corneal bleeding and vascular disorders	0	0	0	2 (2.5%)
Grade 1	0	0	0	1 (1.3%)
Grade 2	0	0	0	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Lacrimation disorders (cont) (cont)				
Grade 2	0	0	0	0
Dry eye	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 2	0	0	0	0
Lacrimation increased	0	0	0	0
Grade 1	0	0	0	0
Conjunctival and corneal bleeding and vascular disorders	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Conjunctival and corneal bleeding and vascular disorders (cont)				
Conjunctival haemorrhage	0	0	0	2 (2.5%)
Grade 1	0	0	0	1 (1.3%)
Grade 2	0	0	0	1 (1.3%)
Visual impairment and blindness (excl colour blindness)	1 (2.7%)	1 (4.0%)	2 (3.2%)	2 (2.5%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Visual acuity reduced	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Visual impairment	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
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Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Conjunctival and corneal bleeding and vascular disorders (cont)				
Conjunctival haemorrhage	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Visual impairment and blindness (excl colour blindness)	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Visual acuity reduced	0	0	0	0
Grade 2	0	0	0	0
Visual impairment	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
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Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Choroid and vitreous structural change, deposit and degeneration	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Vitreous detachment	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Conjunctival infections, irritations and inflammations	0	0	0	0
Grade 1	0	0	0	0
Conjunctival hyperaemia	0	0	0	0
Grade 1	0	0	0	0
Retinal structural change, deposit and degeneration	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
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Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Choroid and vitreous structural change, deposit and degeneration	0	0	0	0
Grade 3	0	0	0	0
Vitreous detachment	0	0	0	0
Grade 3	0	0	0	0
Conjunctival infections, irritations and inflammations	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Conjunctival hyperaemia	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Retinal structural change, deposit and degeneration	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Retinal structural change, deposit and degeneration (cont) (cont)				
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Retinal drusen	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	9 (24.3%)	2 (8.0%)	11 (17.7%)	13 (16.5%)
Grade 1	0	0	0	1 (1.3%)
Grade 2	4 (10.8%)	1 (4.0%)	5 (8.1%)	5 (6.3%)
Grade 3	2 (5.4%)	1 (4.0%)	3 (4.8%)	3 (3.8%)
Grade 4	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 5	2 (5.4%)	0	2 (3.2%)	3 (3.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-et.pdf 24AUG2023:15:00

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Retinal structural change, deposit and degeneration (cont) (cont)				
Grade 1	0	0	0	0
Retinal drusen	0	0	0	0
Grade 1	0	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	1 (20.0%)	1 (9.1%)	2 (11.8%)
Grade 1	0	0	0	0
Grade 2	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 3	0	0	0	0
Grade 4	0	0	0	1 (5.9%)
Grade 5	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Skin neoplasms malignant and unspecified (excl melanoma)	3 (8.1%)	0	3 (4.8%)	4 (5.1%)
Grade 2	3 (8.1%)	0	3 (4.8%)	4 (5.1%)
Basal cell carcinoma	2 (5.4%)	0	2 (3.2%)	3 (3.8%)
Grade 2	2 (5.4%)	0	2 (3.2%)	3 (3.8%)
Squamous cell carcinoma of skin	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Grade 2	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Bowen's disease	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Carcinoma in situ of skin	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Skin neoplasms malignant and unspecified (excl melanoma)	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 2	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Basal cell carcinoma	0	0	0	0
Grade 2	0	0	0	0
Squamous cell carcinoma of skin	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 2	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Bowen's disease	0	0	0	0
Grade 2	0	0	0	0
Carcinoma in situ of skin	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Skin neoplasms malignant and unspecified (excl melanoma) (cont)				
Keratoacanthoma	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Leukaemias NEC	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Grade 3	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 4	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Leukaemia	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Grade 3	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 4	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Leukaemias acute myeloid	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Grade 5	1 (2.7%)	0	1 (1.6%)	2 (2.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Skin neoplasms malignant and unspecified (excl melanoma) (cont)				
Keratoacanthoma	0	0	0	0
Grade 2	0	0	0	0
Leukaemias NEC	0	0	0	1 (5.9%)
Grade 3	0	0	0	0
Grade 4	0	0	0	1 (5.9%)
Leukaemia	0	0	0	1 (5.9%)
Grade 3	0	0	0	0
Grade 4	0	0	0	1 (5.9%)
Leukaemias acute myeloid	0	0	0	0
Grade 5	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Leukaemias acute myeloid (cont)				
Acute myeloid leukaemia	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Grade 5	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Urinary tract neoplasms unspecified malignancy NEC	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 3	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Bladder neoplasm	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 3	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Bladder neoplasms malignant	0	0	0	1 (1.3%)
Grade 2	0	0	0	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Leukaemias acute myeloid (cont)				
Acute myeloid leukaemia	0	0	0	0
Grade 5	0	0	0	0
Urinary tract neoplasms unspecified malignancy NEC	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Bladder neoplasm	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Bladder neoplasms malignant	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Bladder neoplasms malignant (cont)				
Bladder cancer	0	0	0	1 (1.3%)
Grade 2	0	0	0	1 (1.3%)
Gastric neoplasms malignant	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Adenocarcinoma gastric	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 2	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Myeloproliferative disorders (excl leukaemias)	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 5	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Myelofibrosis	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Bladder neoplasms malignant (cont)				
Bladder cancer	0	0	0	0
Grade 2	0	0	0	0
Gastric neoplasms malignant	0	0	0	0
Grade 2	0	0	0	0
Adenocarcinoma gastric	0	0	0	0
Grade 2	0	0	0	0
Myeloproliferative disorders (excl leukaemias)	0	0	0	0
Grade 5	0	0	0	0
Myelofibrosis	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Myeloproliferative disorders (excl leukaemias) (cont)				
Myelofibrosis (cont)				
Grade 5	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Plasma cell neoplasms NEC	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Hypergammaglobulinaemia benign monoclonal	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Thyroid neoplasms malignant	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Papillary thyroid cancer	0	1 (4.0%)	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Myeloproliferative disorders (excl leukaemias) (cont)				
Myelofibrosis (cont)				
Grade 5	0	0	0	0
Plasma cell neoplasms NEC	0	0	0	0
Grade 1	0	0	0	0
Hypergammaglobulinaemia benign monoclonal	0	0	0	0
Grade 1	0	0	0	0
Thyroid neoplasms malignant	0	0	0	0
Grade 3	0	0	0	0
Papillary thyroid cancer	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

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	White			
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Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Thyroid neoplasms malignant (cont)				
Papillary thyroid cancer (cont)				
Grade 3	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Upper gastrointestinal neoplasms benign	0	0	0	1 (1.3%)
Grade 1	0	0	0	1 (1.3%)
Oesophageal papilloma	0	0	0	1 (1.3%)
Grade 1	0	0	0	1 (1.3%)
Urinary tract neoplasms malignant NEC	0	0	0	1 (1.3%)
Grade 2	0	0	0	1 (1.3%)
Transitional cell carcinoma	0	0	0	1 (1.3%)
Grade 2	0	0	0	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
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(Continued)	Other Races			
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Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Thyroid neoplasms malignant (cont)				
Papillary thyroid cancer (cont)				
Grade 3	0	0	0	0
Upper gastrointestinal neoplasms benign	0	0	0	0
Grade 1	0	0	0	0
Oesophageal papilloma	0	0	0	0
Grade 1	0	0	0	0
Urinary tract neoplasms malignant NEC	0	0	0	0
Grade 2	0	0	0	0
Transitional cell carcinoma	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
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Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Ear and labyrinth disorders	2 (5.4%)	1 (4.0%)	3 (4.8%)	5 (6.3%)
Grade 1	1 (2.7%)	1 (4.0%)	2 (3.2%)	4 (5.1%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Inner ear signs and symptoms	1 (2.7%)	0	1 (1.6%)	3 (3.8%)
Grade 1	1 (2.7%)	0	1 (1.6%)	3 (3.8%)
Grade 2	0	0	0	0
Vertigo	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Grade 1	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Tinnitus	0	0	0	1 (1.3%)
Grade 1	0	0	0	1 (1.3%)
Grade 2	0	0	0	0
Hearing losses	1 (2.7%)	1 (4.0%)	2 (3.2%)	2 (2.5%)
Grade 1	0	1 (4.0%)	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
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Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
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(Continued)	Other Races			
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Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Ear and labyrinth disorders	1 (16.7%)	1 (20.0%)	2 (18.2%)	3 (17.6%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 2	1 (16.7%)	0	1 (9.1%)	2 (11.8%)
Inner ear signs and symptoms	0	1 (20.0%)	1 (9.1%)	2 (11.8%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 2	0	0	0	1 (5.9%)
Vertigo	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Tinnitus	0	0	0	1 (5.9%)
Grade 1	0	0	0	0
Grade 2	0	0	0	1 (5.9%)
Hearing losses	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Ear and labyrinth disorders (cont)				
Hearing losses (cont)				
(cont)				
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Deafness bilateral	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 1	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Hypoacusis	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Inner ear disorders NEC	0	0	0	0
Grade 2	0	0	0	0
Vestibular disorder	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Ear and labyrinth disorders (cont)				
Hearing losses (cont)				
(cont)				
Grade 2	0	0	0	0
Deafness bilateral	0	0	0	0
Grade 1	0	0	0	0
Hypoacusis	0	0	0	0
Grade 2	0	0	0	0
Inner ear disorders NEC	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 2	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Vestibular disorder	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 2	1 (16.7%)	0	1 (9.1%)	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Hepatobiliary disorders	4 (10.8%)	0	4 (6.5%)	4 (5.1%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Grade 5	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Cholecystitis and cholelithiasis	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Grade 2	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Cholecystitis	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Cholecystitis acute	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Cholestasis and jaundice	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Hepatobiliary disorders	0	1 (20.0%)	1 (9.1%)	2 (11.8%)
Grade 1	0	1 (20.0%)	1 (9.1%)	2 (11.8%)
Grade 2	0	0	0	0
Grade 5	0	0	0	0
Cholecystitis and cholelithiasis	0	0	0	0
Grade 2	0	0	0	0
Cholecystitis	0	0	0	0
Grade 2	0	0	0	0
Cholecystitis acute	0	0	0	0
Grade 2	0	0	0	0
Cholestasis and jaundice	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Hepatobiliary disorders (cont)				
Cholestasis and jaundice (cont)				
Jaundice	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Hepatic failure and associated disorders	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 5	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Hepatic failure	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 5	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Hepatic vascular disorders	0	0	0	0
Grade 1	0	0	0	0
Portal hypertension	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-et.pdf 24AUG2023:15:00

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Hepatobiliary disorders (cont)				
Cholestasis and jaundice (cont)				
Jaundice	0	0	0	0
Grade 1	0	0	0	0
Hepatic failure and associated disorders	0	0	0	0
Grade 5	0	0	0	0
Hepatic failure	0	0	0	0
Grade 5	0	0	0	0
Hepatic vascular disorders	0	0	0	1 (5.9%)
Grade 1	0	0	0	1 (5.9%)
Portal hypertension	0	0	0	1 (5.9%)
Grade 1	0	0	0	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Hepatobiliary disorders (cont)				
Hepatobiliary signs and symptoms	0	0	0	0
Grade 1	0	0	0	0
Hepatic pain	0	0	0	0
Grade 1	0	0	0	0
Endocrine disorders	2 (5.4%)	1 (4.0%)	3 (4.8%)	3 (3.8%)
Grade 1	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 2	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Thyroid hypofunction disorders	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Grade 2	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Hypothyroidism	2 (5.4%)	0	2 (3.2%)	2 (2.5%)
Grade 2	2 (5.4%)	0	2 (3.2%)	2 (2.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Hepatobiliary disorders (cont)				
Hepatobiliary signs and symptoms	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Hepatic pain	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Endocrine disorders	0	1 (20.0%)	1 (9.1%)	2 (11.8%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 2	0	0	0	1 (5.9%)
Thyroid hypofunction disorders	0	0	0	1 (5.9%)
Grade 2	0	0	0	1 (5.9%)
Hypothyroidism	0	0	0	1 (5.9%)
Grade 2	0	0	0	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Endocrine disorders (cont)				
Acute and chronic thyroiditis	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 1	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Autoimmune thyroiditis	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Grade 1	0	1 (4.0%)	1 (1.6%)	1 (1.3%)
Thyroid disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Thyroid mass	0	0	0	0
Grade 1	0	0	0	0
Reproductive system and breast disorders	2 (5.4%)	0	2 (3.2%)	4 (5.1%)
Grade 1	0	0	0	1 (1.3%)
Grade 2	2 (5.4%)	0	2 (3.2%)	3 (3.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Endocrine disorders (cont)				
Acute and chronic thyroiditis	0	0	0	0
Grade 1	0	0	0	0
Autoimmune thyroiditis	0	0	0	0
Grade 1	0	0	0	0
Thyroid disorders NEC	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Thyroid mass	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Reproductive system and breast disorders	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
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Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Reproductive system and breast disorders (cont)				
Prostatic neoplasms and hypertrophy	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Grade 2	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Benign prostatic hyperplasia	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Grade 2	1 (2.7%)	0	1 (1.6%)	2 (2.5%)
Breast signs and symptoms	0	0	0	1 (1.3%)
Grade 1	0	0	0	1 (1.3%)
Breast pain	0	0	0	1 (1.3%)
Grade 1	0	0	0	1 (1.3%)
Scrotal disorders NEC	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Scrotal pain	1 (2.7%)	0	1 (1.6%)	1 (1.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
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Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Reproductive system and breast disorders (cont)				
Prostatic neoplasms and hypertrophy	0	0	0	0
Grade 2	0	0	0	0
Benign prostatic hyperplasia	0	0	0	0
Grade 2	0	0	0	0
Breast signs and symptoms	0	0	0	0
Grade 1	0	0	0	0
Breast pain	0	0	0	0
Grade 1	0	0	0	0
Scrotal disorders NEC	0	0	0	0
Grade 2	0	0	0	0
Scrotal pain	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Reproductive system and breast disorders (cont)				
Scrotal disorders NEC (cont)				
Scrotal pain (cont)				
Grade 2	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Immune system disorders	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Allergic conditions NEC	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Allergic oedema	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Grade 1	1 (2.7%)	0	1 (1.6%)	1 (1.3%)
Allergies to foods, food additives, drugs and other chemicals	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Reproductive system and breast disorders (cont)				
Scrotal disorders NEC (cont)				
Scrotal pain (cont)				
Grade 2	0	0	0	0
Immune system disorders	1 (16.7%)	1 (20.0%)	2 (18.2%)	2 (11.8%)
Grade 1	1 (16.7%)	1 (20.0%)	2 (18.2%)	2 (11.8%)
Allergic conditions NEC	0	0	0	0
Grade 1	0	0	0	0
Allergic oedema	0	0	0	0
Grade 1	0	0	0	0
Allergies to foods, food additives, drugs and other chemicals	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	White			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 Onward) Total (N=62)	Overall Exposed to MMB Total (N=79)
Number of Subjects with Any Treatment-Emergent AE	36 (97.3%)	25 (100.0%)	61 (98.4%)	79 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Immune system disorders (cont)				
Allergies to foods, food additives, drugs and other chemicals (cont)				
Drug hypersensitivity	0	0	0	0
Grade 1	0	0	0	0
Atopic disorders	0	0	0	0
Grade 1	0	0	0	0
Seasonal allergy	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0406: TEAEs by SOC, HLT, PT and Severity by Race
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Other Races			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 Onward) Total (N=11)	Overall Exposed to MMB Total (N=17)
Number of Subjects with Any Treatment-Emergent AE	6 (100.0%)	5 (100.0%)	11 (100.0%)	17 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Immune system disorders (cont)				
Allergies to foods, food additives, drugs and other chemicals (cont)				
Drug hypersensitivity	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Grade 1	0	1 (20.0%)	1 (9.1%)	1 (5.9%)
Atopic disorders	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 1	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Seasonal allergy	1 (16.7%)	0	1 (9.1%)	1 (5.9%)
Grade 1	1 (16.7%)	0	1 (9.1%)	1 (5.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders	32 (59.3%)	13 (38.2%)	45 (51.1%)	10 (27.0%)	12 (48.0%)	22 (35.5%)
Grade 1	14 (25.9%)	5 (14.7%)	19 (21.6%)	4 (10.8%)	5 (20.0%)	9 (14.5%)
Grade 2	14 (25.9%)	5 (14.7%)	19 (21.6%)	3 (8.1%)	5 (20.0%)	8 (12.9%)
Grade 3	4 (7.4%)	3 (8.8%)	7 (8.0%)	3 (8.1%)	2 (8.0%)	5 (8.1%)
Diarrhoea (excl infective)	17 (31.5%)	3 (8.8%)	20 (22.7%)	7 (18.9%)	4 (16.0%)	11 (17.7%)
Grade 1	12 (22.2%)	1 (2.9%)	13 (14.8%)	5 (13.5%)	1 (4.0%)	6 (9.7%)
Grade 2	4 (7.4%)	2 (5.9%)	6 (6.8%)	1 (2.7%)	2 (8.0%)	3 (4.8%)
Grade 3	1 (1.9%)	0	1 (1.1%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Diarrhoea	17 (31.5%)	3 (8.8%)	20 (22.7%)	7 (18.9%)	4 (16.0%)	11 (17.7%)
Grade 1	12 (22.2%)	1 (2.9%)	13 (14.8%)	5 (13.5%)	1 (4.0%)	6 (9.7%)
Grade 2	4 (7.4%)	2 (5.9%)	6 (6.8%)	1 (2.7%)	2 (8.0%)	3 (4.8%)
Grade 3	1 (1.9%)	0	1 (1.1%)	1 (2.7%)	1 (4.0%)	2 (3.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders	8 (66.7%)	4 (80.0%)	12 (70.6%)	3 (50.0%)	3 (60.0%)	6 (54.5%)
Grade 1	3 (25.0%)	1 (20.0%)	4 (23.5%)	1 (16.7%)	2 (40.0%)	3 (27.3%)
Grade 2	4 (33.3%)	3 (60.0%)	7 (41.2%)	2 (33.3%)	0	2 (18.2%)
Grade 3	1 (8.3%)	0	1 (5.9%)	0	1 (20.0%)	1 (9.1%)
Diarrhoea (excl infective)	4 (33.3%)	2 (40.0%)	6 (35.3%)	2 (33.3%)	2 (40.0%)	4 (36.4%)
Grade 1	2 (16.7%)	1 (20.0%)	3 (17.6%)	1 (16.7%)	1 (20.0%)	2 (18.2%)
Grade 2	2 (16.7%)	1 (20.0%)	3 (17.6%)	1 (16.7%)	0	1 (9.1%)
Grade 3	0	0	0	0	1 (20.0%)	1 (9.1%)
Diarrhoea	4 (33.3%)	2 (40.0%)	6 (35.3%)	2 (33.3%)	2 (40.0%)	4 (36.4%)
Grade 1	2 (16.7%)	1 (20.0%)	3 (17.6%)	1 (16.7%)	1 (20.0%)	2 (18.2%)
Grade 2	2 (16.7%)	1 (20.0%)	3 (17.6%)	1 (16.7%)	0	1 (9.1%)
Grade 3	0	0	0	0	1 (20.0%)	1 (9.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal and abdominal pains (excl oral and throat)	13 (24.1%)	5 (14.7%)	18 (20.5%)	3 (8.1%)	2 (8.0%)	5 (8.1%)
Grade 1	5 (9.3%)	1 (2.9%)	6 (6.8%)	0	1 (4.0%)	1 (1.6%)
Grade 2	6 (11.1%)	1 (2.9%)	7 (8.0%)	2 (5.4%)	1 (4.0%)	3 (4.8%)
Grade 3	2 (3.7%)	3 (8.8%)	5 (5.7%)	1 (2.7%)	0	1 (1.6%)
Abdominal pain	8 (14.8%)	4 (11.8%)	12 (13.6%)	3 (8.1%)	1 (4.0%)	4 (6.5%)
Grade 1	4 (7.4%)	1 (2.9%)	5 (5.7%)	0	0	0
Grade 2	3 (5.6%)	0	3 (3.4%)	2 (5.4%)	1 (4.0%)	3 (4.8%)
Grade 3	1 (1.9%)	3 (8.8%)	4 (4.5%)	1 (2.7%)	0	1 (1.6%)
Abdominal pain upper	4 (7.4%)	0	4 (4.5%)	0	1 (4.0%)	1 (1.6%)
Grade 1	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 2	3 (5.6%)	0	3 (3.4%)	0	0	0
Grade 3	1 (1.9%)	0	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal and abdominal pains (excl oral and throat)	3 (25.0%)	2 (40.0%)	5 (29.4%)	0	2 (40.0%)	2 (18.2%)
Grade 1	2 (16.7%)	0	2 (11.8%)	0	2 (40.0%)	2 (18.2%)
Grade 2	1 (8.3%)	2 (40.0%)	3 (17.6%)	0	0	0
Grade 3	0	0	0	0	0	0
Abdominal pain	2 (16.7%)	1 (20.0%)	3 (17.6%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 2	1 (8.3%)	1 (20.0%)	2 (11.8%)	0	0	0
Grade 3	0	0	0	0	0	0
Abdominal pain upper	1 (8.3%)	1 (20.0%)	2 (11.8%)	0	2 (40.0%)	2 (18.2%)
Grade 1	1 (8.3%)	0	1 (5.9%)	0	2 (40.0%)	2 (18.2%)
Grade 2	0	1 (20.0%)	1 (5.9%)	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal and abdominal pains (excl oral and throat) (cont)						
Abdominal pain lower	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Abdominal tenderness	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 2	0	1 (2.9%)	1 (1.1%)	0	0	0
Nausea and vomiting symptoms	11 (20.4%)	4 (11.8%)	15 (17.0%)	4 (10.8%)	3 (12.0%)	7 (11.3%)
Grade 1	10 (18.5%)	3 (8.8%)	13 (14.8%)	4 (10.8%)	1 (4.0%)	5 (8.1%)
Grade 2	1 (1.9%)	0	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Grade 3	0	1 (2.9%)	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Nausea	11 (20.4%)	3 (8.8%)	14 (15.9%)	4 (10.8%)	2 (8.0%)	6 (9.7%)
Grade 1	10 (18.5%)	2 (5.9%)	12 (13.6%)	4 (10.8%)	1 (4.0%)	5 (8.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal and abdominal pains (excl oral and throat) (cont)						
Abdominal pain lower	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Abdominal tenderness	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Nausea and vomiting symptoms	1 (8.3%)	0	1 (5.9%)	1 (16.7%)	1 (20.0%)	2 (18.2%)
Grade 1	1 (8.3%)	0	1 (5.9%)	1 (16.7%)	0	1 (9.1%)
Grade 2	0	0	0	0	1 (20.0%)	1 (9.1%)
Grade 3	0	0	0	0	0	0
Nausea	1 (8.3%)	0	1 (5.9%)	1 (16.7%)	1 (20.0%)	2 (18.2%)
Grade 1	1 (8.3%)	0	1 (5.9%)	1 (16.7%)	0	1 (9.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Nausea and vomiting symptoms (cont)						
Nausea (cont)						
Grade 2	1 (1.9%)	0	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Grade 3	0	1 (2.9%)	1 (1.1%)	0	0	0
Vomiting	2 (3.7%)	1 (2.9%)	3 (3.4%)	2 (5.4%)	3 (12.0%)	5 (8.1%)
Grade 1	2 (3.7%)	1 (2.9%)	3 (3.4%)	2 (5.4%)	1 (4.0%)	3 (4.8%)
Grade 2	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 3	0	0	0	0	1 (4.0%)	1 (1.6%)
Gastrointestinal atonic and hypomotility disorders NEC	9 (16.7%)	3 (8.8%)	12 (13.6%)	2 (5.4%)	0	2 (3.2%)
Grade 1	7 (13.0%)	3 (8.8%)	10 (11.4%)	2 (5.4%)	0	2 (3.2%)
Grade 2	2 (3.7%)	0	2 (2.3%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Nausea and vomiting symptoms (cont)						
Nausea (cont)						
Grade 2	0	0	0	0	1 (20.0%)	1 (9.1%)
Grade 3	0	0	0	0	0	0
Vomiting	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Gastrointestinal atonic and hypomotility disorders NEC	1 (8.3%)	0	1 (5.9%)	0	1 (20.0%)	1 (9.1%)
Grade 1	1 (8.3%)	0	1 (5.9%)	0	1 (20.0%)	1 (9.1%)
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal atonic and hypomotility disorders NEC (cont)						
Constipation	6 (11.1%)	2 (5.9%)	8 (9.1%)	2 (5.4%)	0	2 (3.2%)
Grade 1	6 (11.1%)	2 (5.9%)	8 (9.1%)	2 (5.4%)	0	2 (3.2%)
Gastrooesophageal reflux disease	3 (5.6%)	1 (2.9%)	4 (4.5%)	0	0	0
Grade 1	1 (1.9%)	1 (2.9%)	2 (2.3%)	0	0	0
Grade 2	2 (3.7%)	0	2 (2.3%)	0	0	0
Impaired gastric emptying	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 1	0	0	0	1 (2.7%)	0	1 (1.6%)
Dyspeptic signs and symptoms	6 (11.1%)	0	6 (6.8%)	0	0	0
Grade 1	3 (5.6%)	0	3 (3.4%)	0	0	0
Grade 2	3 (5.6%)	0	3 (3.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal atonic and hypomotility disorders NEC (cont)						
Constipation	0	0	0	0	1 (20.0%)	1 (9.1%)
Grade 1	0	0	0	0	1 (20.0%)	1 (9.1%)
Gastrooesophageal reflux disease	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Impaired gastric emptying	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dyspeptic signs and symptoms	2 (16.7%)	0	2 (11.8%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 2	1 (8.3%)	0	1 (5.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Dyspeptic signs and symptoms (cont)						
Dyspepsia	5 (9.3%)	0	5 (5.7%)	0	0	0
Grade 1	2 (3.7%)	0	2 (2.3%)	0	0	0
Grade 2	3 (5.6%)	0	3 (3.4%)	0	0	0
Epigastric discomfort	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Non-site specific gastrointestinal haemorrhages	2 (3.7%)	2 (5.9%)	4 (4.5%)	1 (2.7%)	3 (12.0%)	4 (6.5%)
Grade 1	0	1 (2.9%)	1 (1.1%)	0	2 (8.0%)	2 (3.2%)
Grade 2	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 3	2 (3.7%)	0	2 (2.3%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Gastrointestinal haemorrhage	1 (1.9%)	0	1 (1.1%)	1 (2.7%)	1 (4.0%)	2 (3.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Dyspeptic signs and symptoms (cont)						
Dyspepsia	2 (16.7%)	0	2 (11.8%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 2	1 (8.3%)	0	1 (5.9%)	0	0	0
Epigastric discomfort	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Non-site specific gastrointestinal haemorrhages	1 (8.3%)	0	1 (5.9%)	1 (16.7%)	0	1 (9.1%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	1 (16.7%)	0	1 (9.1%)
Grade 3	1 (8.3%)	0	1 (5.9%)	0	0	0
Gastrointestinal haemorrhage	1 (8.3%)	0	1 (5.9%)	1 (16.7%)	0	1 (9.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Non-site specific gastrointestinal haemorrhages (cont)						
Gastrointestinal haemorrhage (cont)						
Grade 2	0	0	0	0	0	0
Grade 3	1 (1.9%)	0	1 (1.1%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Haematemesis	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 3	1 (1.9%)	0	1 (1.1%)	0	0	0
Upper gastrointestinal haemorrhage	1 (1.9%)	1 (2.9%)	2 (2.3%)	0	0	0
Grade 2	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 3	1 (1.9%)	0	1 (1.1%)	0	0	0
Melaena	1 (1.9%)	1 (2.9%)	2 (2.3%)	0	2 (8.0%)	2 (3.2%)
Grade 1	0	1 (2.9%)	1 (1.1%)	0	2 (8.0%)	2 (3.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Non-site specific gastrointestinal haemorrhages (cont)						
Gastrointestinal haemorrhage (cont)						
Grade 2	1 (8.3%)	0	1 (5.9%)	1 (16.7%)	0	1 (9.1%)
Grade 3	0	0	0	0	0	0
Haematemesis	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 3	1 (8.3%)	0	1 (5.9%)	0	0	0
Upper gastrointestinal haemorrhage	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	1 (8.3%)	0	1 (5.9%)	0	0	0
Melaena	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Non-site specific gastrointestinal haemorrhages (cont)						
Melaena (cont)						
Grade 3	1 (1.9%)	0	1 (1.1%)	0	0	0
Peritoneal and retroperitoneal disorders	1 (1.9%)	2 (5.9%)	3 (3.4%)	0	2 (8.0%)	2 (3.2%)
Grade 1	1 (1.9%)	1 (2.9%)	2 (2.3%)	0	0	0
Grade 2	0	0	0	0	2 (8.0%)	2 (3.2%)
Grade 3	0	1 (2.9%)	1 (1.1%)	0	0	0
Ascites	1 (1.9%)	2 (5.9%)	3 (3.4%)	0	2 (8.0%)	2 (3.2%)
Grade 1	1 (1.9%)	1 (2.9%)	2 (2.3%)	0	0	0
Grade 2	0	0	0	0	2 (8.0%)	2 (3.2%)
Grade 3	0	1 (2.9%)	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Non-site specific gastrointestinal haemorrhages (cont)						
Melaena (cont)						
Grade 3	0	0	0	0	0	0
Peritoneal and retroperitoneal disorders	2 (16.7%)	0	2 (11.8%)	1 (16.7%)	0	1 (9.1%)
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 2	1 (8.3%)	0	1 (5.9%)	1 (16.7%)	0	1 (9.1%)
Grade 3	0	0	0	0	0	0
Ascites	2 (16.7%)	0	2 (11.8%)	1 (16.7%)	0	1 (9.1%)
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 2	1 (8.3%)	0	1 (5.9%)	1 (16.7%)	0	1 (9.1%)
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-rt.pdf 24AUG2023:15:00

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Flatulence, bloating and distension	2 (3.7%)	0	2 (2.3%)	1 (2.7%)	0	1 (1.6%)
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Flatulence	2 (3.7%)	0	2 (2.3%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Abdominal distension	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	1 (2.7%)	0	1 (1.6%)
Gastrointestinal spastic and hypermotility disorders	2 (3.7%)	0	2 (2.3%)	0	0	0
Grade 1	2 (3.7%)	0	2 (2.3%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Flatulence, bloating and distension	0	1 (20.0%)	1 (5.9%)	0	0	0
Grade 1	0	1 (20.0%)	1 (5.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Flatulence	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Abdominal distension	0	1 (20.0%)	1 (5.9%)	0	0	0
Grade 1	0	1 (20.0%)	1 (5.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Gastrointestinal spastic and hypermotility disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal spastic and hypermotility disorders (cont)						
Defaecation urgency	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Frequent bowel movements	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Anal and rectal signs and symptoms	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Anorectal discomfort	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dental pain and sensation disorders	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal spastic and hypermotility disorders (cont)						
Defaecation urgency	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Frequent bowel movements	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Anal and rectal signs and symptoms	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Anorectal discomfort	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Dental pain and sensation disorders	1 (8.3%)	0	1 (5.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Dental pain and sensation disorders (cont)						
(cont)						
Grade 2	0	0	0	0	0	0
Toothache	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Gastric and oesophageal haemorrhages	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Oesophageal haemorrhage	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Gastric ulcers and perforation	1 (1.9%)	0	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Dental pain and sensation disorders (cont) (cont)						
Grade 2	1 (8.3%)	0	1 (5.9%)	0	0	0
Toothache	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 2	1 (8.3%)	0	1 (5.9%)	0	0	0
Gastric and oesophageal haemorrhages	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Oesophageal haemorrhage	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Gastric ulcers and perforation	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastric ulcers and perforation (cont) (cont)						
Grade 3	1 (1.9%)	0	1 (1.1%)	0	0	0
Gastric ulcer	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 3	1 (1.9%)	0	1 (1.1%)	0	0	0
Gastritis (excl infective)	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Gastritis	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Gastrointestinal mucosal dystrophies and secretion disorders	1 (1.9%)	0	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-rt.pdf 24AUG2023:15:00

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastric ulcers and perforation (cont) (cont)						
Grade 3	0	0	0	0	0	0
Gastric ulcer	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Gastritis (excl infective)	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Gastritis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Gastrointestinal mucosal dystrophies and secretion disorders	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal mucosal dystrophies and secretion disorders (cont) (cont)						
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Gastrointestinal melanosis	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Gastrointestinal signs and symptoms NEC	1 (1.9%)	0	1 (1.1%)	0	2 (8.0%)	2 (3.2%)
Grade 1	1 (1.9%)	0	1 (1.1%)	0	2 (8.0%)	2 (3.2%)
Abdominal discomfort	1 (1.9%)	0	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Grade 1	1 (1.9%)	0	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Dysphagia	0	0	0	0	1 (4.0%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal mucosal dystrophies and secretion disorders (cont) (cont)						
Grade 1	0	0	0	0	0	0
Gastrointestinal melanosis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Gastrointestinal signs and symptoms NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Abdominal discomfort	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dysphagia	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal signs and symptoms NEC (cont)						
Dysphagia (cont)						
Grade 1	0	0	0	0	1 (4.0%)	1 (1.6%)
Intestinal haemorrhages	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Anal haemorrhage	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Stomatitis and ulceration	1 (1.9%)	1 (2.9%)	2 (2.3%)	0	1 (4.0%)	1 (1.6%)
Grade 1	1 (1.9%)	0	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Grade 2	0	1 (2.9%)	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal signs and symptoms NEC (cont)						
Dysphagia (cont)						
Grade 1	0	0	0	0	0	0
Intestinal haemorrhages	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Anal haemorrhage	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Stomatitis and ulceration	0	0	0	1 (16.7%)	0	1 (9.1%)
Grade 1	0	0	0	1 (16.7%)	0	1 (9.1%)
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Stomatitis and ulceration (cont)						
Mouth ulceration	1 (1.9%)	0	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Grade 1	1 (1.9%)	0	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Palatal ulcer	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Stomatitis	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 2	0	1 (2.9%)	1 (1.1%)	0	0	0
Anal and rectal disorders NEC	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 2	0	0	0	0	1 (4.0%)	1 (1.6%)
Anal fissure	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 2	0	0	0	0	1 (4.0%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Stomatitis and ulceration (cont)						
Mouth ulceration	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Palatal ulcer	0	0	0	1 (16.7%)	0	1 (9.1%)
Grade 1	0	0	0	1 (16.7%)	0	1 (9.1%)
Stomatitis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Anal and rectal disorders NEC	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Anal fissure	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Dental and periodontal infections and inflammations	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Dental caries	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Oesophageal varices	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 2	0	0	0	0	1 (4.0%)	1 (1.6%)
Varices oesophageal	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 2	0	0	0	0	1 (4.0%)	1 (1.6%)
Oral dryness and saliva altered	0	1 (2.9%)	1 (1.1%)	0	2 (8.0%)	2 (3.2%)
Grade 1	0	0	0	0	1 (4.0%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Dental and periodontal infections and inflammations	0	1 (20.0%)	1 (5.9%)	0	0	0
Grade 2	0	1 (20.0%)	1 (5.9%)	0	0	0
Dental caries	0	1 (20.0%)	1 (5.9%)	0	0	0
Grade 2	0	1 (20.0%)	1 (5.9%)	0	0	0
Oesophageal varices	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Varices oesophageal	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Oral dryness and saliva altered	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Oral dryness and saliva altered (cont) (cont)						
Grade 2	0	1 (2.9%)	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Dry mouth	0	1 (2.9%)	1 (1.1%)	0	2 (8.0%)	2 (3.2%)
Grade 1	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 2	0	1 (2.9%)	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Oral soft tissue pain and paraesthesia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Odynophagia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Umbilical hernias	0	0	0	1 (2.7%)	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-rt.pdf 24AUG2023:15:00

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Oral dryness and saliva altered (cont) (cont)						
Grade 2	0	0	0	0	0	0
Dry mouth	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Oral soft tissue pain and paraesthesia	0	1 (20.0%)	1 (5.9%)	0	0	0
Grade 1	0	1 (20.0%)	1 (5.9%)	0	0	0
Odynophagia	0	1 (20.0%)	1 (5.9%)	0	0	0
Grade 1	0	1 (20.0%)	1 (5.9%)	0	0	0
Umbilical hernias	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Umbilical hernias (cont)						
(cont)						
Grade 1	0	0	0	1 (2.7%)	0	1 (1.6%)
Umbilical hernia	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 1	0	0	0	1 (2.7%)	0	1 (1.6%)
Infections and infestations	26 (48.1%)	13 (38.2%)	39 (44.3%)	15 (40.5%)	10 (40.0%)	25 (40.3%)
Grade 1	10 (18.5%)	2 (5.9%)	12 (13.6%)	1 (2.7%)	4 (16.0%)	5 (8.1%)
Grade 2	12 (22.2%)	7 (20.6%)	19 (21.6%)	11 (29.7%)	4 (16.0%)	15 (24.2%)
Grade 3	3 (5.6%)	2 (5.9%)	5 (5.7%)	2 (5.4%)	1 (4.0%)	3 (4.8%)
Grade 4	0	0	0	1 (2.7%)	1 (4.0%)	2 (3.2%)
Grade 5	1 (1.9%)	2 (5.9%)	3 (3.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-rt.pdf 24AUG2023:15:00

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Umbilical hernias (cont)						
(cont)						
Grade 1	0	0	0	0	0	0
Umbilical hernia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Infections and infestations	8 (66.7%)	3 (60.0%)	11 (64.7%)	3 (50.0%)	4 (80.0%)	7 (63.6%)
Grade 1	0	1 (20.0%)	1 (5.9%)	1 (16.7%)	1 (20.0%)	2 (18.2%)
Grade 2	3 (25.0%)	2 (40.0%)	5 (29.4%)	1 (16.7%)	3 (60.0%)	4 (36.4%)
Grade 3	3 (25.0%)	0	3 (17.6%)	0	0	0
Grade 4	2 (16.7%)	0	2 (11.8%)	1 (16.7%)	0	1 (9.1%)
Grade 5	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Upper respiratory tract infections	9 (16.7%)	4 (11.8%)	13 (14.8%)	7 (18.9%)	5 (20.0%)	12 (19.4%)
Grade 1	5 (9.3%)	2 (5.9%)	7 (8.0%)	2 (5.4%)	4 (16.0%)	6 (9.7%)
Grade 2	4 (7.4%)	2 (5.9%)	6 (6.8%)	5 (13.5%)	1 (4.0%)	6 (9.7%)
Grade 4	0	0	0	0	0	0
Upper respiratory tract infection	6 (11.1%)	3 (8.8%)	9 (10.2%)	3 (8.1%)	3 (12.0%)	6 (9.7%)
Grade 1	3 (5.6%)	1 (2.9%)	4 (4.5%)	1 (2.7%)	2 (8.0%)	3 (4.8%)
Grade 2	3 (5.6%)	2 (5.9%)	5 (5.7%)	2 (5.4%)	1 (4.0%)	3 (4.8%)
Grade 4	0	0	0	0	0	0
Nasopharyngitis	2 (3.7%)	1 (2.9%)	3 (3.4%)	2 (5.4%)	2 (8.0%)	4 (6.5%)
Grade 1	2 (3.7%)	1 (2.9%)	3 (3.4%)	1 (2.7%)	2 (8.0%)	3 (4.8%)
Grade 2	0	0	0	1 (2.7%)	0	1 (1.6%)
Sinusitis	1 (1.9%)	0	1 (1.1%)	2 (5.4%)	0	2 (3.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-rt.pdf 24AUG2023:15:00

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Upper respiratory tract infections	2 (16.7%)	1 (20.0%)	3 (17.6%)	1 (16.7%)	0	1 (9.1%)
Grade 1	0	1 (20.0%)	1 (5.9%)	0	0	0
Grade 2	1 (8.3%)	0	1 (5.9%)	1 (16.7%)	0	1 (9.1%)
Grade 4	1 (8.3%)	0	1 (5.9%)	0	0	0
Upper respiratory tract infection	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 4	1 (8.3%)	0	1 (5.9%)	0	0	0
Nasopharyngitis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Sinusitis	1 (8.3%)	0	1 (5.9%)	1 (16.7%)	0	1 (9.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Upper respiratory tract infections (cont)						
Sinusitis (cont)						
Grade 2	1 (1.9%)	0	1 (1.1%)	2 (5.4%)	0	2 (3.2%)
Rhinitis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Urinary tract infections	6 (11.1%)	3 (8.8%)	9 (10.2%)	3 (8.1%)	2 (8.0%)	5 (8.1%)
Grade 1	1 (1.9%)	1 (2.9%)	2 (2.3%)	0	0	0
Grade 2	4 (7.4%)	2 (5.9%)	6 (6.8%)	3 (8.1%)	2 (8.0%)	5 (8.1%)
Grade 3	1 (1.9%)	0	1 (1.1%)	0	0	0
Urinary tract infection	4 (7.4%)	2 (5.9%)	6 (6.8%)	2 (5.4%)	2 (8.0%)	4 (6.5%)
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-rt.pdf 24AUG2023:15:00

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Upper respiratory tract infections (cont)						
Sinusitis (cont)						
Grade 2	1 (8.3%)	0	1 (5.9%)	1 (16.7%)	0	1 (9.1%)
Rhinitis	0	1 (20.0%)	1 (5.9%)	0	0	0
Grade 1	0	1 (20.0%)	1 (5.9%)	0	0	0
Urinary tract infections	2 (16.7%)	1 (20.0%)	3 (17.6%)	1 (16.7%)	1 (20.0%)	2 (18.2%)
Grade 1	0	0	0	0	0	0
Grade 2	1 (8.3%)	1 (20.0%)	2 (11.8%)	0	1 (20.0%)	1 (9.1%)
Grade 3	1 (8.3%)	0	1 (5.9%)	1 (16.7%)	0	1 (9.1%)
Urinary tract infection	2 (16.7%)	1 (20.0%)	3 (17.6%)	1 (16.7%)	1 (20.0%)	2 (18.2%)
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Urinary tract infections (cont)						
Urinary tract infection (cont)						
Grade 2	2 (3.7%)	2 (5.9%)	4 (4.5%)	2 (5.4%)	2 (8.0%)	4 (6.5%)
Grade 3	1 (1.9%)	0	1 (1.1%)	0	0	0
Cystitis	2 (3.7%)	0	2 (2.3%)	1 (2.7%)	0	1 (1.6%)
Grade 2	2 (3.7%)	0	2 (2.3%)	1 (2.7%)	0	1 (1.6%)
Kidney infection	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 1	0	1 (2.9%)	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Urinary tract infections (cont)						
Urinary tract infection (cont)						
Grade 2	1 (8.3%)	1 (20.0%)	2 (11.8%)	0	1 (20.0%)	1 (9.1%)
Grade 3	1 (8.3%)	0	1 (5.9%)	1 (16.7%)	0	1 (9.1%)
Cystitis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Kidney infection	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Lower respiratory tract and lung infections	3 (5.6%)	3 (8.8%)	6 (6.8%)	6 (16.2%)	1 (4.0%)	7 (11.3%)
Grade 1	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 2	3 (5.6%)	1 (2.9%)	4 (4.5%)	3 (8.1%)	0	3 (4.8%)
Grade 3	0	2 (5.9%)	2 (2.3%)	2 (5.4%)	1 (4.0%)	3 (4.8%)
Grade 4	0	0	0	0	0	0
Pneumonia	0	1 (2.9%)	1 (1.1%)	4 (10.8%)	1 (4.0%)	5 (8.1%)
Grade 2	0	0	0	2 (5.4%)	0	2 (3.2%)
Grade 3	0	1 (2.9%)	1 (1.1%)	2 (5.4%)	1 (4.0%)	3 (4.8%)
Grade 4	0	0	0	0	0	0
Bronchitis	2 (3.7%)	0	2 (2.3%)	3 (8.1%)	0	3 (4.8%)
Grade 1	0	0	0	0	0	0
Grade 2	2 (3.7%)	0	2 (2.3%)	3 (8.1%)	0	3 (4.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Lower respiratory tract and lung infections	4 (33.3%)	0	4 (23.5%)	1 (16.7%)	2 (40.0%)	3 (27.3%)
Grade 1	0	0	0	0	1 (20.0%)	1 (9.1%)
Grade 2	2 (16.7%)	0	2 (11.8%)	0	1 (20.0%)	1 (9.1%)
Grade 3	1 (8.3%)	0	1 (5.9%)	1 (16.7%)	0	1 (9.1%)
Grade 4	1 (8.3%)	0	1 (5.9%)	0	0	0
Pneumonia	3 (25.0%)	0	3 (17.6%)	0	0	0
Grade 2	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 3	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 4	1 (8.3%)	0	1 (5.9%)	0	0	0
Bronchitis	0	0	0	0	2 (40.0%)	2 (18.2%)
Grade 1	0	0	0	0	1 (20.0%)	1 (9.1%)
Grade 2	0	0	0	0	1 (20.0%)	1 (9.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Lower respiratory tract and lung infections (cont)						
Lung infection	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 3	0	0	0	0	0	0
Atypical pneumonia	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 1	0	0	0	1 (2.7%)	0	1 (1.6%)
Lower respiratory tract infection	0	2 (5.9%)	2 (2.3%)	0	0	0
Grade 2	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 3	0	1 (2.9%)	1 (1.1%)	0	0	0
Herpes viral infections	3 (5.6%)	1 (2.9%)	4 (4.5%)	0	1 (4.0%)	1 (1.6%)
Grade 1	3 (5.6%)	0	3 (3.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Lower respiratory tract and lung infections (cont)						
Lung infection	1 (8.3%)	0	1 (5.9%)	1 (16.7%)	0	1 (9.1%)
Grade 2	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 3	0	0	0	1 (16.7%)	0	1 (9.1%)
Atypical pneumonia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Lower respiratory tract infection	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Herpes viral infections	2 (16.7%)	0	2 (11.8%)	1 (16.7%)	1 (20.0%)	2 (18.2%)
Grade 1	0	0	0	1 (16.7%)	0	1 (9.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Herpes viral infections (cont)						
(cont)						
Grade 2	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 3	0	1 (2.9%)	1 (1.1%)	0	0	0
Oral herpes	3 (5.6%)	0	3 (3.4%)	0	1 (4.0%)	1 (1.6%)
Grade 1	3 (5.6%)	0	3 (3.4%)	0	0	0
Grade 2	0	0	0	0	1 (4.0%)	1 (1.6%)
Herpes zoster	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	1 (2.9%)	1 (1.1%)	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Herpes viral infections (cont)						
(cont)						
Grade 2	1 (8.3%)	0	1 (5.9%)	0	1 (20.0%)	1 (9.1%)
Grade 3	1 (8.3%)	0	1 (5.9%)	0	0	0
Oral herpes	1 (8.3%)	0	1 (5.9%)	1 (16.7%)	0	1 (9.1%)
Grade 1	0	0	0	1 (16.7%)	0	1 (9.1%)
Grade 2	1 (8.3%)	0	1 (5.9%)	0	0	0
Herpes zoster	1 (8.3%)	0	1 (5.9%)	0	1 (20.0%)	1 (9.1%)
Grade 2	1 (8.3%)	0	1 (5.9%)	0	1 (20.0%)	1 (9.1%)
Grade 3	0	0	0	0	0	0
Ophthalmic herpes zoster	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 3	1 (8.3%)	0	1 (5.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Herpes viral infections (cont)						
Herpes simplex	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 2	0	0	0	0	1 (4.0%)	1 (1.6%)
Bacterial infections NEC	4 (7.4%)	0	4 (4.5%)	2 (5.4%)	0	2 (3.2%)
Grade 2	1 (1.9%)	0	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Grade 3	2 (3.7%)	0	2 (2.3%)	1 (2.7%)	0	1 (1.6%)
Grade 5	1 (1.9%)	0	1 (1.1%)	0	0	0
Bacterial sepsis	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 5	1 (1.9%)	0	1 (1.1%)	0	0	0
Cellulitis	1 (1.9%)	0	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Grade 3	1 (1.9%)	0	1 (1.1%)	1 (2.7%)	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Herpes viral infections (cont)						
Herpes simplex	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Bacterial infections NEC	0	0	0	1 (16.7%)	0	1 (9.1%)
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	1 (16.7%)	0	1 (9.1%)
Grade 5	0	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Cellulitis	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Bacterial infections NEC (cont)						
Peritonitis bacterial	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 3	1 (1.9%)	0	1 (1.1%)	0	0	0
Propionibacterium infection	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Citrobacter infection	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Urinary tract infection bacterial	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 2	0	0	0	1 (2.7%)	0	1 (1.6%)
Candida infections	3 (5.6%)	1 (2.9%)	4 (4.5%)	0	1 (4.0%)	1 (1.6%)
Grade 1	2 (3.7%)	1 (2.9%)	3 (3.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Bacterial infections NEC (cont)						
Peritonitis bacterial	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Propionibacterium infection	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Citrobacter infection	0	0	0	1 (16.7%)	0	1 (9.1%)
Grade 3	0	0	0	1 (16.7%)	0	1 (9.1%)
Urinary tract infection bacterial	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Candida infections	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-rt.pdf 24AUG2023:15:00

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Candida infections (cont)						
(cont)						
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 3	0	0	0	0	1 (4.0%)	1 (1.6%)
Oral candidiasis	2 (3.7%)	1 (2.9%)	3 (3.4%)	0	1 (4.0%)	1 (1.6%)
Grade 1	1 (1.9%)	1 (2.9%)	2 (2.3%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 3	0	0	0	0	1 (4.0%)	1 (1.6%)
Oropharyngeal candidiasis	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Candida infections (cont)						
(cont)						
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Oral candidiasis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Oropharyngeal candidiasis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Sepsis, bacteraemia, viraemia and fungaemia NEC	0	2 (5.9%)	2 (2.3%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Grade 3	0	0	0	0	0	0
Grade 4	0	0	0	1 (2.7%)	1 (4.0%)	2 (3.2%)
Grade 5	0	2 (5.9%)	2 (2.3%)	0	0	0
Sepsis	0	2 (5.9%)	2 (2.3%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Grade 3	0	0	0	0	0	0
Grade 4	0	0	0	1 (2.7%)	1 (4.0%)	2 (3.2%)
Grade 5	0	2 (5.9%)	2 (2.3%)	0	0	0
Urosepsis	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 3	0	0	0	0	1 (4.0%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Sepsis, bacteraemia, viraemia and fungaemia NEC	3 (25.0%)	0	3 (17.6%)	1 (16.7%)	0	1 (9.1%)
Grade 3	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 4	2 (16.7%)	0	2 (11.8%)	1 (16.7%)	0	1 (9.1%)
Grade 5	0	0	0	0	0	0
Sepsis	3 (25.0%)	0	3 (17.6%)	1 (16.7%)	0	1 (9.1%)
Grade 3	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 4	2 (16.7%)	0	2 (11.8%)	1 (16.7%)	0	1 (9.1%)
Grade 5	0	0	0	0	0	0
Urosepsis	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Skin structures and soft tissue infections	2 (3.7%)	1 (2.9%)	3 (3.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 2	1 (1.9%)	1 (2.9%)	2 (2.3%)	0	0	0
Folliculitis	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Skin infection	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Rash pustular	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 2	0	1 (2.9%)	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Skin structures and soft tissue infections	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Folliculitis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Skin infection	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Rash pustular	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Abdominal and gastrointestinal infections	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 2	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 3	0	0	0	0	0	0
Diverticulitis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Gastroenteritis	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 2	0	1 (2.9%)	1 (1.1%)	0	0	0
Enterococcal infections	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Abdominal and gastrointestinal infections	1 (8.3%)	1 (20.0%)	2 (11.8%)	0	0	0
Grade 2	0	1 (20.0%)	1 (5.9%)	0	0	0
Grade 3	1 (8.3%)	0	1 (5.9%)	0	0	0
Diverticulitis	1 (8.3%)	1 (20.0%)	2 (11.8%)	0	0	0
Grade 2	0	1 (20.0%)	1 (5.9%)	0	0	0
Grade 3	1 (8.3%)	0	1 (5.9%)	0	0	0
Gastroenteritis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Enterococcal infections	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 2	1 (8.3%)	0	1 (5.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-rt.pdf 24AUG2023:15:00

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Enterococcal infections (cont)						
Urinary tract infection enterococcal	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Escherichia infections	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Escherichia urinary tract infection	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Eye and eyelid infections	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Enterococcal infections (cont)						
Urinary tract infection enterococcal	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 2	1 (8.3%)	0	1 (5.9%)	0	0	0
Escherichia infections	1 (8.3%)	0	1 (5.9%)	1 (16.7%)	0	1 (9.1%)
Grade 2	0	0	0	1 (16.7%)	0	1 (9.1%)
Grade 3	1 (8.3%)	0	1 (5.9%)	0	0	0
Escherichia urinary tract infection	1 (8.3%)	0	1 (5.9%)	1 (16.7%)	0	1 (9.1%)
Grade 2	0	0	0	1 (16.7%)	0	1 (9.1%)
Grade 3	1 (8.3%)	0	1 (5.9%)	0	0	0
Eye and eyelid infections	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 2	1 (8.3%)	0	1 (5.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-rt.pdf 24AUG2023:15:00

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Eye and eyelid infections (cont)						
Conjunctivitis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Infections NEC	1 (1.9%)	2 (5.9%)	3 (3.4%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 2	0	2 (5.9%)	2 (2.3%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Respiratory tract infection	1 (1.9%)	2 (5.9%)	3 (3.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 2	0	2 (5.9%)	2 (2.3%)	0	0	0
Localised infection	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 2	0	0	0	0	1 (4.0%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Eye and eyelid infections (cont)						
Conjunctivitis	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 2	1 (8.3%)	0	1 (5.9%)	0	0	0
Infections NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Localised infection	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Infections NEC (cont)						
Wound infection	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 2	0	0	0	1 (2.7%)	0	1 (1.6%)
Influenza viral infections	1 (1.9%)	0	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 2	0	0	0	0	1 (4.0%)	1 (1.6%)
Influenza	1 (1.9%)	0	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 2	0	0	0	0	1 (4.0%)	1 (1.6%)
Staphylococcal infections	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-rt.pdf 24AUG2023:15:00

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Infections NEC (cont)						
Wound infection	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Influenza viral infections	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Influenza	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Staphylococcal infections	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Staphylococcal infections (cont)						
Staphylococcal infection	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Streptococcal infections	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Erysipelas	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Clostridia infections	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 3	0	0	0	1 (2.7%)	0	1 (1.6%)
Clostridium difficile infection	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 3	0	0	0	1 (2.7%)	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Staphylococcal infections (cont)						
Staphylococcal infection	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Streptococcal infections	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 2	1 (8.3%)	0	1 (5.9%)	0	0	0
Erysipelas	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 2	1 (8.3%)	0	1 (5.9%)	0	0	0
Clostridia infections	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Dental and oral soft tissue infections	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 2	0	0	0	1 (2.7%)	0	1 (1.6%)
Dental fistula	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 2	0	0	0	1 (2.7%)	0	1 (1.6%)
Viral infections NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Viral rash	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Dental and oral soft tissue infections	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Dental fistula	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Viral infections NEC	0	0	0	0	1 (20.0%)	1 (9.1%)
Grade 1	0	0	0	0	1 (20.0%)	1 (9.1%)
Viral rash	0	0	0	0	1 (20.0%)	1 (9.1%)
Grade 1	0	0	0	0	1 (20.0%)	1 (9.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions	26 (48.1%)	18 (52.9%)	44 (50.0%)	11 (29.7%)	11 (44.0%)	22 (35.5%)
Grade 1	8 (14.8%)	5 (14.7%)	13 (14.8%)	5 (13.5%)	2 (8.0%)	7 (11.3%)
Grade 2	13 (24.1%)	12 (35.3%)	25 (28.4%)	4 (10.8%)	5 (20.0%)	9 (14.5%)
Grade 3	5 (9.3%)	1 (2.9%)	6 (6.8%)	2 (5.4%)	4 (16.0%)	6 (9.7%)
Asthenic conditions	18 (33.3%)	12 (35.3%)	30 (34.1%)	3 (8.1%)	6 (24.0%)	9 (14.5%)
Grade 1	7 (13.0%)	2 (5.9%)	9 (10.2%)	0	0	0
Grade 2	8 (14.8%)	9 (26.5%)	17 (19.3%)	2 (5.4%)	3 (12.0%)	5 (8.1%)
Grade 3	3 (5.6%)	1 (2.9%)	4 (4.5%)	1 (2.7%)	3 (12.0%)	4 (6.5%)
Asthenia	9 (16.7%)	6 (17.6%)	15 (17.0%)	2 (5.4%)	5 (20.0%)	7 (11.3%)
Grade 1	3 (5.6%)	0	3 (3.4%)	0	0	0
Grade 2	3 (5.6%)	5 (14.7%)	8 (9.1%)	1 (2.7%)	2 (8.0%)	3 (4.8%)
Grade 3	3 (5.6%)	1 (2.9%)	4 (4.5%)	1 (2.7%)	3 (12.0%)	4 (6.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions	7 (58.3%)	2 (40.0%)	9 (52.9%)	2 (33.3%)	4 (80.0%)	6 (54.5%)
Grade 1	2 (16.7%)	0	2 (11.8%)	2 (33.3%)	2 (40.0%)	4 (36.4%)
Grade 2	2 (16.7%)	2 (40.0%)	4 (23.5%)	0	2 (40.0%)	2 (18.2%)
Grade 3	3 (25.0%)	0	3 (17.6%)	0	0	0
Asthenic conditions	4 (33.3%)	2 (40.0%)	6 (35.3%)	1 (16.7%)	4 (80.0%)	5 (45.5%)
Grade 1	0	0	0	1 (16.7%)	3 (60.0%)	4 (36.4%)
Grade 2	3 (25.0%)	2 (40.0%)	5 (29.4%)	0	1 (20.0%)	1 (9.1%)
Grade 3	1 (8.3%)	0	1 (5.9%)	0	0	0
Asthenia	4 (33.3%)	2 (40.0%)	6 (35.3%)	1 (16.7%)	3 (60.0%)	4 (36.4%)
Grade 1	0	0	0	1 (16.7%)	2 (40.0%)	3 (27.3%)
Grade 2	3 (25.0%)	2 (40.0%)	5 (29.4%)	0	1 (20.0%)	1 (9.1%)
Grade 3	1 (8.3%)	0	1 (5.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Asthenic conditions (cont)						
Fatigue	10 (18.5%)	6 (17.6%)	16 (18.2%)	1 (2.7%)	2 (8.0%)	3 (4.8%)
Grade 1	5 (9.3%)	2 (5.9%)	7 (8.0%)	0	0	0
Grade 2	5 (9.3%)	4 (11.8%)	9 (10.2%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Grade 3	0	0	0	0	1 (4.0%)	1 (1.6%)
Febrile disorders	8 (14.8%)	3 (8.8%)	11 (12.5%)	6 (16.2%)	5 (20.0%)	11 (17.7%)
Grade 1	5 (9.3%)	2 (5.9%)	7 (8.0%)	3 (8.1%)	4 (16.0%)	7 (11.3%)
Grade 2	2 (3.7%)	1 (2.9%)	3 (3.4%)	2 (5.4%)	1 (4.0%)	3 (4.8%)
Grade 3	1 (1.9%)	0	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Pyrexia	8 (14.8%)	3 (8.8%)	11 (12.5%)	6 (16.2%)	5 (20.0%)	11 (17.7%)
Grade 1	5 (9.3%)	2 (5.9%)	7 (8.0%)	3 (8.1%)	4 (16.0%)	7 (11.3%)
Grade 2	2 (3.7%)	1 (2.9%)	3 (3.4%)	2 (5.4%)	1 (4.0%)	3 (4.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Asthenic conditions (cont)						
Fatigue	0	1 (20.0%)	1 (5.9%)	0	1 (20.0%)	1 (9.1%)
Grade 1	0	0	0	0	1 (20.0%)	1 (9.1%)
Grade 2	0	1 (20.0%)	1 (5.9%)	0	0	0
Grade 3	0	0	0	0	0	0
Febrile disorders	3 (25.0%)	0	3 (17.6%)	1 (16.7%)	2 (40.0%)	3 (27.3%)
Grade 1	2 (16.7%)	0	2 (11.8%)	1 (16.7%)	1 (20.0%)	2 (18.2%)
Grade 2	0	0	0	0	1 (20.0%)	1 (9.1%)
Grade 3	1 (8.3%)	0	1 (5.9%)	0	0	0
Pyrexia	3 (25.0%)	0	3 (17.6%)	1 (16.7%)	2 (40.0%)	3 (27.3%)
Grade 1	2 (16.7%)	0	2 (11.8%)	1 (16.7%)	1 (20.0%)	2 (18.2%)
Grade 2	0	0	0	0	1 (20.0%)	1 (9.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Febrile disorders (cont)						
Pyrexia (cont)						
Grade 3	1 (1.9%)	0	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Oedema NEC	5 (9.3%)	6 (17.6%)	11 (12.5%)	4 (10.8%)	2 (8.0%)	6 (9.7%)
Grade 1	3 (5.6%)	5 (14.7%)	8 (9.1%)	2 (5.4%)	0	2 (3.2%)
Grade 2	2 (3.7%)	1 (2.9%)	3 (3.4%)	2 (5.4%)	1 (4.0%)	3 (4.8%)
Grade 3	0	0	0	0	1 (4.0%)	1 (1.6%)
Oedema peripheral	5 (9.3%)	5 (14.7%)	10 (11.4%)	4 (10.8%)	2 (8.0%)	6 (9.7%)
Grade 1	3 (5.6%)	4 (11.8%)	7 (8.0%)	2 (5.4%)	0	2 (3.2%)
Grade 2	2 (3.7%)	1 (2.9%)	3 (3.4%)	2 (5.4%)	1 (4.0%)	3 (4.8%)
Grade 3	0	0	0	0	1 (4.0%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Febrile disorders (cont)						
Pyrexia (cont)						
Grade 3	1 (8.3%)	0	1 (5.9%)	0	0	0
Oedema NEC	3 (25.0%)	0	3 (17.6%)	0	1 (20.0%)	1 (9.1%)
Grade 1	1 (8.3%)	0	1 (5.9%)	0	1 (20.0%)	1 (9.1%)
Grade 2	2 (16.7%)	0	2 (11.8%)	0	0	0
Grade 3	0	0	0	0	0	0
Oedema peripheral	3 (25.0%)	0	3 (17.6%)	0	1 (20.0%)	1 (9.1%)
Grade 1	1 (8.3%)	0	1 (5.9%)	0	1 (20.0%)	1 (9.1%)
Grade 2	2 (16.7%)	0	2 (11.8%)	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Oedema NEC (cont)						
Generalised oedema	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 1	0	1 (2.9%)	1 (1.1%)	0	0	0
Feelings and sensations NEC	3 (5.6%)	4 (11.8%)	7 (8.0%)	3 (8.1%)	0	3 (4.8%)
Grade 1	3 (5.6%)	3 (8.8%)	6 (6.8%)	2 (5.4%)	0	2 (3.2%)
Grade 2	0	1 (2.9%)	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Early satiety	1 (1.9%)	4 (11.8%)	5 (5.7%)	0	0	0
Grade 1	1 (1.9%)	3 (8.8%)	4 (4.5%)	0	0	0
Grade 2	0	1 (2.9%)	1 (1.1%)	0	0	0
Chills	1 (1.9%)	0	1 (1.1%)	2 (5.4%)	0	2 (3.2%)
Grade 1	1 (1.9%)	0	1 (1.1%)	1 (2.7%)	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Oedema NEC (cont)						
Generalised oedema	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Feelings and sensations NEC	1 (8.3%)	0	1 (5.9%)	0	1 (20.0%)	1 (9.1%)
Grade 1	0	0	0	0	1 (20.0%)	1 (9.1%)
Grade 2	1 (8.3%)	0	1 (5.9%)	0	0	0
Early satiety	1 (8.3%)	0	1 (5.9%)	0	1 (20.0%)	1 (9.1%)
Grade 1	0	0	0	0	1 (20.0%)	1 (9.1%)
Grade 2	1 (8.3%)	0	1 (5.9%)	0	0	0
Chills	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Feelings and sensations NEC (cont)						
Chills (cont)						
Grade 2	0	0	0	1 (2.7%)	0	1 (1.6%)
Feeling hot	1 (1.9%)	0	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Grade 1	1 (1.9%)	0	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Pain and discomfort NEC	3 (5.6%)	0	3 (3.4%)	1 (2.7%)	0	1 (1.6%)
Grade 2	3 (5.6%)	0	3 (3.4%)	1 (2.7%)	0	1 (1.6%)
Chest pain	1 (1.9%)	0	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Grade 2	1 (1.9%)	0	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Non-cardiac chest pain	1 (1.9%)	0	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Feelings and sensations NEC (cont)						
Chills (cont)						
Grade 2	0	0	0	0	0	0
Feeling hot	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Pain and discomfort NEC	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Chest pain	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Non-cardiac chest pain	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Pain and discomfort NEC (cont)						
Non-cardiac chest pain (cont)						
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Pain	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Gait disturbances	2 (3.7%)	1 (2.9%)	3 (3.4%)	1 (2.7%)	0	1 (1.6%)
Grade 1	0	1 (2.9%)	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Grade 2	2 (3.7%)	0	2 (2.3%)	0	0	0
Gait disturbance	2 (3.7%)	1 (2.9%)	3 (3.4%)	1 (2.7%)	0	1 (1.6%)
Grade 1	0	1 (2.9%)	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Grade 2	2 (3.7%)	0	2 (2.3%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Pain and discomfort NEC (cont)						
Non-cardiac chest pain (cont)						
Grade 2	0	0	0	0	0	0
Pain	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Gait disturbances	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Gait disturbance	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
General signs and symptoms NEC	1 (1.9%)	3 (8.8%)	4 (4.5%)	0	0	0
Grade 1	0	2 (5.9%)	2 (2.3%)	0	0	0
Grade 2	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 3	1 (1.9%)	0	1 (1.1%)	0	0	0
Disease progression	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 3	1 (1.9%)	0	1 (1.1%)	0	0	0
General physical health deterioration	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 2	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 3	0	0	0	0	0	0
Influenza like illness	0	1 (2.9%)	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
General signs and symptoms NEC	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	1 (8.3%)	0	1 (5.9%)	0	0	0
Disease progression	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
General physical health deterioration	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	1 (8.3%)	0	1 (5.9%)	0	0	0
Influenza like illness	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
General signs and symptoms NEC (cont)						
Influenza like illness (cont)						
Grade 1	0	1 (2.9%)	1 (1.1%)	0	0	0
Peripheral swelling	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 1	0	1 (2.9%)	1 (1.1%)	0	0	0
Injection site reactions	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Injection site pain	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Body temperature altered	0	1 (2.9%)	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
General signs and symptoms NEC (cont)						
Influenza like illness (cont)						
Grade 1	0	0	0	0	0	0
Peripheral swelling	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Injection site reactions	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Injection site pain	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Body temperature altered	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Body temperature altered (cont)						
(cont)						
Grade 1	0	1 (2.9%)	1 (1.1%)	0	0	0
Temperature regulation disorder	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 1	0	1 (2.9%)	1 (1.1%)	0	0	0
Nervous system disorders	26 (48.1%)	6 (17.6%)	32 (36.4%)	9 (24.3%)	12 (48.0%)	21 (33.9%)
Grade 1	19 (35.2%)	3 (8.8%)	22 (25.0%)	8 (21.6%)	9 (36.0%)	17 (27.4%)
Grade 2	6 (11.1%)	2 (5.9%)	8 (9.1%)	0	2 (8.0%)	2 (3.2%)
Grade 3	1 (1.9%)	1 (2.9%)	2 (2.3%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Neurological signs and symptoms NEC	11 (20.4%)	3 (8.8%)	14 (15.9%)	4 (10.8%)	2 (8.0%)	6 (9.7%)
Grade 1	9 (16.7%)	3 (8.8%)	12 (13.6%)	3 (8.1%)	2 (8.0%)	5 (8.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Body temperature altered (cont)						
(cont)						
Grade 1	0	0	0	0	0	0
Temperature regulation disorder	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Nervous system disorders	6 (50.0%)	2 (40.0%)	8 (47.1%)	2 (33.3%)	2 (40.0%)	4 (36.4%)
Grade 1	3 (25.0%)	2 (40.0%)	5 (29.4%)	1 (16.7%)	1 (20.0%)	2 (18.2%)
Grade 2	2 (16.7%)	0	2 (11.8%)	0	1 (20.0%)	1 (9.1%)
Grade 3	1 (8.3%)	0	1 (5.9%)	1 (16.7%)	0	1 (9.1%)
Neurological signs and symptoms NEC	3 (25.0%)	0	3 (17.6%)	2 (33.3%)	0	2 (18.2%)
Grade 1	1 (8.3%)	0	1 (5.9%)	1 (16.7%)	0	1 (9.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Neurological signs and symptoms NEC (cont)						
(cont)						
Grade 2	2 (3.7%)	0	2 (2.3%)	1 (2.7%)	0	1 (1.6%)
Grade 3	0	0	0	0	0	0
Dizziness	8 (14.8%)	3 (8.8%)	11 (12.5%)	3 (8.1%)	2 (8.0%)	5 (8.1%)
Grade 1	7 (13.0%)	3 (8.8%)	10 (11.4%)	3 (8.1%)	2 (8.0%)	5 (8.1%)
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 3	0	0	0	0	0	0
Presyncope	2 (3.7%)	0	2 (2.3%)	1 (2.7%)	0	1 (1.6%)
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Neurological signs and symptoms NEC (cont)						
(cont)						
Grade 2	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 3	1 (8.3%)	0	1 (5.9%)	1 (16.7%)	0	1 (9.1%)
Dizziness	3 (25.0%)	0	3 (17.6%)	2 (33.3%)	0	2 (18.2%)
Grade 1	2 (16.7%)	0	2 (11.8%)	1 (16.7%)	0	1 (9.1%)
Grade 2	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 3	0	0	0	1 (16.7%)	0	1 (9.1%)
Presyncope	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	1 (8.3%)	0	1 (5.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-rt.pdf 24AUG2023:15:00

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Neurological signs and symptoms NEC (cont)						
Dizziness exertional	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Dizziness postural	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Headaches NEC	8 (14.8%)	3 (8.8%)	11 (12.5%)	0	4 (16.0%)	4 (6.5%)
Grade 1	6 (11.1%)	0	6 (6.8%)	0	1 (4.0%)	1 (1.6%)
Grade 2	2 (3.7%)	2 (5.9%)	4 (4.5%)	0	2 (8.0%)	2 (3.2%)
Grade 3	0	1 (2.9%)	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Headache	8 (14.8%)	3 (8.8%)	11 (12.5%)	0	4 (16.0%)	4 (6.5%)
Grade 1	6 (11.1%)	0	6 (6.8%)	0	1 (4.0%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Neurological signs and symptoms NEC (cont)						
Dizziness exertional	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dizziness postural	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Headaches NEC	0	0	0	0	1 (20.0%)	1 (9.1%)
Grade 1	0	0	0	0	1 (20.0%)	1 (9.1%)
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Headache	0	0	0	0	1 (20.0%)	1 (9.1%)
Grade 1	0	0	0	0	1 (20.0%)	1 (9.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Headaches NEC (cont)						
Headache (cont)						
Grade 2	2 (3.7%)	2 (5.9%)	4 (4.5%)	0	2 (8.0%)	2 (3.2%)
Grade 3	0	1 (2.9%)	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Peripheral neuropathies NEC	7 (13.0%)	0	7 (8.0%)	1 (2.7%)	4 (16.0%)	5 (8.1%)
Grade 1	6 (11.1%)	0	6 (6.8%)	1 (2.7%)	4 (16.0%)	5 (8.1%)
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Peripheral sensory neuropathy	6 (11.1%)	0	6 (6.8%)	1 (2.7%)	4 (16.0%)	5 (8.1%)
Grade 1	5 (9.3%)	0	5 (5.7%)	1 (2.7%)	4 (16.0%)	5 (8.1%)
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Peripheral motor neuropathy	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Headaches NEC (cont)						
Headache (cont)						
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Peripheral neuropathies NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Peripheral sensory neuropathy	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Peripheral motor neuropathy	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Paraesthesias and dysaesthesias	3 (5.6%)	1 (2.9%)	4 (4.5%)	2 (5.4%)	2 (8.0%)	4 (6.5%)
Grade 1	2 (3.7%)	1 (2.9%)	3 (3.4%)	2 (5.4%)	2 (8.0%)	4 (6.5%)
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Paraesthesia	3 (5.6%)	1 (2.9%)	4 (4.5%)	1 (2.7%)	2 (8.0%)	3 (4.8%)
Grade 1	2 (3.7%)	1 (2.9%)	3 (3.4%)	1 (2.7%)	2 (8.0%)	3 (4.8%)
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Hypoaesthesia	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 1	0	0	0	1 (2.7%)	0	1 (1.6%)
Sensory abnormalities NEC	3 (5.6%)	0	3 (3.4%)	1 (2.7%)	0	1 (1.6%)
Grade 1	2 (3.7%)	0	2 (2.3%)	1 (2.7%)	0	1 (1.6%)
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Paraesthesias and dysaesthesias	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Paraesthesia	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Hypoaesthesia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Sensory abnormalities NEC	1 (8.3%)	0	1 (5.9%)	0	1 (20.0%)	1 (9.1%)
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 2	0	0	0	0	1 (20.0%)	1 (9.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Sensory abnormalities NEC (cont)						
Restless legs syndrome	2 (3.7%)	0	2 (2.3%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Neuralgia	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Taste disorder	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hypogeusia	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 1	0	0	0	1 (2.7%)	0	1 (1.6%)
Post herpetic neuralgia	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Sensory abnormalities NEC (cont)						
Restless legs syndrome	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Neuralgia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Taste disorder	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Hypogeusia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Post herpetic neuralgia	0	0	0	0	1 (20.0%)	1 (9.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Sensory abnormalities NEC (cont)						
Post herpetic neuralgia (cont)						
Grade 2	0	0	0	0	0	0
Disturbances in consciousness NEC	2 (3.7%)	0	2 (2.3%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Grade 1	1 (1.9%)	0	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Grade 3	1 (1.9%)	0	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Loss of consciousness	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 3	1 (1.9%)	0	1 (1.1%)	0	0	0
Somnolence	1 (1.9%)	0	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Grade 1	1 (1.9%)	0	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Syncope	1 (1.9%)	0	1 (1.1%)	1 (2.7%)	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Sensory abnormalities NEC (cont)						
Post herpetic neuralgia (cont)						
Grade 2	0	0	0	0	1 (20.0%)	1 (9.1%)
Disturbances in consciousness NEC	0	1 (20.0%)	1 (5.9%)	0	1 (20.0%)	1 (9.1%)
Grade 1	0	1 (20.0%)	1 (5.9%)	0	1 (20.0%)	1 (9.1%)
Grade 3	0	0	0	0	0	0
Loss of consciousness	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Somnolence	0	1 (20.0%)	1 (5.9%)	0	1 (20.0%)	1 (9.1%)
Grade 1	0	1 (20.0%)	1 (5.9%)	0	1 (20.0%)	1 (9.1%)
Syncope	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Disturbances in consciousness NEC (cont)						
Syncope (cont)						
Grade 3	1 (1.9%)	0	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Tremor (excl congenital)	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Tremor	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Cervical spinal cord and nerve root disorders	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Disturbances in consciousness NEC (cont)						
Syncope (cont)						
Grade 3	0	0	0	0	0	0
Tremor (excl congenital)	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Tremor	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Cervical spinal cord and nerve root disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Cervical spinal cord and nerve root disorders (cont)						
Cervical radiculopathy	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Coordination and balance disturbances	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Balance disorder	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Memory loss (excl dementia)	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Memory impairment	1 (1.9%)	0	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Cervical spinal cord and nerve root disorders (cont)						
Cervical radiculopathy	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Coordination and balance disturbances	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Balance disorder	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Memory loss (excl dementia)	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Memory impairment	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Memory loss (excl dementia) (cont)						
Memory impairment (cont)						
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Mental impairment (excl dementia and memory loss)	1 (1.9%)	0	1 (1.1%)	2 (5.4%)	0	2 (3.2%)
Grade 1	1 (1.9%)	0	1 (1.1%)	2 (5.4%)	0	2 (3.2%)
Disturbance in attention	1 (1.9%)	0	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Grade 1	1 (1.9%)	0	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Cognitive disorder	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 1	0	0	0	1 (2.7%)	0	1 (1.6%)
Mononeuropathies	1 (1.9%)	0	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Memory loss (excl dementia) (cont)						
Memory impairment (cont)						
Grade 1	0	0	0	0	0	0
Mental impairment (excl dementia and memory loss)	0	0	0	0	1 (20.0%)	1 (9.1%)
Grade 1	0	0	0	0	1 (20.0%)	1 (9.1%)
Disturbance in attention	0	0	0	0	1 (20.0%)	1 (9.1%)
Grade 1	0	0	0	0	1 (20.0%)	1 (9.1%)
Cognitive disorder	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Mononeuropathies	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Mononeuropathies (cont)						
(cont)						
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Nerve compression	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Neurologic visual problems NEC	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Visual field defect	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Olfactory nerve disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Mononeuropathies (cont)						
(cont)						
Grade 1	0	0	0	0	0	0
Nerve compression	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Neurologic visual problems NEC	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 2	1 (8.3%)	0	1 (5.9%)	0	0	0
Visual field defect	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 2	1 (8.3%)	0	1 (5.9%)	0	0	0
Olfactory nerve disorders	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Olfactory nerve disorders (cont)						
Parosmia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Speech and language abnormalities	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Speech disorder	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Central nervous system haemorrhages and cerebrovascular accidents	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 1	0	0	0	0	1 (4.0%)	1 (1.6%)
Cerebral infarction	0	0	0	0	1 (4.0%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Olfactory nerve disorders (cont)						
Parosmia	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Speech and language abnormalities	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Speech disorder	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Central nervous system haemorrhages and cerebrovascular accidents	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Cerebral infarction	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Central nervous system haemorrhages and cerebrovascular accidents (cont)						
Cerebral infarction (cont)						
Grade 1	0	0	0	0	1 (4.0%)	1 (1.6%)
Dementia (excl Alzheimer's type)	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 1	0	0	0	0	1 (4.0%)	1 (1.6%)
Dementia	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 1	0	0	0	0	1 (4.0%)	1 (1.6%)
Muscle tone abnormal	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hypertonia	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Central nervous system haemorrhages and cerebrovascular accidents (cont)						
Cerebral infarction (cont)						
Grade 1	0	0	0	0	0	0
Dementia (excl Alzheimer's type)	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dementia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Muscle tone abnormal	0	1 (20.0%)	1 (5.9%)	0	0	0
Grade 1	0	1 (20.0%)	1 (5.9%)	0	0	0
Hypertonia	0	1 (20.0%)	1 (5.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Muscle tone abnormal (cont)						
Hypertonia (cont)						
Grade 1	0	0	0	0	0	0
Nervous system cysts and polyps	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Arachnoid cyst	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Blood and lymphatic system disorders	21 (38.9%)	14 (41.2%)	35 (39.8%)	7 (18.9%)	13 (52.0%)	20 (32.3%)
Grade 1	3 (5.6%)	1 (2.9%)	4 (4.5%)	0	1 (4.0%)	1 (1.6%)
Grade 2	4 (7.4%)	2 (5.9%)	6 (6.8%)	2 (5.4%)	5 (20.0%)	7 (11.3%)
Grade 3	10 (18.5%)	10 (29.4%)	20 (22.7%)	4 (10.8%)	6 (24.0%)	10 (16.1%)
Grade 4	4 (7.4%)	1 (2.9%)	5 (5.7%)	1 (2.7%)	1 (4.0%)	2 (3.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Muscle tone abnormal (cont)						
Hypertonia (cont)						
Grade 1	0	1 (20.0%)	1 (5.9%)	0	0	0
Nervous system cysts and polyps	0	0	0	0	1 (20.0%)	1 (9.1%)
Grade 1	0	0	0	0	1 (20.0%)	1 (9.1%)
Arachnoid cyst	0	0	0	0	1 (20.0%)	1 (9.1%)
Grade 1	0	0	0	0	1 (20.0%)	1 (9.1%)
Blood and lymphatic system disorders	5 (41.7%)	2 (40.0%)	7 (41.2%)	0	2 (40.0%)	2 (18.2%)
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 2	0	1 (20.0%)	1 (5.9%)	0	0	0
Grade 3	3 (25.0%)	1 (20.0%)	4 (23.5%)	0	1 (20.0%)	1 (9.1%)
Grade 4	1 (8.3%)	0	1 (5.9%)	0	1 (20.0%)	1 (9.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Anaemias NEC	9 (16.7%)	8 (23.5%)	17 (19.3%)	4 (10.8%)	5 (20.0%)	9 (14.5%)
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 3	7 (13.0%)	8 (23.5%)	15 (17.0%)	4 (10.8%)	5 (20.0%)	9 (14.5%)
Grade 4	1 (1.9%)	0	1 (1.1%)	0	0	0
Anaemia	9 (16.7%)	8 (23.5%)	17 (19.3%)	4 (10.8%)	5 (20.0%)	9 (14.5%)
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 3	7 (13.0%)	8 (23.5%)	15 (17.0%)	4 (10.8%)	5 (20.0%)	9 (14.5%)
Grade 4	1 (1.9%)	0	1 (1.1%)	0	0	0
Thrombocytopenias	10 (18.5%)	4 (11.8%)	14 (15.9%)	2 (5.4%)	5 (20.0%)	7 (11.3%)
Grade 1	2 (3.7%)	0	2 (2.3%)	0	0	0
Grade 2	3 (5.6%)	2 (5.9%)	5 (5.7%)	2 (5.4%)	3 (12.0%)	5 (8.1%)
Grade 3	2 (3.7%)	2 (5.9%)	4 (4.5%)	0	1 (4.0%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Anaemias NEC	4 (33.3%)	2 (40.0%)	6 (35.3%)	0	0	0
Grade 2	0	1 (20.0%)	1 (5.9%)	0	0	0
Grade 3	4 (33.3%)	1 (20.0%)	5 (29.4%)	0	0	0
Grade 4	0	0	0	0	0	0
Anaemia	4 (33.3%)	2 (40.0%)	6 (35.3%)	0	0	0
Grade 2	0	1 (20.0%)	1 (5.9%)	0	0	0
Grade 3	4 (33.3%)	1 (20.0%)	5 (29.4%)	0	0	0
Grade 4	0	0	0	0	0	0
Thrombocytopenias	1 (8.3%)	0	1 (5.9%)	0	2 (40.0%)	2 (18.2%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	1 (20.0%)	1 (9.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Thrombocytopenias (cont) (cont)						
Grade 4	3 (5.6%)	0	3 (3.4%)	0	1 (4.0%)	1 (1.6%)
Thrombocytopenia	10 (18.5%)	4 (11.8%)	14 (15.9%)	2 (5.4%)	5 (20.0%)	7 (11.3%)
Grade 1	2 (3.7%)	0	2 (2.3%)	0	0	0
Grade 2	3 (5.6%)	2 (5.9%)	5 (5.7%)	2 (5.4%)	3 (12.0%)	5 (8.1%)
Grade 3	2 (3.7%)	2 (5.9%)	4 (4.5%)	0	1 (4.0%)	1 (1.6%)
Grade 4	3 (5.6%)	0	3 (3.4%)	0	1 (4.0%)	1 (1.6%)
Neutropenias	6 (11.1%)	1 (2.9%)	7 (8.0%)	1 (2.7%)	2 (8.0%)	3 (4.8%)
Grade 1	0	0	0	0	0	0
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 3	2 (3.7%)	0	2 (2.3%)	0	2 (8.0%)	2 (3.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Thrombocytopenias (cont) (cont)						
Grade 4	1 (8.3%)	0	1 (5.9%)	0	1 (20.0%)	1 (9.1%)
Thrombocytopenia	1 (8.3%)	0	1 (5.9%)	0	2 (40.0%)	2 (18.2%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	1 (20.0%)	1 (9.1%)
Grade 4	1 (8.3%)	0	1 (5.9%)	0	1 (20.0%)	1 (9.1%)
Neutropenias	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Neutropenias (cont) (cont)						
Grade 4	3 (5.6%)	1 (2.9%)	4 (4.5%)	1 (2.7%)	0	1 (1.6%)
Neutropenia	6 (11.1%)	1 (2.9%)	7 (8.0%)	1 (2.7%)	2 (8.0%)	3 (4.8%)
Grade 1	0	0	0	0	0	0
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 3	2 (3.7%)	0	2 (2.3%)	0	2 (8.0%)	2 (3.2%)
Grade 4	3 (5.6%)	1 (2.9%)	4 (4.5%)	1 (2.7%)	0	1 (1.6%)
Spleen disorders	2 (3.7%)	2 (5.9%)	4 (4.5%)	0	2 (8.0%)	2 (3.2%)
Grade 1	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 2	1 (1.9%)	1 (2.9%)	2 (2.3%)	0	2 (8.0%)	2 (3.2%)
Grade 3	1 (1.9%)	0	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Neutropenias (cont) (cont)						
Grade 4	0	0	0	0	0	0
Neutropenia	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Spleen disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Spleen disorders (cont)						
Splenic infarction	1 (1.9%)	0	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Grade 2	1 (1.9%)	0	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Splenomegaly	1 (1.9%)	2 (5.9%)	3 (3.4%)	0	1 (4.0%)	1 (1.6%)
Grade 1	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 2	0	1 (2.9%)	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Grade 3	1 (1.9%)	0	1 (1.1%)	0	0	0
Bleeding tendencies	1 (1.9%)	0	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Grade 1	1 (1.9%)	0	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Increased tendency to bruise	1 (1.9%)	0	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Grade 1	1 (1.9%)	0	1 (1.1%)	0	1 (4.0%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Spleen disorders (cont)						
Splenic infarction	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Splenomegaly	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Bleeding tendencies	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Increased tendency to bruise	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Coagulopathies	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hyperfibrinogenaemia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Leukocytoses NEC	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Neutrophilia	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Leukopenias NEC	1 (1.9%)	0	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Grade 3	1 (1.9%)	0	1 (1.1%)	0	1 (4.0%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Coagulopathies	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Hyperfibrinogenaemia	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Leukocytoses NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Neutrophilia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Leukopenias NEC	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-rt.pdf 24AUG2023:15:00

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Leukopenias NEC (cont)						
Leukopenia	1 (1.9%)	0	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Grade 3	1 (1.9%)	0	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Lymphatic system disorders NEC	1 (1.9%)	1 (2.9%)	2 (2.3%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 3	0	1 (2.9%)	1 (1.1%)	0	0	0
Lymphadenopathy	1 (1.9%)	1 (2.9%)	2 (2.3%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 3	0	1 (2.9%)	1 (1.1%)	0	0	0
Anaemias haemolytic NEC	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 3	0	1 (2.9%)	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Leukopenias NEC (cont)						
Leukopenia	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Lymphatic system disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Lymphadenopathy	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Anaemias haemolytic NEC	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Anaemias haemolytic NEC (cont)						
Haemolytic anaemia	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 3	0	1 (2.9%)	1 (1.1%)	0	0	0
Metabolism and nutrition disorders	20 (37.0%)	8 (23.5%)	28 (31.8%)	6 (16.2%)	6 (24.0%)	12 (19.4%)
Grade 1	16 (29.6%)	2 (5.9%)	18 (20.5%)	3 (8.1%)	3 (12.0%)	6 (9.7%)
Grade 2	1 (1.9%)	2 (5.9%)	3 (3.4%)	2 (5.4%)	2 (8.0%)	4 (6.5%)
Grade 3	3 (5.6%)	3 (8.8%)	6 (6.8%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Grade 4	0	1 (2.9%)	1 (1.1%)	0	0	0
Water soluble vitamin deficiencies	7 (13.0%)	1 (2.9%)	8 (9.1%)	3 (8.1%)	1 (4.0%)	4 (6.5%)
Grade 1	6 (11.1%)	1 (2.9%)	7 (8.0%)	2 (5.4%)	1 (4.0%)	3 (4.8%)
Grade 2	1 (1.9%)	0	1 (1.1%)	1 (2.7%)	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Anaemias haemolytic NEC (cont)						
Haemolytic anaemia	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Metabolism and nutrition disorders	5 (41.7%)	0	5 (29.4%)	2 (33.3%)	1 (20.0%)	3 (27.3%)
Grade 1	1 (8.3%)	0	1 (5.9%)	1 (16.7%)	0	1 (9.1%)
Grade 2	2 (16.7%)	0	2 (11.8%)	1 (16.7%)	1 (20.0%)	2 (18.2%)
Grade 3	2 (16.7%)	0	2 (11.8%)	0	0	0
Grade 4	0	0	0	0	0	0
Water soluble vitamin deficiencies	2 (16.7%)	0	2 (11.8%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 2	1 (8.3%)	0	1 (5.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Water soluble vitamin deficiencies (cont)						
Vitamin B1 deficiency	5 (9.3%)	1 (2.9%)	6 (6.8%)	3 (8.1%)	1 (4.0%)	4 (6.5%)
Grade 1	4 (7.4%)	1 (2.9%)	5 (5.7%)	2 (5.4%)	1 (4.0%)	3 (4.8%)
Grade 2	1 (1.9%)	0	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Vitamin B complex deficiency	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Vitamin B6 deficiency	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Potassium imbalance	4 (7.4%)	0	4 (4.5%)	1 (2.7%)	2 (8.0%)	3 (4.8%)
Grade 1	3 (5.6%)	0	3 (3.4%)	0	0	0
Grade 2	0	0	0	0	1 (4.0%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Water soluble vitamin deficiencies (cont)						
Vitamin B1 deficiency	2 (16.7%)	0	2 (11.8%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 2	1 (8.3%)	0	1 (5.9%)	0	0	0
Vitamin B complex deficiency	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Vitamin B6 deficiency	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Potassium imbalance	2 (16.7%)	0	2 (11.8%)	1 (16.7%)	1 (20.0%)	2 (18.2%)
Grade 1	1 (8.3%)	0	1 (5.9%)	0	1 (20.0%)	1 (9.1%)
Grade 2	1 (8.3%)	0	1 (5.9%)	1 (16.7%)	0	1 (9.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Potassium imbalance (cont)						
(cont)						
Grade 3	1 (1.9%)	0	1 (1.1%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Hyperkalaemia	4 (7.4%)	0	4 (4.5%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Grade 1	3 (5.6%)	0	3 (3.4%)	1 (2.7%)	0	1 (1.6%)
Grade 2	1 (1.9%)	0	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Hypokalaemia	1 (1.9%)	0	1 (1.1%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	1 (1.9%)	0	1 (1.1%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Appetite disorders	3 (5.6%)	2 (5.9%)	5 (5.7%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Grade 1	3 (5.6%)	0	3 (3.4%)	0	1 (4.0%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Potassium imbalance (cont)						
(cont)						
Grade 3	0	0	0	0	0	0
Hyperkalaemia	2 (16.7%)	0	2 (11.8%)	1 (16.7%)	0	1 (9.1%)
Grade 1	2 (16.7%)	0	2 (11.8%)	0	0	0
Grade 2	0	0	0	1 (16.7%)	0	1 (9.1%)
Hypokalaemia	1 (8.3%)	0	1 (5.9%)	0	1 (20.0%)	1 (9.1%)
Grade 1	0	0	0	0	1 (20.0%)	1 (9.1%)
Grade 2	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 3	0	0	0	0	0	0
Appetite disorders	2 (16.7%)	0	2 (11.8%)	0	1 (20.0%)	1 (9.1%)
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Appetite disorders (cont)						
(cont)						
Grade 2	0	1 (2.9%)	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Grade 3	0	1 (2.9%)	1 (1.1%)	0	0	0
Decreased appetite	3 (5.6%)	2 (5.9%)	5 (5.7%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Grade 1	3 (5.6%)	0	3 (3.4%)	0	1 (4.0%)	1 (1.6%)
Grade 2	0	1 (2.9%)	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Grade 3	0	1 (2.9%)	1 (1.1%)	0	0	0
Appetite disorder	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Calcium metabolism disorders	3 (5.6%)	1 (2.9%)	4 (4.5%)	2 (5.4%)	2 (8.0%)	4 (6.5%)
Grade 1	3 (5.6%)	1 (2.9%)	4 (4.5%)	2 (5.4%)	1 (4.0%)	3 (4.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Appetite disorders (cont)						
(cont)						
Grade 2	1 (8.3%)	0	1 (5.9%)	0	1 (20.0%)	1 (9.1%)
Grade 3	0	0	0	0	0	0
Decreased appetite	1 (8.3%)	0	1 (5.9%)	0	1 (20.0%)	1 (9.1%)
Grade 1	0	0	0	0	0	0
Grade 2	1 (8.3%)	0	1 (5.9%)	0	1 (20.0%)	1 (9.1%)
Grade 3	0	0	0	0	0	0
Appetite disorder	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Calcium metabolism disorders	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Calcium metabolism disorders (cont)						
(cont)						
Grade 3	0	0	0	0	1 (4.0%)	1 (1.6%)
Hypocalcaemia	3 (5.6%)	1 (2.9%)	4 (4.5%)	2 (5.4%)	2 (8.0%)	4 (6.5%)
Grade 1	3 (5.6%)	1 (2.9%)	4 (4.5%)	2 (5.4%)	1 (4.0%)	3 (4.8%)
Grade 3	0	0	0	0	1 (4.0%)	1 (1.6%)
Disorders of purine metabolism	2 (3.7%)	3 (8.8%)	5 (5.7%)	0	1 (4.0%)	1 (1.6%)
Grade 1	1 (1.9%)	1 (2.9%)	2 (2.3%)	0	0	0
Grade 2	0	1 (2.9%)	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Grade 3	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 4	0	1 (2.9%)	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Calcium metabolism disorders (cont)						
(cont)						
Grade 3	0	0	0	0	0	0
Hypocalcaemia	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 3	0	0	0	0	0	0
Disorders of purine metabolism	2 (16.7%)	0	2 (11.8%)	1 (16.7%)	0	1 (9.1%)
Grade 1	2 (16.7%)	0	2 (11.8%)	1 (16.7%)	0	1 (9.1%)
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Disorders of purine metabolism (cont)						
Hyperuricaemia	2 (3.7%)	2 (5.9%)	4 (4.5%)	0	1 (4.0%)	1 (1.6%)
Grade 1	1 (1.9%)	1 (2.9%)	2 (2.3%)	0	0	0
Grade 2	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 3	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 4	0	1 (2.9%)	1 (1.1%)	0	0	0
Gout	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 2	0	1 (2.9%)	1 (1.1%)	0	0	0
Hyperglycaemic conditions NEC	2 (3.7%)	0	2 (2.3%)	0	1 (4.0%)	1 (1.6%)
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 2	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 3	1 (1.9%)	0	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Disorders of purine metabolism (cont)						
Hyperuricaemia	2 (16.7%)	0	2 (11.8%)	1 (16.7%)	0	1 (9.1%)
Grade 1	2 (16.7%)	0	2 (11.8%)	1 (16.7%)	0	1 (9.1%)
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Gout	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Hyperglycaemic conditions NEC	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	1 (8.3%)	0	1 (5.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-rt.pdf 24AUG2023:15:00

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Hyperglycaemic conditions NEC (cont)						
Hyperglycaemia	2 (3.7%)	0	2 (2.3%)	0	1 (4.0%)	1 (1.6%)
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 2	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 3	1 (1.9%)	0	1 (1.1%)	0	0	0
Sodium imbalance	2 (3.7%)	1 (2.9%)	3 (3.4%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Grade 1	2 (3.7%)	1 (2.9%)	3 (3.4%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Hyponatraemia	2 (3.7%)	1 (2.9%)	3 (3.4%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Grade 1	2 (3.7%)	1 (2.9%)	3 (3.4%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Hypernatraemia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Hyperglycaemic conditions NEC (cont)						
Hyperglycaemia	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	1 (8.3%)	0	1 (5.9%)	0	0	0
Sodium imbalance	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Hyponatraemia	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Hypernatraemia	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Phosphorus metabolism disorders	1 (1.9%)	0	1 (1.1%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 2	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 3	0	0	0	0	1 (4.0%)	1 (1.6%)
Hyperphosphataemia	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Hypophosphataemia	0	0	0	1 (2.7%)	1 (4.0%)	2 (3.2%)
Grade 2	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 3	0	0	0	0	1 (4.0%)	1 (1.6%)
Total fluid volume decreased	2 (3.7%)	0	2 (2.3%)	0	0	0
Grade 1	2 (3.7%)	0	2 (2.3%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Phosphorus metabolism disorders	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 3	0	0	0	0	0	0
Hyperphosphataemia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hypophosphataemia	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 2	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 3	0	0	0	0	0	0
Total fluid volume decreased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Total fluid volume decreased (cont)						
Dehydration	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Hypovolaemia	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Electrolyte imbalance NEC	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Magnesium metabolism disorders	1 (1.9%)	1 (2.9%)	2 (2.3%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Grade 1	1 (1.9%)	1 (2.9%)	2 (2.3%)	1 (2.7%)	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Total fluid volume decreased (cont)						
Dehydration	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hypovolaemia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Electrolyte imbalance NEC	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 3	1 (8.3%)	0	1 (5.9%)	0	0	0
Tumour lysis syndrome	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 3	1 (8.3%)	0	1 (5.9%)	0	0	0
Magnesium metabolism disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Magnesium metabolism disorders (cont) (cont)						
Grade 3	0	0	0	0	1 (4.0%)	1 (1.6%)
Hypomagnesaemia	1 (1.9%)	1 (2.9%)	2 (2.3%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Grade 1	1 (1.9%)	1 (2.9%)	2 (2.3%)	1 (2.7%)	0	1 (1.6%)
Grade 3	0	0	0	0	1 (4.0%)	1 (1.6%)
Protein metabolism disorders NEC	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 1	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 2	0	0	0	0	0	0
Hypoalbuminaemia	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 1	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Magnesium metabolism disorders (cont)						
(cont)						
Grade 3	0	0	0	0	0	0
Hypomagnesaemia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Protein metabolism disorders NEC	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	1 (8.3%)	0	1 (5.9%)	0	0	0
Hypoalbuminaemia	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	1 (8.3%)	0	1 (5.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Fat soluble vitamin deficiencies and disorders	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 1	0	1 (2.9%)	1 (1.1%)	0	0	0
Vitamin D deficiency	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 1	0	1 (2.9%)	1 (1.1%)	0	0	0
General nutritional disorders NEC	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 2	0	1 (2.9%)	1 (1.1%)	0	0	0
Cachexia	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 2	0	1 (2.9%)	1 (1.1%)	0	0	0
Iron excess	0	2 (5.9%)	2 (2.3%)	0	0	0
Grade 3	0	2 (5.9%)	2 (2.3%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Fat soluble vitamin deficiencies and disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Vitamin D deficiency	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
General nutritional disorders NEC	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Cachexia	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Iron excess	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Iron excess (cont)						
Iron overload	0	2 (5.9%)	2 (2.3%)	0	0	0
Grade 3	0	2 (5.9%)	2 (2.3%)	0	0	0
Respiratory, thoracic and mediastinal disorders	21 (38.9%)	10 (29.4%)	31 (35.2%)	12 (32.4%)	8 (32.0%)	20 (32.3%)
Grade 1	10 (18.5%)	4 (11.8%)	14 (15.9%)	9 (24.3%)	3 (12.0%)	12 (19.4%)
Grade 2	8 (14.8%)	5 (14.7%)	13 (14.8%)	1 (2.7%)	2 (8.0%)	3 (4.8%)
Grade 3	2 (3.7%)	1 (2.9%)	3 (3.4%)	1 (2.7%)	2 (8.0%)	3 (4.8%)
Grade 4	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 5	1 (1.9%)	0	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Coughing and associated symptoms	11 (20.4%)	2 (5.9%)	13 (14.8%)	9 (24.3%)	4 (16.0%)	13 (21.0%)
Grade 1	8 (14.8%)	1 (2.9%)	9 (10.2%)	6 (16.2%)	2 (8.0%)	8 (12.9%)
Grade 2	3 (5.6%)	1 (2.9%)	4 (4.5%)	2 (5.4%)	1 (4.0%)	3 (4.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Iron excess (cont)						
Iron overload	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Respiratory, thoracic and mediastinal disorders	3 (25.0%)	3 (60.0%)	6 (35.3%)	1 (16.7%)	4 (80.0%)	5 (45.5%)
Grade 1	0	2 (40.0%)	2 (11.8%)	1 (16.7%)	2 (40.0%)	3 (27.3%)
Grade 2	1 (8.3%)	1 (20.0%)	2 (11.8%)	0	2 (40.0%)	2 (18.2%)
Grade 3	0	0	0	0	0	0
Grade 4	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 5	1 (8.3%)	0	1 (5.9%)	0	0	0
Coughing and associated symptoms	0	2 (40.0%)	2 (11.8%)	1 (16.7%)	2 (40.0%)	3 (27.3%)
Grade 1	0	2 (40.0%)	2 (11.8%)	1 (16.7%)	1 (20.0%)	2 (18.2%)
Grade 2	0	0	0	0	1 (20.0%)	1 (9.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Coughing and associated symptoms (cont) (cont)						
Grade 3	0	0	0	1 (2.7%)	1 (4.0%)	2 (3.2%)
Cough	9 (16.7%)	2 (5.9%)	11 (12.5%)	9 (24.3%)	4 (16.0%)	13 (21.0%)
Grade 1	7 (13.0%)	1 (2.9%)	8 (9.1%)	6 (16.2%)	2 (8.0%)	8 (12.9%)
Grade 2	2 (3.7%)	1 (2.9%)	3 (3.4%)	2 (5.4%)	1 (4.0%)	3 (4.8%)
Grade 3	0	0	0	1 (2.7%)	1 (4.0%)	2 (3.2%)
Haemoptysis	2 (3.7%)	0	2 (2.3%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Productive cough	1 (1.9%)	0	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Coughing and associated symptoms (cont) (cont)						
Grade 3	0	0	0	0	0	0
Cough	0	2 (40.0%)	2 (11.8%)	1 (16.7%)	2 (40.0%)	3 (27.3%)
Grade 1	0	2 (40.0%)	2 (11.8%)	1 (16.7%)	1 (20.0%)	2 (18.2%)
Grade 2	0	0	0	0	1 (20.0%)	1 (9.1%)
Grade 3	0	0	0	0	0	0
Haemoptysis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Productive cough	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-rt.pdf 24AUG2023:15:00

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Coughing and associated symptoms (cont)						
Productive cough (cont)						
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Sputum discoloured	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Breathing abnormalities	8 (14.8%)	4 (11.8%)	12 (13.6%)	3 (8.1%)	2 (8.0%)	5 (8.1%)
Grade 1	3 (5.6%)	2 (5.9%)	5 (5.7%)	2 (5.4%)	1 (4.0%)	3 (4.8%)
Grade 2	3 (5.6%)	2 (5.9%)	5 (5.7%)	0	1 (4.0%)	1 (1.6%)
Grade 3	2 (3.7%)	0	2 (2.3%)	0	0	0
Grade 5	0	0	0	1 (2.7%)	0	1 (1.6%)
Dyspnoea	7 (13.0%)	4 (11.8%)	11 (12.5%)	1 (2.7%)	2 (8.0%)	3 (4.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Coughing and associated symptoms (cont)						
Productive cough (cont)						
Grade 1	0	0	0	0	0	0
Sputum discoloured	0	0	0	0	1 (20.0%)	1 (9.1%)
Grade 2	0	0	0	0	1 (20.0%)	1 (9.1%)
Breathing abnormalities	1 (8.3%)	3 (60.0%)	4 (23.5%)	0	1 (20.0%)	1 (9.1%)
Grade 1	0	2 (40.0%)	2 (11.8%)	0	1 (20.0%)	1 (9.1%)
Grade 2	1 (8.3%)	1 (20.0%)	2 (11.8%)	0	0	0
Grade 3	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Dyspnoea	1 (8.3%)	2 (40.0%)	3 (17.6%)	0	1 (20.0%)	1 (9.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Breathing abnormalities (cont)						
Dyspnoea (cont)						
Grade 1	2 (3.7%)	2 (5.9%)	4 (4.5%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Grade 2	3 (5.6%)	2 (5.9%)	5 (5.7%)	0	1 (4.0%)	1 (1.6%)
Grade 3	2 (3.7%)	0	2 (2.3%)	0	0	0
Dyspnoea exertional	1 (1.9%)	0	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Grade 1	1 (1.9%)	0	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Respiratory distress	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 5	0	0	0	1 (2.7%)	0	1 (1.6%)
Nasal disorders NEC	6 (11.1%)	3 (8.8%)	9 (10.2%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Grade 1	4 (7.4%)	1 (2.9%)	5 (5.7%)	1 (2.7%)	1 (4.0%)	2 (3.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Breathing abnormalities (cont)						
Dyspnoea (cont)						
Grade 1	0	1 (20.0%)	1 (5.9%)	0	1 (20.0%)	1 (9.1%)
Grade 2	1 (8.3%)	1 (20.0%)	2 (11.8%)	0	0	0
Grade 3	0	0	0	0	0	0
Dyspnoea exertional	0	1 (20.0%)	1 (5.9%)	0	0	0
Grade 1	0	1 (20.0%)	1 (5.9%)	0	0	0
Respiratory distress	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Nasal disorders NEC	0	2 (40.0%)	2 (11.8%)	0	1 (20.0%)	1 (9.1%)
Grade 1	0	2 (40.0%)	2 (11.8%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Nasal disorders NEC (cont) (cont)						
Grade 2	2 (3.7%)	2 (5.9%)	4 (4.5%)	0	0	0
Epistaxis	6 (11.1%)	3 (8.8%)	9 (10.2%)	0	1 (4.0%)	1 (1.6%)
Grade 1	4 (7.4%)	1 (2.9%)	5 (5.7%)	0	1 (4.0%)	1 (1.6%)
Grade 2	2 (3.7%)	2 (5.9%)	4 (4.5%)	0	0	0
Nasal septum ulceration	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 1	0	0	0	1 (2.7%)	0	1 (1.6%)
Upper respiratory tract signs and symptoms	2 (3.7%)	0	2 (2.3%)	3 (8.1%)	0	3 (4.8%)
Grade 1	2 (3.7%)	0	2 (2.3%)	3 (8.1%)	0	3 (4.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Nasal disorders NEC (cont) (cont)						
Grade 2	0	0	0	0	1 (20.0%)	1 (9.1%)
Epistaxis	0	2 (40.0%)	2 (11.8%)	0	1 (20.0%)	1 (9.1%)
Grade 1	0	2 (40.0%)	2 (11.8%)	0	0	0
Grade 2	0	0	0	0	1 (20.0%)	1 (9.1%)
Nasal septum ulceration	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Upper respiratory tract signs and symptoms	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Upper respiratory tract signs and symptoms (cont)						
Dysphonia	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Oropharyngeal pain	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 1	0	0	0	1 (2.7%)	0	1 (1.6%)
Rhinorrhoea	1 (1.9%)	0	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Grade 1	1 (1.9%)	0	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Upper-airway cough syndrome	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 1	0	0	0	1 (2.7%)	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Upper respiratory tract signs and symptoms (cont)						
Dysphonia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Oropharyngeal pain	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Rhinorrhoea	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Upper-airway cough syndrome	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Pulmonary hypertensions	2 (3.7%)	1 (2.9%)	3 (3.4%)	0	0	0
Grade 2	1 (1.9%)	1 (2.9%)	2 (2.3%)	0	0	0
Grade 3	1 (1.9%)	0	1 (1.1%)	0	0	0
Pulmonary hypertension	2 (3.7%)	1 (2.9%)	3 (3.4%)	0	0	0
Grade 2	1 (1.9%)	1 (2.9%)	2 (2.3%)	0	0	0
Grade 3	1 (1.9%)	0	1 (1.1%)	0	0	0
Respiratory failures (excl neonatal)	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 5	1 (1.9%)	0	1 (1.1%)	0	0	0
Respiratory failure	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 5	1 (1.9%)	0	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Pulmonary hypertensions	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Pulmonary hypertension	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Respiratory failures (excl neonatal)	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 5	1 (8.3%)	0	1 (5.9%)	0	0	0
Respiratory failure	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 5	1 (8.3%)	0	1 (5.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Parenchymal lung disorders NEC	1 (1.9%)	0	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 3	0	0	0	0	1 (4.0%)	1 (1.6%)
Atelectasis	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Interstitial lung disease	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 3	0	0	0	0	1 (4.0%)	1 (1.6%)
Pneumothorax and pleural effusions NEC	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Pleural effusion	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Parenchymal lung disorders NEC	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Atelectasis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Interstitial lung disease	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Pneumothorax and pleural effusions NEC	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 3	1 (8.3%)	0	1 (5.9%)	0	0	0
Pleural effusion	1 (8.3%)	0	1 (5.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Pneumothorax and pleural effusions NEC (cont)						
Pleural effusion (cont)						
Grade 3	0	0	0	0	0	0
Pulmonary oedemas	0	1 (2.9%)	1 (1.1%)	0	2 (8.0%)	2 (3.2%)
Grade 3	0	1 (2.9%)	1 (1.1%)	0	2 (8.0%)	2 (3.2%)
Grade 4	0	0	0	0	0	0
Acute respiratory distress syndrome	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Pulmonary congestion	0	1 (2.9%)	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Grade 3	0	1 (2.9%)	1 (1.1%)	0	1 (4.0%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Pneumothorax and pleural effusions NEC (cont)						
Pleural effusion (cont)						
Grade 3	1 (8.3%)	0	1 (5.9%)	0	0	0
Pulmonary oedemas	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 3	0	0	0	0	0	0
Grade 4	1 (8.3%)	0	1 (5.9%)	0	0	0
Acute respiratory distress syndrome	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 4	1 (8.3%)	0	1 (5.9%)	0	0	0
Pulmonary congestion	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Pulmonary oedemas (cont)						
Pulmonary oedema	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 3	0	0	0	0	1 (4.0%)	1 (1.6%)
Conditions associated with abnormal gas exchange	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 4	0	0	0	0	1 (4.0%)	1 (1.6%)
Hypoxia	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 4	0	0	0	0	1 (4.0%)	1 (1.6%)
Lower respiratory tract inflammatory and immunologic conditions	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 2	0	0	0	1 (2.7%)	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Pulmonary oedemas (cont)						
Pulmonary oedema	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Conditions associated with abnormal gas exchange	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Hypoxia	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Lower respiratory tract inflammatory and immunologic conditions	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Lower respiratory tract inflammatory and immunologic conditions (cont)						
Pneumonitis	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 2	0	0	0	1 (2.7%)	0	1 (1.6%)
Nasal congestion and inflammations	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 1	0	1 (2.9%)	1 (1.1%)	0	0	0
Rhinitis allergic	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 1	0	1 (2.9%)	1 (1.1%)	0	0	0
Paranasal sinus disorders (excl infections and neoplasms)	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 1	0	1 (2.9%)	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Lower respiratory tract inflammatory and immunologic conditions (cont)						
Pneumonitis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Nasal congestion and inflammations	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Rhinitis allergic	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Paranasal sinus disorders (excl infections and neoplasms)	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Paranasal sinus disorders (excl infections and neoplasms) (cont)						
Sinus congestion	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 1	0	1 (2.9%)	1 (1.1%)	0	0	0
Skin and subcutaneous tissue disorders	15 (27.8%)	8 (23.5%)	23 (26.1%)	9 (24.3%)	4 (16.0%)	13 (21.0%)
Grade 1	12 (22.2%)	5 (14.7%)	17 (19.3%)	7 (18.9%)	2 (8.0%)	9 (14.5%)
Grade 2	3 (5.6%)	2 (5.9%)	5 (5.7%)	2 (5.4%)	0	2 (3.2%)
Grade 3	0	1 (2.9%)	1 (1.1%)	0	2 (8.0%)	2 (3.2%)
Pruritus NEC	9 (16.7%)	3 (8.8%)	12 (13.6%)	2 (5.4%)	2 (8.0%)	4 (6.5%)
Grade 1	6 (11.1%)	2 (5.9%)	8 (9.1%)	2 (5.4%)	0	2 (3.2%)
Grade 2	3 (5.6%)	1 (2.9%)	4 (4.5%)	0	1 (4.0%)	1 (1.6%)
Grade 3	0	0	0	0	1 (4.0%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Paranasal sinus disorders (excl infections and neoplasms) (cont)						
Sinus congestion	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Skin and subcutaneous tissue disorders	7 (58.3%)	3 (60.0%)	10 (58.8%)	0	2 (40.0%)	2 (18.2%)
Grade 1	6 (50.0%)	2 (40.0%)	8 (47.1%)	0	1 (20.0%)	1 (9.1%)
Grade 2	1 (8.3%)	1 (20.0%)	2 (11.8%)	0	1 (20.0%)	1 (9.1%)
Grade 3	0	0	0	0	0	0
Pruritus NEC	3 (25.0%)	1 (20.0%)	4 (23.5%)	0	0	0
Grade 1	2 (16.7%)	0	2 (11.8%)	0	0	0
Grade 2	1 (8.3%)	1 (20.0%)	2 (11.8%)	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Pruritus NEC (cont)						
Pruritus	7 (13.0%)	2 (5.9%)	9 (10.2%)	2 (5.4%)	1 (4.0%)	3 (4.8%)
Grade 1	5 (9.3%)	2 (5.9%)	7 (8.0%)	2 (5.4%)	0	2 (3.2%)
Grade 2	2 (3.7%)	0	2 (2.3%)	0	0	0
Grade 3	0	0	0	0	1 (4.0%)	1 (1.6%)
Pruritus generalised	2 (3.7%)	1 (2.9%)	3 (3.4%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Grade 1	1 (1.9%)	0	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Grade 2	1 (1.9%)	1 (2.9%)	2 (2.3%)	0	1 (4.0%)	1 (1.6%)
Apocrine and eccrine gland disorders	6 (11.1%)	4 (11.8%)	10 (11.4%)	3 (8.1%)	4 (16.0%)	7 (11.3%)
Grade 1	5 (9.3%)	2 (5.9%)	7 (8.0%)	1 (2.7%)	2 (8.0%)	3 (4.8%)
Grade 2	1 (1.9%)	1 (2.9%)	2 (2.3%)	2 (5.4%)	0	2 (3.2%)
Grade 3	0	1 (2.9%)	1 (1.1%)	0	2 (8.0%)	2 (3.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-rt.pdf 24AUG2023:15:00

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Pruritus NEC (cont)						
Pruritus	3 (25.0%)	1 (20.0%)	4 (23.5%)	0	0	0
Grade 1	2 (16.7%)	0	2 (11.8%)	0	0	0
Grade 2	1 (8.3%)	1 (20.0%)	2 (11.8%)	0	0	0
Grade 3	0	0	0	0	0	0
Pruritus generalised	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Apocrine and eccrine gland disorders	0	1 (20.0%)	1 (5.9%)	0	0	0
Grade 1	0	1 (20.0%)	1 (5.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Apocrine and eccrine gland disorders (cont)						
Night sweats	5 (9.3%)	1 (2.9%)	6 (6.8%)	2 (5.4%)	2 (8.0%)	4 (6.5%)
Grade 1	4 (7.4%)	1 (2.9%)	5 (5.7%)	0	1 (4.0%)	1 (1.6%)
Grade 2	1 (1.9%)	0	1 (1.1%)	2 (5.4%)	0	2 (3.2%)
Grade 3	0	0	0	0	1 (4.0%)	1 (1.6%)
Hyperhidrosis	2 (3.7%)	4 (11.8%)	6 (6.8%)	1 (2.7%)	2 (8.0%)	3 (4.8%)
Grade 1	2 (3.7%)	2 (5.9%)	4 (4.5%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Grade 2	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 3	0	1 (2.9%)	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Rashes, eruptions and exanthems NEC	3 (5.6%)	1 (2.9%)	4 (4.5%)	2 (5.4%)	0	2 (3.2%)
Grade 1	3 (5.6%)	1 (2.9%)	4 (4.5%)	2 (5.4%)	0	2 (3.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Apocrine and eccrine gland disorders (cont)						
Night sweats	0	1 (20.0%)	1 (5.9%)	0	0	0
Grade 1	0	1 (20.0%)	1 (5.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Hyperhidrosis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Rashes, eruptions and exanthems NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Rashes, eruptions and exanthems NEC (cont)						
Rash	1 (1.9%)	1 (2.9%)	2 (2.3%)	1 (2.7%)	0	1 (1.6%)
Grade 1	1 (1.9%)	1 (2.9%)	2 (2.3%)	1 (2.7%)	0	1 (1.6%)
Rash generalised	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Rash maculo-papular	1 (1.9%)	0	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Grade 1	1 (1.9%)	0	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Purpura and related conditions	0	1 (2.9%)	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Grade 1	0	1 (2.9%)	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Rashes, eruptions and exanthems NEC (cont)						
Rash	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Rash generalised	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Rash maculo-papular	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Purpura and related conditions	2 (16.7%)	0	2 (11.8%)	0	2 (40.0%)	2 (18.2%)
Grade 1	2 (16.7%)	0	2 (11.8%)	0	1 (20.0%)	1 (9.1%)
Grade 2	0	0	0	0	1 (20.0%)	1 (9.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Purpura and related conditions (cont)						
Ecchymosis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Purpura senile	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Petechiae	0	1 (2.9%)	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Grade 1	0	1 (2.9%)	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Purpura	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Dermal and epidermal conditions NEC	0	1 (2.9%)	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Purpura and related conditions (cont)						
Ecchymosis	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Purpura senile	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Petechiae	0	0	0	0	1 (20.0%)	1 (9.1%)
Grade 1	0	0	0	0	1 (20.0%)	1 (9.1%)
Purpura	0	0	0	0	1 (20.0%)	1 (9.1%)
Grade 2	0	0	0	0	1 (20.0%)	1 (9.1%)
Dermal and epidermal conditions NEC	1 (8.3%)	0	1 (5.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Dermal and epidermal conditions NEC (cont)						
(cont)						
Grade 1	0	1 (2.9%)	1 (1.1%)	0	0	0
Dry skin	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Skin lesion	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 1	0	1 (2.9%)	1 (1.1%)	0	0	0
Dermatitis ascribed to specific agent	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Dermal and epidermal conditions NEC (cont)						
(cont)						
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Dry skin	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Skin lesion	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dermatitis ascribed to specific agent	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Dermatitis ascribed to specific agent (cont)						
Palmar-plantar erythrodysaesthesia syndrome	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Alopecias	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 1	0	0	0	1 (2.7%)	0	1 (1.6%)
Alopecia	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 1	0	0	0	1 (2.7%)	0	1 (1.6%)
Angioedemas	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 1	0	0	0	1 (2.7%)	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Dermatitis ascribed to specific agent (cont)						
Palmar-plantar erythrodysaesthesia syndrome	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Alopecias	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Alopecia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Angioedemas	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Angioedemas (cont)						
Swelling face	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 1	0	0	0	1 (2.7%)	0	1 (1.6%)
Erythemas	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 1	0	0	0	1 (2.7%)	0	1 (1.6%)
Erythema	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 1	0	0	0	1 (2.7%)	0	1 (1.6%)
Ichthyoses	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Xeroderma	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Angioedemas (cont)						
Swelling face	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Erythemas	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Erythema	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Ichthyoses	0	1 (20.0%)	1 (5.9%)	0	0	0
Grade 1	0	1 (20.0%)	1 (5.9%)	0	0	0
Xeroderma	0	1 (20.0%)	1 (5.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Ichthyoses (cont)						
Xeroderma (cont)						
Grade 1	0	0	0	0	0	0
Skin and subcutaneous tissue ulcerations	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 2	0	1 (2.9%)	1 (1.1%)	0	0	0
Skin ulcer	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 2	0	1 (2.9%)	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Ichthyoses (cont)						
Xeroderma (cont)						
Grade 1	0	1 (20.0%)	1 (5.9%)	0	0	0
Skin and subcutaneous tissue ulcerations	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Skin ulcer	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders	17 (31.5%)	9 (26.5%)	26 (29.5%)	8 (21.6%)	5 (20.0%)	13 (21.0%)
Grade 1	9 (16.7%)	6 (17.6%)	15 (17.0%)	3 (8.1%)	3 (12.0%)	6 (9.7%)
Grade 2	6 (11.1%)	3 (8.8%)	9 (10.2%)	5 (13.5%)	2 (8.0%)	7 (11.3%)
Grade 3	2 (3.7%)	0	2 (2.3%)	0	0	0
Joint related signs and symptoms	6 (11.1%)	2 (5.9%)	8 (9.1%)	0	0	0
Grade 1	5 (9.3%)	2 (5.9%)	7 (8.0%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Arthralgia	6 (11.1%)	2 (5.9%)	8 (9.1%)	0	0	0
Grade 1	5 (9.3%)	2 (5.9%)	7 (8.0%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders	4 (33.3%)	5 (100.0%)	9 (52.9%)	3 (50.0%)	0	3 (27.3%)
Grade 1	4 (33.3%)	2 (40.0%)	6 (35.3%)	2 (33.3%)	0	2 (18.2%)
Grade 2	0	3 (60.0%)	3 (17.6%)	1 (16.7%)	0	1 (9.1%)
Grade 3	0	0	0	0	0	0
Joint related signs and symptoms	2 (16.7%)	1 (20.0%)	3 (17.6%)	0	0	0
Grade 1	2 (16.7%)	1 (20.0%)	3 (17.6%)	0	0	0
Grade 2	0	0	0	0	0	0
Arthralgia	2 (16.7%)	1 (20.0%)	3 (17.6%)	0	0	0
Grade 1	2 (16.7%)	1 (20.0%)	3 (17.6%)	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Musculoskeletal and connective tissue pain and discomfort	5 (9.3%)	5 (14.7%)	10 (11.4%)	7 (18.9%)	3 (12.0%)	10 (16.1%)
Grade 1	4 (7.4%)	5 (14.7%)	9 (10.2%)	3 (8.1%)	2 (8.0%)	5 (8.1%)
Grade 2	1 (1.9%)	0	1 (1.1%)	4 (10.8%)	1 (4.0%)	5 (8.1%)
Pain in extremity	3 (5.6%)	3 (8.8%)	6 (6.8%)	4 (10.8%)	0	4 (6.5%)
Grade 1	3 (5.6%)	3 (8.8%)	6 (6.8%)	2 (5.4%)	0	2 (3.2%)
Grade 2	0	0	0	2 (5.4%)	0	2 (3.2%)
Back pain	1 (1.9%)	1 (2.9%)	2 (2.3%)	3 (8.1%)	1 (4.0%)	4 (6.5%)
Grade 1	0	1 (2.9%)	1 (1.1%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Grade 2	1 (1.9%)	0	1 (1.1%)	2 (5.4%)	0	2 (3.2%)
Limb discomfort	1 (1.9%)	0	1 (1.1%)	0	1 (4.0%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Musculoskeletal and connective tissue pain and discomfort	2 (16.7%)	3 (60.0%)	5 (29.4%)	1 (16.7%)	0	1 (9.1%)
Grade 1	2 (16.7%)	2 (40.0%)	4 (23.5%)	1 (16.7%)	0	1 (9.1%)
Grade 2	0	1 (20.0%)	1 (5.9%)	0	0	0
Pain in extremity	0	1 (20.0%)	1 (5.9%)	1 (16.7%)	0	1 (9.1%)
Grade 1	0	1 (20.0%)	1 (5.9%)	1 (16.7%)	0	1 (9.1%)
Grade 2	0	0	0	0	0	0
Back pain	1 (8.3%)	1 (20.0%)	2 (11.8%)	0	0	0
Grade 1	1 (8.3%)	1 (20.0%)	2 (11.8%)	0	0	0
Grade 2	0	0	0	0	0	0
Limb discomfort	1 (8.3%)	1 (20.0%)	2 (11.8%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Musculoskeletal and connective tissue pain and discomfort (cont)						
Limb discomfort (cont)						
Grade 1	1 (1.9%)	0	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Flank pain	1 (1.9%)	1 (2.9%)	2 (2.3%)	0	0	0
Grade 1	1 (1.9%)	1 (2.9%)	2 (2.3%)	0	0	0
Grade 2	0	0	0	0	0	0
Musculoskeletal chest pain	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 1	0	0	0	1 (2.7%)	0	1 (1.6%)
Musculoskeletal pain	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 2	0	0	0	0	1 (4.0%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Musculoskeletal and connective tissue pain and discomfort (cont)						
Limb discomfort (cont)						
Grade 1	1 (8.3%)	1 (20.0%)	2 (11.8%)	0	0	0
Flank pain	0	1 (20.0%)	1 (5.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (20.0%)	1 (5.9%)	0	0	0
Musculoskeletal chest pain	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Musculoskeletal pain	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Musculoskeletal and connective tissue pain and discomfort (cont)						
Neck pain	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 2	0	0	0	1 (2.7%)	0	1 (1.6%)
Bone related signs and symptoms	3 (5.6%)	3 (8.8%)	6 (6.8%)	0	1 (4.0%)	1 (1.6%)
Grade 1	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 2	3 (5.6%)	3 (8.8%)	6 (6.8%)	0	0	0
Bone pain	2 (3.7%)	3 (8.8%)	5 (5.7%)	0	1 (4.0%)	1 (1.6%)
Grade 1	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 2	2 (3.7%)	3 (8.8%)	5 (5.7%)	0	0	0
Spinal pain	1 (1.9%)	0	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Musculoskeletal and connective tissue pain and discomfort (cont)						
Neck pain	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Bone related signs and symptoms	0	1 (20.0%)	1 (5.9%)	2 (33.3%)	0	2 (18.2%)
Grade 1	0	0	0	1 (16.7%)	0	1 (9.1%)
Grade 2	0	1 (20.0%)	1 (5.9%)	1 (16.7%)	0	1 (9.1%)
Bone pain	0	1 (20.0%)	1 (5.9%)	1 (16.7%)	0	1 (9.1%)
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (20.0%)	1 (5.9%)	1 (16.7%)	0	1 (9.1%)
Spinal pain	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Bone related signs and symptoms (cont)						
Spinal pain (cont)						
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Metatarsalgia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Muscle related signs and symptoms NEC	3 (5.6%)	0	3 (3.4%)	2 (5.4%)	1 (4.0%)	3 (4.8%)
Grade 1	3 (5.6%)	0	3 (3.4%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Grade 2	0	0	0	1 (2.7%)	0	1 (1.6%)
Muscle spasms	3 (5.6%)	0	3 (3.4%)	2 (5.4%)	1 (4.0%)	3 (4.8%)
Grade 1	3 (5.6%)	0	3 (3.4%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Grade 2	0	0	0	1 (2.7%)	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Bone related signs and symptoms (cont)						
Spinal pain (cont)						
Grade 2	0	0	0	0	0	0
Metatarsalgia	0	0	0	1 (16.7%)	0	1 (9.1%)
Grade 1	0	0	0	1 (16.7%)	0	1 (9.1%)
Muscle related signs and symptoms NEC	0	1 (20.0%)	1 (5.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (20.0%)	1 (5.9%)	0	0	0
Muscle spasms	0	1 (20.0%)	1 (5.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (20.0%)	1 (5.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Muscle pains	2 (3.7%)	0	2 (2.3%)	0	1 (4.0%)	1 (1.6%)
Grade 1	1 (1.9%)	0	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Myalgia	2 (3.7%)	0	2 (2.3%)	0	1 (4.0%)	1 (1.6%)
Grade 1	1 (1.9%)	0	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Crystal arthropathic disorders	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 3	1 (1.9%)	0	1 (1.1%)	0	0	0
Gouty arthritis	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 3	1 (1.9%)	0	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Muscle pains	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Myalgia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Crystal arthropathic disorders	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Gouty arthritis	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Soft tissue disorders NEC	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 3	1 (1.9%)	0	1 (1.1%)	0	0	0
Groin pain	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 3	1 (1.9%)	0	1 (1.1%)	0	0	0
Arthropathies NEC	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 1	0	1 (2.9%)	1 (1.1%)	0	0	0
Arthritis	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 1	0	1 (2.9%)	1 (1.1%)	0	0	0
Bone disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Soft tissue disorders NEC	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Groin pain	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Arthropathies NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Arthritis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Bone disorders NEC	0	1 (20.0%)	1 (5.9%)	1 (16.7%)	0	1 (9.1%)
Grade 1	0	1 (20.0%)	1 (5.9%)	1 (16.7%)	0	1 (9.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Bone disorders NEC (cont)						
Bone lesion	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Osteosis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Bursal disorders	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 2	0	0	0	1 (2.7%)	0	1 (1.6%)
Bursitis	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 2	0	0	0	1 (2.7%)	0	1 (1.6%)
Metabolic bone disorders	0	1 (2.9%)	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Bone disorders NEC (cont)						
Bone lesion	0	1 (20.0%)	1 (5.9%)	0	0	0
Grade 1	0	1 (20.0%)	1 (5.9%)	0	0	0
Osteosis	0	0	0	1 (16.7%)	0	1 (9.1%)
Grade 1	0	0	0	1 (16.7%)	0	1 (9.1%)
Bursal disorders	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Bursitis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Metabolic bone disorders	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Metabolic bone disorders (cont) (cont)						
Grade 1	0	1 (2.9%)	1 (1.1%)	0	0	0
Osteoporosis	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 1	0	1 (2.9%)	1 (1.1%)	0	0	0
Muscle weakness conditions	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 2	0	0	0	0	1 (4.0%)	1 (1.6%)
Muscular weakness	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 2	0	0	0	0	1 (4.0%)	1 (1.6%)
Osteoarthropathies	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Metabolic bone disorders (cont) (cont)						
Grade 1	0	0	0	0	0	0
Osteoporosis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Muscle weakness conditions	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Muscular weakness	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Osteoarthropathies	0	1 (20.0%)	1 (5.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Osteoarthropathies (cont)						
(cont)						
Grade 1	0	0	0	0	0	0
Osteoarthritis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Spine and neck deformities	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Scoliosis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Tendon disorders	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Osteoarthropathies (cont) (cont)						
Grade 1	0	1 (20.0%)	1 (5.9%)	0	0	0
Osteoarthritis	0	1 (20.0%)	1 (5.9%)	0	0	0
Grade 1	0	1 (20.0%)	1 (5.9%)	0	0	0
Spine and neck deformities	0	1 (20.0%)	1 (5.9%)	0	0	0
Grade 1	0	1 (20.0%)	1 (5.9%)	0	0	0
Scoliosis	0	1 (20.0%)	1 (5.9%)	0	0	0
Grade 1	0	1 (20.0%)	1 (5.9%)	0	0	0
Tendon disorders	0	0	0	1 (16.7%)	0	1 (9.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Tendon disorders (cont)						
(cont)						
Grade 1	0	0	0	0	0	0
Tendonitis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Investigations	15 (27.8%)	2 (5.9%)	17 (19.3%)	7 (18.9%)	5 (20.0%)	12 (19.4%)
Grade 1	12 (22.2%)	0	12 (13.6%)	5 (13.5%)	1 (4.0%)	6 (9.7%)
Grade 2	2 (3.7%)	2 (5.9%)	4 (4.5%)	2 (5.4%)	3 (12.0%)	5 (8.1%)
Grade 3	1 (1.9%)	0	1 (1.1%)	0	1 (4.0%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Tendon disorders (cont)						
(cont)						
Grade 1	0	0	0	1 (16.7%)	0	1 (9.1%)
Tendonitis	0	0	0	1 (16.7%)	0	1 (9.1%)
Grade 1	0	0	0	1 (16.7%)	0	1 (9.1%)
Investigations	2 (16.7%)	1 (20.0%)	3 (17.6%)	0	1 (20.0%)	1 (9.1%)
Grade 1	0	1 (20.0%)	1 (5.9%)	0	1 (20.0%)	1 (9.1%)
Grade 2	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 3	1 (8.3%)	0	1 (5.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Physical examination procedures and organ system status	8 (14.8%)	1 (2.9%)	9 (10.2%)	2 (5.4%)	2 (8.0%)	4 (6.5%)
Grade 1	6 (11.1%)	0	6 (6.8%)	2 (5.4%)	1 (4.0%)	3 (4.8%)
Grade 2	2 (3.7%)	1 (2.9%)	3 (3.4%)	0	1 (4.0%)	1 (1.6%)
Weight decreased	6 (11.1%)	1 (2.9%)	7 (8.0%)	0	2 (8.0%)	2 (3.2%)
Grade 1	4 (7.4%)	0	4 (4.5%)	0	1 (4.0%)	1 (1.6%)
Grade 2	2 (3.7%)	1 (2.9%)	3 (3.4%)	0	1 (4.0%)	1 (1.6%)
Body temperature increased	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Weight increased	1 (1.9%)	0	1 (1.1%)	2 (5.4%)	0	2 (3.2%)
Grade 1	1 (1.9%)	0	1 (1.1%)	2 (5.4%)	0	2 (3.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Physical examination procedures and organ system status	1 (8.3%)	0	1 (5.9%)	0	1 (20.0%)	1 (9.1%)
Grade 1	1 (8.3%)	0	1 (5.9%)	0	1 (20.0%)	1 (9.1%)
Grade 2	0	0	0	0	0	0
Weight decreased	1 (8.3%)	0	1 (5.9%)	0	1 (20.0%)	1 (9.1%)
Grade 1	1 (8.3%)	0	1 (5.9%)	0	1 (20.0%)	1 (9.1%)
Grade 2	0	0	0	0	0	0
Body temperature increased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Weight increased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Liver function analyses	3 (5.6%)	1 (2.9%)	4 (4.5%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Grade 1	2 (3.7%)	0	2 (2.3%)	1 (2.7%)	0	1 (1.6%)
Grade 2	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 3	1 (1.9%)	0	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Blood bilirubin increased	1 (1.9%)	1 (2.9%)	2 (2.3%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 2	0	1 (2.9%)	1 (1.1%)	0	0	0
Alanine aminotransferase increased	2 (3.7%)	0	2 (2.3%)	1 (2.7%)	0	1 (1.6%)
Grade 1	1 (1.9%)	0	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Grade 3	1 (1.9%)	0	1 (1.1%)	0	0	0
Aspartate aminotransferase increased	2 (3.7%)	0	2 (2.3%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Liver function analyses	2 (16.7%)	0	2 (11.8%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	2 (16.7%)	0	2 (11.8%)	0	0	0
Grade 3	0	0	0	0	0	0
Blood bilirubin increased	2 (16.7%)	0	2 (11.8%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	2 (16.7%)	0	2 (11.8%)	0	0	0
Alanine aminotransferase increased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Aspartate aminotransferase increased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Liver function analyses (cont)						
Aspartate aminotransferase increased (cont)						
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Gamma-glutamyltransferase increased	1 (1.9%)	0	1 (1.1%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Grade 1	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 3	1 (1.9%)	0	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Liver function test increased	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 3	0	0	0	0	1 (4.0%)	1 (1.6%)
Renal function analyses	2 (3.7%)	0	2 (2.3%)	2 (5.4%)	1 (4.0%)	3 (4.8%)
Grade 1	2 (3.7%)	0	2 (2.3%)	0	0	0
Grade 2	0	0	0	2 (5.4%)	1 (4.0%)	3 (4.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Liver function analyses (cont)						
Aspartate aminotransferase increased (cont)						
Grade 2	0	0	0	0	0	0
Gamma-glutamyltransferase increased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Liver function test increased	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Renal function analyses	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Renal function analyses (cont)						
(cont)						
Grade 3	0	0	0	0	0	0
Blood creatinine increased	2 (3.7%)	0	2 (2.3%)	2 (5.4%)	1 (4.0%)	3 (4.8%)
Grade 1	2 (3.7%)	0	2 (2.3%)	0	0	0
Grade 2	0	0	0	2 (5.4%)	1 (4.0%)	3 (4.8%)
Grade 3	0	0	0	0	0	0
Tissue enzyme analyses NEC	3 (5.6%)	1 (2.9%)	4 (4.5%)	1 (2.7%)	0	1 (1.6%)
Grade 1	2 (3.7%)	1 (2.9%)	3 (3.4%)	1 (2.7%)	0	1 (1.6%)
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Blood alkaline phosphatase increased	2 (3.7%)	1 (2.9%)	3 (3.4%)	1 (2.7%)	0	1 (1.6%)
Grade 1	1 (1.9%)	1 (2.9%)	2 (2.3%)	1 (2.7%)	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Renal function analyses (cont)						
(cont)						
Grade 3	1 (8.3%)	0	1 (5.9%)	0	0	0
Blood creatinine increased	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	1 (8.3%)	0	1 (5.9%)	0	0	0
Tissue enzyme analyses NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Blood alkaline phosphatase increased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Tissue enzyme analyses NEC (cont)						
Blood alkaline phosphatase increased (cont)						
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Blood lactate dehydrogenase increased	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Cardiac auscultatory investigations	2 (3.7%)	0	2 (2.3%)	1 (2.7%)	0	1 (1.6%)
Grade 1	2 (3.7%)	0	2 (2.3%)	1 (2.7%)	0	1 (1.6%)
Cardiac murmur	2 (3.7%)	0	2 (2.3%)	1 (2.7%)	0	1 (1.6%)
Grade 1	2 (3.7%)	0	2 (2.3%)	1 (2.7%)	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Tissue enzyme analyses NEC (cont)						
Blood alkaline phosphatase increased (cont)						
Grade 2	0	0	0	0	0	0
Blood lactate dehydrogenase increased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Cardiac auscultatory investigations	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Cardiac murmur	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Coagulation and bleeding analyses	0	0	0	1 (2.7%)	1 (4.0%)	2 (3.2%)
Grade 1	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 2	0	0	0	0	1 (4.0%)	1 (1.6%)
International normalised ratio increased	0	0	0	1 (2.7%)	1 (4.0%)	2 (3.2%)
Grade 1	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 2	0	0	0	0	1 (4.0%)	1 (1.6%)
Cardiac function diagnostic procedures	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 2	0	0	0	0	1 (4.0%)	1 (1.6%)
Ejection fraction decreased	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 2	0	0	0	0	1 (4.0%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Coagulation and bleeding analyses	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 2	0	0	0	0	0	0
International normalised ratio increased	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Cardiac function diagnostic procedures	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Ejection fraction decreased	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Mineral and electrolyte analyses	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 1	0	0	0	1 (2.7%)	0	1 (1.6%)
Blood bicarbonate decreased	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 1	0	0	0	1 (2.7%)	0	1 (1.6%)
Vascular tests NEC (incl blood pressure)	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Blood pressure increased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Mineral and electrolyte analyses	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Blood bicarbonate decreased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Vascular tests NEC (incl blood pressure)	0	1 (20.0%)	1 (5.9%)	0	0	0
Grade 1	0	1 (20.0%)	1 (5.9%)	0	0	0
Blood pressure increased	0	1 (20.0%)	1 (5.9%)	0	0	0
Grade 1	0	1 (20.0%)	1 (5.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders	6 (11.1%)	2 (5.9%)	8 (9.1%)	4 (10.8%)	5 (20.0%)	9 (14.5%)
Grade 1	1 (1.9%)	0	1 (1.1%)	1 (2.7%)	2 (8.0%)	3 (4.8%)
Grade 2	3 (5.6%)	1 (2.9%)	4 (4.5%)	1 (2.7%)	3 (12.0%)	4 (6.5%)
Grade 3	2 (3.7%)	1 (2.9%)	3 (3.4%)	2 (5.4%)	0	2 (3.2%)
Grade 4	0	0	0	0	0	0
Vascular hypertensive disorders NEC	4 (7.4%)	0	4 (4.5%)	2 (5.4%)	1 (4.0%)	3 (4.8%)
Grade 2	3 (5.6%)	0	3 (3.4%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Grade 3	1 (1.9%)	0	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Grade 4	0	0	0	0	0	0
Hypertension	4 (7.4%)	0	4 (4.5%)	2 (5.4%)	1 (4.0%)	3 (4.8%)
Grade 2	3 (5.6%)	0	3 (3.4%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Grade 3	1 (1.9%)	0	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Grade 4	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders	3 (25.0%)	0	3 (17.6%)	0	1 (20.0%)	1 (9.1%)
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 2	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 3	0	0	0	0	1 (20.0%)	1 (9.1%)
Grade 4	1 (8.3%)	0	1 (5.9%)	0	0	0
Vascular hypertensive disorders NEC	2 (16.7%)	0	2 (11.8%)	0	0	0
Grade 2	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 3	0	0	0	0	0	0
Grade 4	1 (8.3%)	0	1 (5.9%)	0	0	0
Hypertension	2 (16.7%)	0	2 (11.8%)	0	0	0
Grade 2	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 3	0	0	0	0	0	0
Grade 4	1 (8.3%)	0	1 (5.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Vascular hypotensive disorders	1 (1.9%)	0	1 (1.1%)	0	2 (8.0%)	2 (3.2%)
Grade 1	1 (1.9%)	0	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Grade 2	0	0	0	0	1 (4.0%)	1 (1.6%)
Hypotension	1 (1.9%)	0	1 (1.1%)	0	2 (8.0%)	2 (3.2%)
Grade 1	1 (1.9%)	0	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Grade 2	0	0	0	0	1 (4.0%)	1 (1.6%)
Orthostatic hypotension	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Aortic necrosis and vascular insufficiency	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 3	1 (1.9%)	0	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Vascular hypotensive disorders	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Hypotension	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Orthostatic hypotension	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Aortic necrosis and vascular insufficiency	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-rt.pdf 24AUG2023:15:00

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Aortic necrosis and vascular insufficiency (cont)						
Aortic stenosis	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 3	1 (1.9%)	0	1 (1.1%)	0	0	0
Peripheral vascular disorders NEC	1 (1.9%)	0	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Grade 1	1 (1.9%)	0	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Hot flush	1 (1.9%)	0	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Grade 1	1 (1.9%)	0	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Haemorrhages NEC	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Haematoma	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Aortic necrosis and vascular insufficiency (cont)						
Aortic stenosis	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Peripheral vascular disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hot flush	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Haemorrhages NEC	0	0	0	0	1 (20.0%)	1 (9.1%)
Grade 3	0	0	0	0	1 (20.0%)	1 (9.1%)
Haematoma	0	0	0	0	1 (20.0%)	1 (9.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Haemorrhages NEC (cont)						
Haematoma (cont)						
Grade 3	0	0	0	0	0	0
Non-site specific embolism and thrombosis	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 3	0	0	0	1 (2.7%)	0	1 (1.6%)
Embolism	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 3	0	0	0	1 (2.7%)	0	1 (1.6%)
Non-site specific necrosis and vascular insufficiency NEC	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 2	0	1 (2.9%)	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Haemorrhages NEC (cont)						
Haematoma (cont)						
Grade 3	0	0	0	0	1 (20.0%)	1 (9.1%)
Non-site specific embolism and thrombosis	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Embolism	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Non-site specific necrosis and vascular insufficiency NEC	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Non-site specific necrosis and vascular insufficiency NEC (cont)						
Peripheral venous disease	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 2	0	1 (2.9%)	1 (1.1%)	0	0	0
Non-site specific vascular disorders NEC	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 3	0	1 (2.9%)	1 (1.1%)	0	0	0
Arterial disorder	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 3	0	1 (2.9%)	1 (1.1%)	0	0	0
Peripheral embolism and thrombosis	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 2	0	0	0	0	1 (4.0%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Non-site specific necrosis and vascular insufficiency NEC (cont)						
Peripheral venous disease	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Non-site specific vascular disorders NEC	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Arterial disorder	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Peripheral embolism and thrombosis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Peripheral embolism and thrombosis (cont)						
Thrombophlebitis	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 2	0	0	0	0	1 (4.0%)	1 (1.6%)
Peripheral vasoconstriction, necrosis and vascular insufficiency	0	1 (2.9%)	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Grade 1	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 3	0	1 (2.9%)	1 (1.1%)	0	0	0
Diabetic vascular disorder	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 3	0	1 (2.9%)	1 (1.1%)	0	0	0
Peripheral coldness	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 1	0	0	0	0	1 (4.0%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Peripheral embolism and thrombosis (cont)						
Thrombophlebitis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Peripheral vasoconstriction, necrosis and vascular insufficiency	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Diabetic vascular disorder	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Peripheral coldness	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Site specific vascular disorders NEC	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 1	0	0	0	1 (2.7%)	0	1 (1.6%)
Jugular vein distension	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 1	0	0	0	1 (2.7%)	0	1 (1.6%)
Cardiac disorders	6 (11.1%)	5 (14.7%)	11 (12.5%)	4 (10.8%)	4 (16.0%)	8 (12.9%)
Grade 1	1 (1.9%)	1 (2.9%)	2 (2.3%)	0	0	0
Grade 2	1 (1.9%)	2 (5.9%)	3 (3.4%)	2 (5.4%)	3 (12.0%)	5 (8.1%)
Grade 3	4 (7.4%)	2 (5.9%)	6 (6.8%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Grade 4	0	0	0	1 (2.7%)	0	1 (1.6%)
Heart failures NEC	3 (5.6%)	1 (2.9%)	4 (4.5%)	2 (5.4%)	1 (4.0%)	3 (4.8%)
Grade 2	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 3	3 (5.6%)	0	3 (3.4%)	2 (5.4%)	1 (4.0%)	3 (4.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Site specific vascular disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Jugular vein distension	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Cardiac disorders	2 (16.7%)	0	2 (11.8%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	2 (16.7%)	0	2 (11.8%)	0	0	0
Grade 4	0	0	0	0	0	0
Heart failures NEC	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	1 (8.3%)	0	1 (5.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Heart failures NEC (cont)						
Cardiac failure	2 (3.7%)	0	2 (2.3%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Grade 3	2 (3.7%)	0	2 (2.3%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Cardiac failure congestive	1 (1.9%)	1 (2.9%)	2 (2.3%)	1 (2.7%)	0	1 (1.6%)
Grade 2	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 3	1 (1.9%)	0	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Supraventricular arrhythmias	3 (5.6%)	2 (5.9%)	5 (5.7%)	3 (8.1%)	1 (4.0%)	4 (6.5%)
Grade 2	1 (1.9%)	1 (2.9%)	2 (2.3%)	2 (5.4%)	1 (4.0%)	3 (4.8%)
Grade 3	2 (3.7%)	1 (2.9%)	3 (3.4%)	0	0	0
Grade 4	0	0	0	1 (2.7%)	0	1 (1.6%)
Atrial fibrillation	2 (3.7%)	2 (5.9%)	4 (4.5%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Grade 2	1 (1.9%)	1 (2.9%)	2 (2.3%)	0	1 (4.0%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Heart failures NEC (cont)						
Cardiac failure	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 3	1 (8.3%)	0	1 (5.9%)	0	0	0
Cardiac failure congestive	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Supraventricular arrhythmias	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 4	0	0	0	0	0	0
Atrial fibrillation	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Supraventricular arrhythmias (cont)						
Atrial fibrillation (cont)						
Grade 3	1 (1.9%)	1 (2.9%)	2 (2.3%)	0	0	0
Grade 4	0	0	0	1 (2.7%)	0	1 (1.6%)
Sinus tachycardia	0	0	0	2 (5.4%)	0	2 (3.2%)
Grade 2	0	0	0	2 (5.4%)	0	2 (3.2%)
Grade 3	0	0	0	0	0	0
Supraventricular tachycardia	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 3	1 (1.9%)	0	1 (1.1%)	0	0	0
Cardiac signs and symptoms NEC	1 (1.9%)	1 (2.9%)	2 (2.3%)	0	0	0
Grade 1	1 (1.9%)	1 (2.9%)	2 (2.3%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Supraventricular arrhythmias (cont)						
Atrial fibrillation (cont)						
Grade 3	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Sinus tachycardia	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	1 (8.3%)	0	1 (5.9%)	0	0	0
Supraventricular tachycardia	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Cardiac signs and symptoms NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Cardiac signs and symptoms NEC (cont)						
Palpitations	1 (1.9%)	1 (2.9%)	2 (2.3%)	0	0	0
Grade 1	1 (1.9%)	1 (2.9%)	2 (2.3%)	0	0	0
Ischaemic coronary artery disorders	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 2	0	0	0	0	1 (4.0%)	1 (1.6%)
Myocardial ischaemia	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 2	0	0	0	0	1 (4.0%)	1 (1.6%)
Left ventricular failures	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 2	0	0	0	1 (2.7%)	0	1 (1.6%)
Left ventricular failure	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 2	0	0	0	1 (2.7%)	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Cardiac signs and symptoms NEC (cont)						
Palpitations	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Ischaemic coronary artery disorders	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Myocardial ischaemia	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Left ventricular failures	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Left ventricular failure	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Pericardial disorders NEC	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 2	0	0	0	0	1 (4.0%)	1 (1.6%)
Pericardial effusion	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 2	0	0	0	0	1 (4.0%)	1 (1.6%)
Rate and rhythm disorders NEC	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 3	0	1 (2.9%)	1 (1.1%)	0	0	0
Tachycardia	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 3	0	1 (2.9%)	1 (1.1%)	0	0	0
Psychiatric disorders	8 (14.8%)	4 (11.8%)	12 (13.6%)	3 (8.1%)	5 (20.0%)	8 (12.9%)
Grade 1	4 (7.4%)	3 (8.8%)	7 (8.0%)	1 (2.7%)	2 (8.0%)	3 (4.8%)
Grade 2	4 (7.4%)	1 (2.9%)	5 (5.7%)	2 (5.4%)	3 (12.0%)	5 (8.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Pericardial disorders NEC	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Pericardial effusion	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Rate and rhythm disorders NEC	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Tachycardia	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Psychiatric disorders	0	1 (20.0%)	1 (5.9%)	0	0	0
Grade 1	0	1 (20.0%)	1 (5.9%)	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Anxiety symptoms	3 (5.6%)	1 (2.9%)	4 (4.5%)	1 (2.7%)	0	1 (1.6%)
Grade 1	3 (5.6%)	0	3 (3.4%)	0	0	0
Grade 2	0	1 (2.9%)	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Agitation	2 (3.7%)	0	2 (2.3%)	0	0	0
Grade 1	2 (3.7%)	0	2 (2.3%)	0	0	0
Anxiety	1 (1.9%)	1 (2.9%)	2 (2.3%)	1 (2.7%)	0	1 (1.6%)
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 2	0	1 (2.9%)	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Depressive disorders	2 (3.7%)	1 (2.9%)	3 (3.4%)	0	0	0
Grade 1	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 2	2 (3.7%)	0	2 (2.3%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Anxiety symptoms	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Agitation	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Anxiety	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Depressive disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Depressive disorders (cont)						
Depression	2 (3.7%)	1 (2.9%)	3 (3.4%)	0	0	0
Grade 1	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 2	2 (3.7%)	0	2 (2.3%)	0	0	0
Disturbances in initiating and maintaining sleep	2 (3.7%)	2 (5.9%)	4 (4.5%)	1 (2.7%)	2 (8.0%)	3 (4.8%)
Grade 1	1 (1.9%)	2 (5.9%)	3 (3.4%)	0	1 (4.0%)	1 (1.6%)
Grade 2	1 (1.9%)	0	1 (1.1%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Insomnia	2 (3.7%)	2 (5.9%)	4 (4.5%)	1 (2.7%)	2 (8.0%)	3 (4.8%)
Grade 1	1 (1.9%)	2 (5.9%)	3 (3.4%)	0	1 (4.0%)	1 (1.6%)
Grade 2	1 (1.9%)	0	1 (1.1%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Confusion and disorientation	1 (1.9%)	1 (2.9%)	2 (2.3%)	1 (2.7%)	2 (8.0%)	3 (4.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Depressive disorders (cont)						
Depression	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Disturbances in initiating and maintaining sleep	0	1 (20.0%)	1 (5.9%)	0	0	0
Grade 1	0	1 (20.0%)	1 (5.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Insomnia	0	1 (20.0%)	1 (5.9%)	0	0	0
Grade 1	0	1 (20.0%)	1 (5.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Confusion and disorientation	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Confusion and disorientation (cont)						
(cont)						
Grade 1	0	1 (2.9%)	1 (1.1%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Grade 2	1 (1.9%)	0	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Confusional state	1 (1.9%)	1 (2.9%)	2 (2.3%)	1 (2.7%)	2 (8.0%)	3 (4.8%)
Grade 1	0	1 (2.9%)	1 (1.1%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Grade 2	1 (1.9%)	0	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Emotional and mood disturbances NEC	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Irritability	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Confusion and disorientation (cont)						
(cont)						
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Confusional state	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Emotional and mood disturbances NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Irritability	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Increased physical activity levels	1 (1.9%)	1 (2.9%)	2 (2.3%)	0	0	0
Grade 1	1 (1.9%)	1 (2.9%)	2 (2.3%)	0	0	0
Restlessness	1 (1.9%)	1 (2.9%)	2 (2.3%)	0	0	0
Grade 1	1 (1.9%)	1 (2.9%)	2 (2.3%)	0	0	0
Deliria	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 2	0	0	0	0	1 (4.0%)	1 (1.6%)
Delirium	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 2	0	0	0	0	1 (4.0%)	1 (1.6%)
Mood alterations with depressive symptoms	0	1 (2.9%)	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Grade 1	0	1 (2.9%)	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Increased physical activity levels	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Restlessness	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Deliria	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Delirium	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Mood alterations with depressive symptoms	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-rt.pdf 24AUG2023:15:00

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Mood alterations with depressive symptoms (cont) (cont)						
Grade 2	0	0	0	0	1 (4.0%)	1 (1.6%)
Depressed mood	0	1 (2.9%)	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Grade 1	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 2	0	0	0	0	1 (4.0%)	1 (1.6%)
Eye disorders	6 (11.1%)	3 (8.8%)	9 (10.2%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Grade 1	3 (5.6%)	3 (8.8%)	6 (6.8%)	1 (2.7%)	0	1 (1.6%)
Grade 2	3 (5.6%)	0	3 (3.4%)	0	1 (4.0%)	1 (1.6%)
Cataract conditions	3 (5.6%)	0	3 (3.4%)	0	0	0
Grade 1	2 (3.7%)	0	2 (2.3%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Mood alterations with depressive symptoms (cont) (cont)						
Grade 2	0	0	0	0	0	0
Depressed mood	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Eye disorders	1 (8.3%)	1 (20.0%)	2 (11.8%)	0	1 (20.0%)	1 (9.1%)
Grade 1	1 (8.3%)	1 (20.0%)	2 (11.8%)	0	1 (20.0%)	1 (9.1%)
Grade 2	0	0	0	0	0	0
Cataract conditions	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-rt.pdf 24AUG2023:15:00

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Cataract conditions (cont)						
(cont)						
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Cataract	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Cataract nuclear	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Cataract subcapsular	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Cataract conditions (cont)						
(cont)						
Grade 2	0	0	0	0	0	0
Cataract	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Cataract nuclear	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Cataract subcapsular	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Conjunctival and corneal bleeding and vascular disorders	2 (3.7%)	2 (5.9%)	4 (4.5%)	0	0	0
Grade 1	1 (1.9%)	2 (5.9%)	3 (3.4%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Conjunctival haemorrhage	2 (3.7%)	1 (2.9%)	3 (3.4%)	0	0	0
Grade 1	1 (1.9%)	1 (2.9%)	2 (2.3%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Corneal bleeding	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 1	0	1 (2.9%)	1 (1.1%)	0	0	0
Visual disorders NEC	1 (1.9%)	0	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Grade 1	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Conjunctival and corneal bleeding and vascular disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Conjunctival haemorrhage	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Corneal bleeding	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Visual disorders NEC	1 (8.3%)	0	1 (5.9%)	0	1 (20.0%)	1 (9.1%)
Grade 1	1 (8.3%)	0	1 (5.9%)	0	1 (20.0%)	1 (9.1%)
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Visual disorders NEC (cont)						
Vision blurred	1 (1.9%)	0	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Grade 1	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Photopsia	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Lacrimation disorders	1 (1.9%)	0	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 2	0	0	0	0	1 (4.0%)	1 (1.6%)
Lacrimation increased	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Visual disorders NEC (cont)						
Vision blurred	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Photopsia	0	0	0	0	1 (20.0%)	1 (9.1%)
Grade 1	0	0	0	0	1 (20.0%)	1 (9.1%)
Grade 2	0	0	0	0	0	0
Lacrimation disorders	0	0	0	0	1 (20.0%)	1 (9.1%)
Grade 1	0	0	0	0	1 (20.0%)	1 (9.1%)
Grade 2	0	0	0	0	0	0
Lacrimation increased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-rt.pdf 24AUG2023:15:00

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Lacrimation disorders (cont)						
Dry eye	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (4.0%)	1 (1.6%)
Ocular infections, inflammations and associated manifestations	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 1	0	1 (2.9%)	1 (1.1%)	0	0	0
Ocular hyperaemia	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 1	0	1 (2.9%)	1 (1.1%)	0	0	0
Retinal structural change, deposit and degeneration	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Lacrimation disorders (cont)						
Dry eye	0	0	0	0	1 (20.0%)	1 (9.1%)
Grade 1	0	0	0	0	1 (20.0%)	1 (9.1%)
Grade 2	0	0	0	0	0	0
Ocular infections, inflammations and associated manifestations	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Ocular hyperaemia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Retinal structural change, deposit and degeneration	0	1 (20.0%)	1 (5.9%)	0	0	0
Grade 1	0	1 (20.0%)	1 (5.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Retinal structural change, deposit and degeneration (cont)						
Myopic chorioretinal degeneration	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Visual impairment and blindness (excl colour blindness)	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 1	0	1 (2.9%)	1 (1.1%)	0	0	0
Visual acuity reduced	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 1	0	1 (2.9%)	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Retinal structural change, deposit and degeneration (cont)						
Myopic chorioretinal degeneration	0	1 (20.0%)	1 (5.9%)	0	0	0
Grade 1	0	1 (20.0%)	1 (5.9%)	0	0	0
Visual impairment and blindness (excl colour blindness)	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Visual acuity reduced	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications	7 (13.0%)	4 (11.8%)	11 (12.5%)	2 (5.4%)	1 (4.0%)	3 (4.8%)
Grade 1	5 (9.3%)	2 (5.9%)	7 (8.0%)	2 (5.4%)	1 (4.0%)	3 (4.8%)
Grade 2	1 (1.9%)	2 (5.9%)	3 (3.4%)	0	0	0
Grade 3	1 (1.9%)	0	1 (1.1%)	0	0	0
Skin injuries NEC	5 (9.3%)	3 (8.8%)	8 (9.1%)	0	1 (4.0%)	1 (1.6%)
Grade 1	5 (9.3%)	2 (5.9%)	7 (8.0%)	0	1 (4.0%)	1 (1.6%)
Grade 2	0	1 (2.9%)	1 (1.1%)	0	0	0
Contusion	5 (9.3%)	3 (8.8%)	8 (9.1%)	0	1 (4.0%)	1 (1.6%)
Grade 1	5 (9.3%)	2 (5.9%)	7 (8.0%)	0	1 (4.0%)	1 (1.6%)
Grade 2	0	1 (2.9%)	1 (1.1%)	0	0	0
Limb fractures and dislocations	2 (3.7%)	0	2 (2.3%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications	0	0	0	0	1 (20.0%)	1 (9.1%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (20.0%)	1 (9.1%)
Grade 3	0	0	0	0	0	0
Skin injuries NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Contusion	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Limb fractures and dislocations	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Limb fractures and dislocations (cont) (cont)						
Grade 3	1 (1.9%)	0	1 (1.1%)	0	0	0
Femur fracture	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 3	1 (1.9%)	0	1 (1.1%)	0	0	0
Radius fracture	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Non-site specific injuries NEC	1 (1.9%)	3 (8.8%)	4 (4.5%)	2 (5.4%)	0	2 (3.2%)
Grade 1	0	2 (5.9%)	2 (2.3%)	2 (5.4%)	0	2 (3.2%)
Grade 2	1 (1.9%)	1 (2.9%)	2 (2.3%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Limb fractures and dislocations (cont) (cont)						
Grade 3	0	0	0	0	0	0
Femur fracture	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Radius fracture	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Non-site specific injuries NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Non-site specific injuries NEC (cont)						
Fall	1 (1.9%)	2 (5.9%)	3 (3.4%)	2 (5.4%)	0	2 (3.2%)
Grade 1	0	2 (5.9%)	2 (2.3%)	2 (5.4%)	0	2 (3.2%)
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Post-traumatic pain	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 2	0	1 (2.9%)	1 (1.1%)	0	0	0
Muscle, tendon and ligament injuries	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Muscle rupture	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Non-site specific injuries NEC (cont)						
Fall	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Post-traumatic pain	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Muscle, tendon and ligament injuries	0	0	0	0	1 (20.0%)	1 (9.1%)
Grade 2	0	0	0	0	1 (20.0%)	1 (9.1%)
Muscle rupture	0	0	0	0	1 (20.0%)	1 (9.1%)
Grade 2	0	0	0	0	1 (20.0%)	1 (9.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Non-site specific procedural complications	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 1	0	0	0	0	1 (4.0%)	1 (1.6%)
Procedural pain	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 1	0	0	0	0	1 (4.0%)	1 (1.6%)
Site specific injuries NEC	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 1	0	1 (2.9%)	1 (1.1%)	0	0	0
Limb injury	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 1	0	1 (2.9%)	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Non-site specific procedural complications	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Procedural pain	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Site specific injuries NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Limb injury	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	6 (11.1%)	4 (11.8%)	10 (11.4%)	3 (8.1%)	0	3 (4.8%)
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 2	4 (7.4%)	1 (2.9%)	5 (5.7%)	2 (5.4%)	0	2 (3.2%)
Grade 3	0	1 (2.9%)	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Grade 4	0	0	0	0	0	0
Grade 5	1 (1.9%)	2 (5.9%)	3 (3.4%)	0	0	0
Skin neoplasms malignant and unspecified (excl melanoma)	2 (3.7%)	1 (2.9%)	3 (3.4%)	1 (2.7%)	0	1 (1.6%)
Grade 2	2 (3.7%)	1 (2.9%)	3 (3.4%)	1 (2.7%)	0	1 (1.6%)
Basal cell carcinoma	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Bowen's disease	1 (1.9%)	0	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Grade 4	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 5	0	0	0	0	0	0
Skin neoplasms malignant and unspecified (excl melanoma)	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Basal cell carcinoma	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Bowen's disease	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Skin neoplasms malignant and unspecified (excl melanoma) (cont)						
Bowen's disease (cont)						
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Carcinoma in situ of skin	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Squamous cell carcinoma of skin	1 (1.9%)	1 (2.9%)	2 (2.3%)	1 (2.7%)	0	1 (1.6%)
Grade 2	1 (1.9%)	1 (2.9%)	2 (2.3%)	1 (2.7%)	0	1 (1.6%)
Bladder neoplasms malignant	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Skin neoplasms malignant and unspecified (excl melanoma) (cont)						
Bowen's disease (cont)						
Grade 2	0	0	0	0	0	0
Carcinoma in situ of skin	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Squamous cell carcinoma of skin	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Bladder neoplasms malignant	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Bladder neoplasms malignant (cont)						
Bladder cancer	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Leukaemias NEC	0	1 (2.9%)	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Grade 3	0	1 (2.9%)	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Grade 4	0	0	0	0	0	0
Leukaemia	0	1 (2.9%)	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Grade 3	0	1 (2.9%)	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Grade 4	0	0	0	0	0	0
Leukaemias acute myeloid	1 (1.9%)	0	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Bladder neoplasms malignant (cont)						
Bladder cancer	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Leukaemias NEC	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 3	0	0	0	0	0	0
Grade 4	1 (8.3%)	0	1 (5.9%)	0	0	0
Leukaemia	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 3	0	0	0	0	0	0
Grade 4	1 (8.3%)	0	1 (5.9%)	0	0	0
Leukaemias acute myeloid	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Leukaemias acute myeloid (cont) (cont)						
Grade 5	1 (1.9%)	0	1 (1.1%)	0	0	0
Acute myeloid leukaemia	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 5	1 (1.9%)	0	1 (1.1%)	0	0	0
Upper gastrointestinal neoplasms benign	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Oesophageal papilloma	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Leukaemias acute myeloid (cont) (cont)						
Grade 5	0	0	0	0	0	0
Acute myeloid leukaemia	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Upper gastrointestinal neoplasms benign	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Oesophageal papilloma	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase	RT Phase	RT Phase	ET Phase (Week 24 - 48) Continuing	ET Phase (Week 24 - 48) Switch	ET Phase (Week 24 - 48)
	MMB (N=54)	BAT (N=34)	Total (N=88)	(MMB->MMB) (N=37)	(BAT->MMB) (N=25)	Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Urinary tract neoplasms malignant NEC	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Transitional cell carcinoma	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Myeloproliferative disorders (excl leukaemias)	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 5	0	1 (2.9%)	1 (1.1%)	0	0	0
Myelofibrosis	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 5	0	1 (2.9%)	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Urinary tract neoplasms malignant NEC	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Transitional cell carcinoma	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Myeloproliferative disorders (excl leukaemias)	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Myelofibrosis	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Non-small cell neoplasms malignant of the respiratory tract cell type specified	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 5	0	1 (2.9%)	1 (1.1%)	0	0	0
Lung adenocarcinoma	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 5	0	1 (2.9%)	1 (1.1%)	0	0	0
Urinary tract neoplasms unspecified malignancy NEC	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 2	0	0	0	1 (2.7%)	0	1 (1.6%)
Bladder neoplasm	0	0	0	1 (2.7%)	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Non-small cell neoplasms malignant of the respiratory tract cell type specified	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Lung adenocarcinoma	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Urinary tract neoplasms unspecified malignancy NEC	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Bladder neoplasm	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Urinary tract neoplasms unspecified malignancy NEC (cont)						
Bladder neoplasm (cont)						
Grade 2	0	0	0	1 (2.7%)	0	1 (1.6%)
Renal and urinary disorders	3 (5.6%)	3 (8.8%)	6 (6.8%)	6 (16.2%)	4 (16.0%)	10 (16.1%)
Grade 1	2 (3.7%)	1 (2.9%)	3 (3.4%)	1 (2.7%)	3 (12.0%)	4 (6.5%)
Grade 2	1 (1.9%)	1 (2.9%)	2 (2.3%)	4 (10.8%)	0	4 (6.5%)
Grade 3	0	1 (2.9%)	1 (1.1%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Renal failure and impairment	2 (3.7%)	2 (5.9%)	4 (4.5%)	2 (5.4%)	3 (12.0%)	5 (8.1%)
Grade 1	1 (1.9%)	0	1 (1.1%)	0	2 (8.0%)	2 (3.2%)
Grade 2	1 (1.9%)	1 (2.9%)	2 (2.3%)	2 (5.4%)	0	2 (3.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Urinary tract neoplasms unspecified malignancy NEC (cont)						
Bladder neoplasm (cont)						
Grade 2	0	0	0	0	0	0
Renal and urinary disorders	2 (16.7%)	0	2 (11.8%)	1 (16.7%)	1 (20.0%)	2 (18.2%)
Grade 1	0	0	0	0	0	0
Grade 2	1 (8.3%)	0	1 (5.9%)	1 (16.7%)	1 (20.0%)	2 (18.2%)
Grade 3	1 (8.3%)	0	1 (5.9%)	0	0	0
Renal failure and impairment	1 (8.3%)	0	1 (5.9%)	1 (16.7%)	1 (20.0%)	2 (18.2%)
Grade 1	0	0	0	0	0	0
Grade 2	1 (8.3%)	0	1 (5.9%)	1 (16.7%)	1 (20.0%)	2 (18.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Renal failure and impairment (cont)						
(cont)						
Grade 3	0	1 (2.9%)	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Acute kidney injury	0	0	0	1 (2.7%)	1 (4.0%)	2 (3.2%)
Grade 1	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 2	0	0	0	1 (2.7%)	0	1 (1.6%)
Renal failure	1 (1.9%)	0	1 (1.1%)	0	1 (4.0%)	1 (1.6%)
Grade 1	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Renal impairment	1 (1.9%)	1 (2.9%)	2 (2.3%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 3	0	1 (2.9%)	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Renal failure and impairment (cont)						
(cont)						
Grade 3	0	0	0	0	0	0
Acute kidney injury	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	1 (8.3%)	0	1 (5.9%)	0	0	0
Renal failure	0	0	0	1 (16.7%)	1 (20.0%)	2 (18.2%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	1 (16.7%)	1 (20.0%)	2 (18.2%)
Renal impairment	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Renal failure and impairment (cont)						
Chronic kidney disease	0	1 (2.9%)	1 (1.1%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Grade 2	0	1 (2.9%)	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Grade 3	0	0	0	0	1 (4.0%)	1 (1.6%)
Bladder and urethral symptoms	1 (1.9%)	1 (2.9%)	2 (2.3%)	2 (5.4%)	1 (4.0%)	3 (4.8%)
Grade 1	1 (1.9%)	1 (2.9%)	2 (2.3%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Grade 2	0	0	0	1 (2.7%)	0	1 (1.6%)
Micturition urgency	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Dysuria	0	0	0	2 (5.4%)	0	2 (3.2%)
Grade 1	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 2	0	0	0	1 (2.7%)	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Renal failure and impairment (cont)						
Chronic kidney disease	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Bladder and urethral symptoms	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Micturition urgency	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dysuria	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Bladder and urethral symptoms (cont)						
Pollakiuria	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 1	0	1 (2.9%)	1 (1.1%)	0	0	0
Urinary incontinence	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 1	0	0	0	0	1 (4.0%)	1 (1.6%)
Renal lithiasis	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 2	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 3	0	0	0	0	0	0
Nephrolithiasis	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 2	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Bladder and urethral symptoms (cont)						
Pollakiuria	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Urinary incontinence	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Renal lithiasis	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	1 (8.3%)	0	1 (5.9%)	0	0	0
Nephrolithiasis	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	1 (8.3%)	0	1 (5.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Urinary abnormalities	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Haematuria	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Urinary tract signs and symptoms NEC	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Renal colic	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Renal neoplasms	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Urinary abnormalities	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Haematuria	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Urinary tract signs and symptoms NEC	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 2	1 (8.3%)	0	1 (5.9%)	0	0	0
Renal colic	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 2	1 (8.3%)	0	1 (5.9%)	0	0	0
Renal neoplasms	0	0	0	1 (16.7%)	0	1 (9.1%)
Grade 1	0	0	0	1 (16.7%)	0	1 (9.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Renal neoplasms (cont)						
Renal cyst	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Urinary tract lithiasis (excl renal)	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 3	0	0	0	1 (2.7%)	0	1 (1.6%)
Ureterolithiasis	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 3	0	0	0	1 (2.7%)	0	1 (1.6%)
Ear and labyrinth disorders	2 (3.7%)	2 (5.9%)	4 (4.5%)	1 (2.7%)	1 (4.0%)	2 (3.2%)
Grade 1	2 (3.7%)	1 (2.9%)	3 (3.4%)	0	1 (4.0%)	1 (1.6%)
Grade 2	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 3	0	1 (2.9%)	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Renal neoplasms (cont)						
Renal cyst	0	0	0	1 (16.7%)	0	1 (9.1%)
Grade 1	0	0	0	1 (16.7%)	0	1 (9.1%)
Urinary tract lithiasis (excl renal)	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Ureterolithiasis	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Ear and labyrinth disorders	1 (8.3%)	0	1 (5.9%)	1 (16.7%)	1 (20.0%)	2 (18.2%)
Grade 1	0	0	0	0	1 (20.0%)	1 (9.1%)
Grade 2	1 (8.3%)	0	1 (5.9%)	1 (16.7%)	0	1 (9.1%)
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Ear and labyrinth disorders (cont)						
Inner ear signs and symptoms	2 (3.7%)	1 (2.9%)	3 (3.4%)	0	0	0
Grade 1	2 (3.7%)	0	2 (2.3%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	1 (2.9%)	1 (1.1%)	0	0	0
Tinnitus	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 2	0	0	0	0	0	0
Vertigo	1 (1.9%)	1 (2.9%)	2 (2.3%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 3	0	1 (2.9%)	1 (1.1%)	0	0	0
Ear disorders NEC	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 1	0	1 (2.9%)	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-race-rt.pdf 24AUG2023:15:00

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Ear and labyrinth disorders (cont)						
Inner ear signs and symptoms	1 (8.3%)	0	1 (5.9%)	0	1 (20.0%)	1 (9.1%)
Grade 1	0	0	0	0	1 (20.0%)	1 (9.1%)
Grade 2	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 3	0	0	0	0	0	0
Tinnitus	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	1 (8.3%)	0	1 (5.9%)	0	0	0
Vertigo	0	0	0	0	1 (20.0%)	1 (9.1%)
Grade 1	0	0	0	0	1 (20.0%)	1 (9.1%)
Grade 3	0	0	0	0	0	0
Ear disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Ear and labyrinth disorders (cont)						
Ear disorders NEC (cont)						
Ear discomfort	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 1	0	1 (2.9%)	1 (1.1%)	0	0	0
Hearing losses	0	0	0	1 (2.7%)	1 (4.0%)	2 (3.2%)
Grade 1	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 2	0	0	0	1 (2.7%)	0	1 (1.6%)
Deafness bilateral	0	0	0	0	1 (4.0%)	1 (1.6%)
Grade 1	0	0	0	0	1 (4.0%)	1 (1.6%)
Hypoacusis	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 2	0	0	0	1 (2.7%)	0	1 (1.6%)
Inner ear disorders NEC	0	1 (2.9%)	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Ear and labyrinth disorders (cont)						
Ear disorders NEC (cont)						
Ear discomfort	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hearing losses	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Deafness bilateral	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hypoacusis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Inner ear disorders NEC	0	0	0	1 (16.7%)	0	1 (9.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Ear and labyrinth disorders (cont)						
Inner ear disorders NEC (cont)						
(cont)						
Grade 2	0	0	0	0	0	0
Grade 3	0	1 (2.9%)	1 (1.1%)	0	0	0
Vestibular disorder	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	1 (2.9%)	1 (1.1%)	0	0	0
Reproductive system and breast disorders	2 (3.7%)	1 (2.9%)	3 (3.4%)	0	0	0
Grade 1	1 (1.9%)	1 (2.9%)	2 (2.3%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Breast signs and symptoms	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Ear and labyrinth disorders (cont)						
Inner ear disorders NEC (cont)						
(cont)						
Grade 2	0	0	0	1 (16.7%)	0	1 (9.1%)
Grade 3	0	0	0	0	0	0
Vestibular disorder	0	0	0	1 (16.7%)	0	1 (9.1%)
Grade 2	0	0	0	1 (16.7%)	0	1 (9.1%)
Grade 3	0	0	0	0	0	0
Reproductive system and breast disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Breast signs and symptoms	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Reproductive system and breast disorders (cont)						
Breast signs and symptoms (cont)						
Breast pain	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.1%)	0	0	0
Prostatic neoplasms and hypertrophy	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Benign prostatic hyperplasia	1 (1.9%)	0	1 (1.1%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.1%)	0	0	0
Vulvovaginal disorders NEC	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 1	0	1 (2.9%)	1 (1.1%)	0	0	0
Vaginal haemorrhage	0	1 (2.9%)	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Reproductive system and breast disorders (cont)						
Breast signs and symptoms (cont)						
Breast pain	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Prostatic neoplasms and hypertrophy	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Benign prostatic hyperplasia	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Vulvovaginal disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Vaginal haemorrhage	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Reproductive system and breast disorders (cont)						
Vulvovaginal disorders NEC (cont)						
Vaginal haemorrhage (cont)						
Grade 1	0	1 (2.9%)	1 (1.1%)	0	0	0
Endocrine disorders	0	0	0	2 (5.4%)	0	2 (3.2%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	2 (5.4%)	0	2 (3.2%)
Thyroid hypofunction disorders	0	0	0	2 (5.4%)	0	2 (3.2%)
Grade 2	0	0	0	2 (5.4%)	0	2 (3.2%)
Hypothyroidism	0	0	0	2 (5.4%)	0	2 (3.2%)
Grade 2	0	0	0	2 (5.4%)	0	2 (3.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Reproductive system and breast disorders (cont)						
Vulvovaginal disorders NEC (cont)						
Vaginal haemorrhage (cont)						
Grade 1	0	0	0	0	0	0
Endocrine disorders	1 (8.3%)	0	1 (5.9%)	0	1 (20.0%)	1 (9.1%)
Grade 1	0	0	0	0	1 (20.0%)	1 (9.1%)
Grade 2	1 (8.3%)	0	1 (5.9%)	0	0	0
Thyroid hypofunction disorders	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 2	1 (8.3%)	0	1 (5.9%)	0	0	0
Hypothyroidism	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 2	1 (8.3%)	0	1 (5.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Endocrine disorders (cont)						
Thyroid disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Thyroid mass	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hepatobiliary disorders	0	1 (2.9%)	1 (1.1%)	1 (2.7%)	0	1 (1.6%)
Grade 1	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 5	0	0	0	1 (2.7%)	0	1 (1.6%)
Hepatic vascular disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Portal hypertension	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Endocrine disorders (cont)						
Thyroid disorders NEC	0	0	0	0	1 (20.0%)	1 (9.1%)
Grade 1	0	0	0	0	1 (20.0%)	1 (9.1%)
Thyroid mass	0	0	0	0	1 (20.0%)	1 (9.1%)
Grade 1	0	0	0	0	1 (20.0%)	1 (9.1%)
Hepatobiliary disorders	1 (8.3%)	1 (20.0%)	2 (11.8%)	0	0	0
Grade 1	1 (8.3%)	1 (20.0%)	2 (11.8%)	0	0	0
Grade 5	0	0	0	0	0	0
Hepatic vascular disorders	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0
Portal hypertension	1 (8.3%)	0	1 (5.9%)	0	0	0
Grade 1	1 (8.3%)	0	1 (5.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Hepatobiliary disorders (cont)						
Cholestasis and jaundice	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Ocular icterus	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hepatic failure and associated disorders	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 5	0	0	0	1 (2.7%)	0	1 (1.6%)
Hepatic failure	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 5	0	0	0	1 (2.7%)	0	1 (1.6%)
Hepatobiliary signs and symptoms	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 1	0	1 (2.9%)	1 (1.1%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Hepatobiliary disorders (cont)						
Cholestasis and jaundice	0	1 (20.0%)	1 (5.9%)	0	0	0
Grade 1	0	1 (20.0%)	1 (5.9%)	0	0	0
Ocular icterus	0	1 (20.0%)	1 (5.9%)	0	0	0
Grade 1	0	1 (20.0%)	1 (5.9%)	0	0	0
Hepatic failure and associated disorders	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Hepatic failure	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Hepatobiliary signs and symptoms	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Hepatobiliary disorders (cont)						
Hepatobiliary signs and symptoms (cont)						
Hepatomegaly	0	1 (2.9%)	1 (1.1%)	0	0	0
Grade 1	0	1 (2.9%)	1 (1.1%)	0	0	0
Immune system disorders	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 1	0	0	0	1 (2.7%)	0	1 (1.6%)
Allergic conditions NEC	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 1	0	0	0	1 (2.7%)	0	1 (1.6%)
Allergic oedema	0	0	0	1 (2.7%)	0	1 (1.6%)
Grade 1	0	0	0	1 (2.7%)	0	1 (1.6%)
Allergies to foods, food additives, drugs and other chemicals	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Hepatobiliary disorders (cont)						
Hepatobiliary signs and symptoms (cont)						
Hepatomegaly	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Immune system disorders	0	0	0	0	1 (20.0%)	1 (9.1%)
Grade 1	0	0	0	0	1 (20.0%)	1 (9.1%)
Allergic conditions NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Allergic oedema	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Allergies to foods, food additives, drugs and other chemicals	0	0	0	0	1 (20.0%)	1 (9.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	White					
	RT Phase MMB (N=54)	RT Phase BAT (N=34)	RT Phase Total (N=88)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=37)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=25)	ET Phase (Week 24 - 48) Total (N=62)
Number of Subjects with Any Treatment-Emergent AE	54 (100.0%)	30 (88.2%)	84 (95.5%)	34 (91.9%)	25 (100.0%)	59 (95.2%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Immune system disorders (cont)						
Allergies to foods, food additives, drugs and other chemicals (cont) (cont)						
Grade 1	0	0	0	0	0	0
Drug hypersensitivity	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0405: TEAEs by SOC, HLT, PT and Severity by Race
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Other Races					
	RT Phase MMB (N=12)	RT Phase BAT (N=5)	RT Phase Total (N=17)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=6)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=5)	ET Phase (Week 24 - 48) Total (N=11)
Number of Subjects with Any Treatment-Emergent AE	12 (100.0%)	5 (100.0%)	17 (100.0%)	6 (100.0%)	5 (100.0%)	11 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Immune system disorders (cont)						
Allergies to foods, food additives, drugs and other chemicals (cont) (cont)						
Grade 1	0	0	0	0	1 (20.0%)	1 (9.1%)
Drug hypersensitivity	0	0	0	0	1 (20.0%)	1 (9.1%)
Grade 1	0	0	0	0	1 (20.0%)	1 (9.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders	16 (47.1%)	8 (72.7%)	24 (53.3%)	45 (71.4%)
Grade 1	7 (20.6%)	5 (45.5%)	12 (26.7%)	20 (31.7%)
Grade 2	7 (20.6%)	1 (9.1%)	8 (17.8%)	17 (27.0%)
Grade 3	2 (5.9%)	1 (9.1%)	3 (6.7%)	7 (11.1%)
Grade 4	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Diarrhoea (excl infective)	10 (29.4%)	2 (18.2%)	12 (26.7%)	24 (38.1%)
Grade 1	8 (23.5%)	2 (18.2%)	10 (22.2%)	16 (25.4%)
Grade 2	2 (5.9%)	0	2 (4.4%)	7 (11.1%)
Grade 3	0	0	0	1 (1.6%)
Diarrhoea	10 (29.4%)	2 (18.2%)	12 (26.7%)	24 (38.1%)
Grade 1	8 (23.5%)	2 (18.2%)	10 (22.2%)	16 (25.4%)
Grade 2	2 (5.9%)	0	2 (4.4%)	7 (11.1%)
Grade 3	0	0	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders	3 (33.3%)	13 (68.4%)	16 (57.1%)	24 (72.7%)
Grade 1	1 (11.1%)	4 (21.1%)	5 (17.9%)	8 (24.2%)
Grade 2	1 (11.1%)	5 (26.3%)	6 (21.4%)	11 (33.3%)
Grade 3	1 (11.1%)	4 (21.1%)	5 (17.9%)	5 (15.2%)
Grade 4	0	0	0	0
Diarrhoea (excl infective)	3 (33.3%)	5 (26.3%)	8 (28.6%)	11 (33.3%)
Grade 1	2 (22.2%)	0	2 (7.1%)	5 (15.2%)
Grade 2	0	3 (15.8%)	3 (10.7%)	3 (9.1%)
Grade 3	1 (11.1%)	2 (10.5%)	3 (10.7%)	3 (9.1%)
Diarrhoea	3 (33.3%)	5 (26.3%)	8 (28.6%)	11 (33.3%)
Grade 1	2 (22.2%)	0	2 (7.1%)	5 (15.2%)
Grade 2	0	3 (15.8%)	3 (10.7%)	3 (9.1%)
Grade 3	1 (11.1%)	2 (10.5%)	3 (10.7%)	3 (9.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal and abdominal pains (excl oral and throat)	3 (8.8%)	3 (27.3%)	6 (13.3%)	18 (28.6%)
Grade 1	1 (2.9%)	2 (18.2%)	3 (6.7%)	8 (12.7%)
Grade 2	1 (2.9%)	1 (9.1%)	2 (4.4%)	7 (11.1%)
Grade 3	1 (2.9%)	0	1 (2.2%)	3 (4.8%)
Abdominal pain	2 (5.9%)	1 (9.1%)	3 (6.7%)	11 (17.5%)
Grade 1	0	0	0	4 (6.3%)
Grade 2	1 (2.9%)	1 (9.1%)	2 (4.4%)	5 (7.9%)
Grade 3	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Abdominal pain upper	1 (2.9%)	2 (18.2%)	3 (6.7%)	7 (11.1%)
Grade 1	1 (2.9%)	2 (18.2%)	3 (6.7%)	4 (6.3%)
Grade 2	0	0	0	2 (3.2%)
Grade 3	0	0	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-et.pdf 24AUG2023:15:00

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal and abdominal pains (excl oral and throat)	1 (11.1%)	3 (15.8%)	4 (14.3%)	7 (21.2%)
Grade 1	0	2 (10.5%)	2 (7.1%)	4 (12.1%)
Grade 2	1 (11.1%)	1 (5.3%)	2 (7.1%)	3 (9.1%)
Grade 3	0	0	0	0
Abdominal pain	1 (11.1%)	2 (10.5%)	3 (10.7%)	4 (12.1%)
Grade 1	0	1 (5.3%)	1 (3.6%)	2 (6.1%)
Grade 2	1 (11.1%)	1 (5.3%)	2 (7.1%)	2 (6.1%)
Grade 3	0	0	0	0
Abdominal pain upper	0	1 (5.3%)	1 (3.6%)	2 (6.1%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	0	0	1 (3.0%)
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-et.pdf 24AUG2023:15:00

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal and abdominal pains (excl oral and throat) (cont)				
Abdominal pain lower	0	0	0	0
Grade 1	0	0	0	0
Nausea and vomiting symptoms	3 (8.8%)	0	3 (6.7%)	12 (19.0%)
Grade 1	3 (8.8%)	0	3 (6.7%)	11 (17.5%)
Grade 2	0	0	0	1 (1.6%)
Grade 3	0	0	0	0
Nausea	3 (8.8%)	0	3 (6.7%)	12 (19.0%)
Grade 1	3 (8.8%)	0	3 (6.7%)	11 (17.5%)
Grade 2	0	0	0	1 (1.6%)
Vomiting	1 (2.9%)	0	1 (2.2%)	3 (4.8%)
Grade 1	1 (2.9%)	0	1 (2.2%)	3 (4.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal and abdominal pains (excl oral and throat) (cont)				
Abdominal pain lower	0	0	0	1 (3.0%)
Grade 1	0	0	0	1 (3.0%)
Nausea and vomiting symptoms	2 (22.2%)	6 (31.6%)	8 (28.6%)	10 (30.3%)
Grade 1	2 (22.2%)	2 (10.5%)	4 (14.3%)	6 (18.2%)
Grade 2	0	3 (15.8%)	3 (10.7%)	3 (9.1%)
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Nausea	2 (22.2%)	5 (26.3%)	7 (25.0%)	9 (27.3%)
Grade 1	2 (22.2%)	2 (10.5%)	4 (14.3%)	6 (18.2%)
Grade 2	0	3 (15.8%)	3 (10.7%)	3 (9.1%)
Vomiting	1 (11.1%)	3 (15.8%)	4 (14.3%)	4 (12.1%)
Grade 1	1 (11.1%)	1 (5.3%)	2 (7.1%)	2 (6.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Nausea and vomiting symptoms (cont)				
Vomiting (cont)				
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Gastrointestinal atonic and hypomotility disorders NEC	4 (11.8%)	0	4 (8.9%)	13 (20.6%)
Grade 1	3 (8.8%)	0	3 (6.7%)	11 (17.5%)
Grade 2	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Constipation	3 (8.8%)	0	3 (6.7%)	9 (14.3%)
Grade 1	3 (8.8%)	0	3 (6.7%)	9 (14.3%)
Gastrooesophageal reflux disease	1 (2.9%)	0	1 (2.2%)	4 (6.3%)
Grade 1	0	0	0	2 (3.2%)
Grade 2	1 (2.9%)	0	1 (2.2%)	2 (3.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Nausea and vomiting symptoms (cont)				
Vomiting (cont)				
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Gastrointestinal atonic and hypomotility disorders NEC	0	1 (5.3%)	1 (3.6%)	2 (6.1%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	0	0	1 (3.0%)
Constipation	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Gastrooesophageal reflux disease	0	0	0	1 (3.0%)
Grade 1	0	0	0	0
Grade 2	0	0	0	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal atonic and hypomotility disorders NEC (cont)				
Impaired gastric emptying	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Dyspeptic signs and symptoms	0	0	0	4 (6.3%)
Grade 1	0	0	0	2 (3.2%)
Grade 2	0	0	0	2 (3.2%)
Dyspepsia	0	0	0	3 (4.8%)
Grade 1	0	0	0	1 (1.6%)
Grade 2	0	0	0	2 (3.2%)
Epigastric discomfort	0	0	0	1 (1.6%)
Grade 1	0	0	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal atonic and hypomotility disorders NEC (cont)				
Impaired gastric emptying	0	0	0	0
Grade 1	0	0	0	0
Dyspeptic signs and symptoms	1 (11.1%)	1 (5.3%)	2 (7.1%)	5 (15.2%)
Grade 1	1 (11.1%)	1 (5.3%)	2 (7.1%)	3 (9.1%)
Grade 2	0	0	0	2 (6.1%)
Dyspepsia	1 (11.1%)	1 (5.3%)	2 (7.1%)	5 (15.2%)
Grade 1	1 (11.1%)	1 (5.3%)	2 (7.1%)	3 (9.1%)
Grade 2	0	0	0	2 (6.1%)
Epigastric discomfort	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Non-site specific gastrointestinal haemorrhages	2 (5.9%)	1 (9.1%)	3 (6.7%)	4 (6.3%)
Grade 1	0	0	0	0
Grade 2	1 (2.9%)	0	1 (2.2%)	0
Grade 3	1 (2.9%)	1 (9.1%)	2 (4.4%)	4 (6.3%)
Melaena	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 1	0	0	0	0
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 3	0	0	0	1 (1.6%)
Gastrointestinal haemorrhage	2 (5.9%)	1 (9.1%)	3 (6.7%)	3 (4.8%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 3	1 (2.9%)	1 (9.1%)	2 (4.4%)	2 (3.2%)
Haematemesis	1 (2.9%)	0	1 (2.2%)	2 (3.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Non-site specific gastrointestinal haemorrhages	0	2 (10.5%)	2 (7.1%)	2 (6.1%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 3	0	0	0	0
Melaena	0	2 (10.5%)	2 (7.1%)	2 (6.1%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 3	0	0	0	0
Gastrointestinal haemorrhage	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Haematemesis	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Non-site specific gastrointestinal haemorrhages (cont)				
Haematemesis (cont)				
Grade 2	1 (2.9%)	0	1 (2.2%)	0
Grade 3	0	0	0	2 (3.2%)
Upper gastrointestinal haemorrhage	0	0	0	2 (3.2%)
Grade 3	0	0	0	2 (3.2%)
Peritoneal and retroperitoneal disorders	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 1	0	0	0	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Ascites	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 1	0	0	0	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Non-site specific gastrointestinal haemorrhages (cont)				
Haematemesis (cont)				
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Upper gastrointestinal haemorrhage	0	0	0	0
Grade 3	0	0	0	0
Peritoneal and retroperitoneal disorders	0	2 (10.5%)	2 (7.1%)	3 (9.1%)
Grade 1	0	0	0	1 (3.0%)
Grade 2	0	2 (10.5%)	2 (7.1%)	2 (6.1%)
Ascites	0	2 (10.5%)	2 (7.1%)	3 (9.1%)
Grade 1	0	0	0	1 (3.0%)
Grade 2	0	2 (10.5%)	2 (7.1%)	2 (6.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Flatulence, bloating and distension	1 (2.9%)	0	1 (2.2%)	3 (4.8%)
Grade 1	0	0	0	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Abdominal distension	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	0	0	0	0
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Flatulence	0	0	0	2 (3.2%)
Grade 1	0	0	0	1 (1.6%)
Grade 2	0	0	0	1 (1.6%)
Gastrointestinal signs and symptoms NEC	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 1	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Abdominal discomfort	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Flatulence, bloating and distension	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	0	0	0
Abdominal distension	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	0	0	0
Flatulence	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Gastrointestinal signs and symptoms NEC	0	2 (10.5%)	2 (7.1%)	3 (9.1%)
Grade 1	0	2 (10.5%)	2 (7.1%)	3 (9.1%)
Abdominal discomfort	0	2 (10.5%)	2 (7.1%)	3 (9.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal signs and symptoms NEC (cont)				
Abdominal discomfort (cont)				
Grade 1	0	0	0	0
Dysphagia	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 1	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Stomatitis and ulceration	1 (2.9%)	1 (9.1%)	2 (4.4%)	3 (4.8%)
Grade 1	1 (2.9%)	1 (9.1%)	2 (4.4%)	3 (4.8%)
Grade 2	0	0	0	0
Mouth ulceration	0	1 (9.1%)	1 (2.2%)	2 (3.2%)
Grade 1	0	1 (9.1%)	1 (2.2%)	2 (3.2%)
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal signs and symptoms NEC (cont)				
Abdominal discomfort (cont)				
Grade 1	0	2 (10.5%)	2 (7.1%)	3 (9.1%)
Dysphagia	0	0	0	0
Grade 1	0	0	0	0
Stomatitis and ulceration	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 1	0	0	0	0
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Mouth ulceration	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 1	0	0	0	0
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Stomatitis and ulceration (cont)				
Palatal ulcer	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Dental and periodontal infections and inflammations	1 (2.9%)	1 (9.1%)	2 (4.4%)	2 (3.2%)
Grade 1	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Dental caries	1 (2.9%)	1 (9.1%)	2 (4.4%)	2 (3.2%)
Grade 1	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Intestinal haemorrhages	0	0	0	1 (1.6%)
Grade 1	0	0	0	1 (1.6%)
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-et.pdf 24AUG2023:15:00

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Stomatitis and ulceration (cont)				
Palatal ulcer	0	0	0	0
Grade 1	0	0	0	0
Dental and periodontal infections and inflammations	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 1	0	0	0	0
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Dental caries	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 1	0	0	0	0
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Intestinal haemorrhages	1 (11.1%)	1 (5.3%)	2 (7.1%)	2 (6.1%)
Grade 1	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Intestinal haemorrhages (cont)				
Rectal haemorrhage	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Anal haemorrhage	0	0	0	1 (1.6%)
Grade 1	0	0	0	1 (1.6%)
Oral dryness and saliva altered	1 (2.9%)	2 (18.2%)	3 (6.7%)	3 (4.8%)
Grade 1	1 (2.9%)	1 (9.1%)	2 (4.4%)	2 (3.2%)
Grade 2	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Dry mouth	1 (2.9%)	2 (18.2%)	3 (6.7%)	3 (4.8%)
Grade 1	1 (2.9%)	1 (9.1%)	2 (4.4%)	2 (3.2%)
Grade 2	0	1 (9.1%)	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Intestinal haemorrhages (cont)				
Rectal haemorrhage	1 (11.1%)	1 (5.3%)	2 (7.1%)	2 (6.1%)
Grade 1	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Anal haemorrhage	0	0	0	0
Grade 1	0	0	0	0
Oral dryness and saliva altered	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Dry mouth	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal spastic and hypermotility disorders	0	0	0	2 (3.2%)
Grade 1	0	0	0	2 (3.2%)
Defaecation urgency	0	0	0	1 (1.6%)
Grade 1	0	0	0	1 (1.6%)
Frequent bowel movements	0	0	0	1 (1.6%)
Grade 1	0	0	0	1 (1.6%)
Haemorrhoids and gastrointestinal varices (excl oesophageal)	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 1	0	0	0	0
Grade 2	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Haemorrhoidal haemorrhage	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal spastic and hypermotility disorders	0	0	0	0
Grade 1	0	0	0	0
Defaecation urgency	0	0	0	0
Grade 1	0	0	0	0
Frequent bowel movements	0	0	0	0
Grade 1	0	0	0	0
Haemorrhoids and gastrointestinal varices (excl oesophageal)	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 1	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 2	0	0	0	0
Haemorrhoidal haemorrhage	1 (11.1%)	0	1 (3.6%)	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Haemorrhoids and gastrointestinal varices (excl oesophageal) (cont)				
Haemorrhoidal haemorrhage (cont)				
Grade 1	0	0	0	0
Haemorrhoids	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 2	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Abdominal wall conditions NEC	0	0	0	0
Grade 3	0	0	0	0
Abdominal wall haematoma	0	0	0	0
Grade 3	0	0	0	0
Anal and rectal disorders NEC	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 2	0	1 (9.1%)	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Haemorrhoids and gastrointestinal varices (excl oesophageal) (cont)				
Haemorrhoidal haemorrhage (cont)				
Grade 1	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Haemorrhoids	0	0	0	0
Grade 2	0	0	0	0
Abdominal wall conditions NEC	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Abdominal wall haematoma	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Anal and rectal disorders NEC	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Anal and rectal disorders NEC (cont)				
Anal fissure	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 2	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Anal and rectal signs and symptoms	0	0	0	1 (1.6%)
Grade 1	0	0	0	1 (1.6%)
Anorectal discomfort	0	0	0	1 (1.6%)
Grade 1	0	0	0	1 (1.6%)
Dental pain and sensation disorders	0	0	0	0
Grade 2	0	0	0	0
Toothache	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Anal and rectal disorders NEC (cont)				
Anal fissure	0	0	0	0
Grade 2	0	0	0	0
Anal and rectal signs and symptoms	0	0	0	0
Grade 1	0	0	0	0
Anorectal discomfort	0	0	0	0
Grade 1	0	0	0	0
Dental pain and sensation disorders	0	0	0	1 (3.0%)
Grade 2	0	0	0	1 (3.0%)
Toothache	0	0	0	1 (3.0%)
Grade 2	0	0	0	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
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SAF-Anemic Analysis Set

	Male			
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Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Diaphragmatic hernias	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Hiatus hernia	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Gastric and oesophageal haemorrhages	0	0	0	0
Grade 2	0	0	0	0
Oesophageal haemorrhage	0	0	0	0
Grade 2	0	0	0	0
Gastric ulcers and perforation	0	0	0	1 (1.6%)
Grade 3	0	0	0	1 (1.6%)
Gastric ulcer	0	0	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
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SAF-Anemic Analysis Set

(Continued)	Female			
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Diaphragmatic hernias	0	0	0	0
Grade 2	0	0	0	0
Hiatus hernia	0	0	0	0
Grade 2	0	0	0	0
Gastric and oesophageal haemorrhages	0	0	0	1 (3.0%)
Grade 2	0	0	0	1 (3.0%)
Oesophageal haemorrhage	0	0	0	1 (3.0%)
Grade 2	0	0	0	1 (3.0%)
Gastric ulcers and perforation	0	0	0	0
Grade 3	0	0	0	0
Gastric ulcer	0	0	0	0

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Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastric ulcers and perforation (cont)				
Gastric ulcer (cont)				
Grade 3	0	0	0	1 (1.6%)
Gastritis (excl infective)	0	0	0	0
Grade 1	0	0	0	0
Gastritis	0	0	0	0
Grade 1	0	0	0	0
Gastrointestinal mucosal dystrophies and secretion disorders	0	0	0	0
Grade 1	0	0	0	0
Gastrointestinal melanosis	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
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SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastric ulcers and perforation (cont)				
Gastric ulcer (cont)				
Grade 3	0	0	0	0
Gastritis (excl infective)	0	0	0	1 (3.0%)
Grade 1	0	0	0	1 (3.0%)
Gastritis	0	0	0	1 (3.0%)
Grade 1	0	0	0	1 (3.0%)
Gastrointestinal mucosal dystrophies and secretion disorders	0	0	0	1 (3.0%)
Grade 1	0	0	0	1 (3.0%)
Gastrointestinal melanosis	0	0	0	1 (3.0%)
Grade 1	0	0	0	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
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	Male			
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Gastrointestinal vascular occlusion and infarction	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 4	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Visceral venous thrombosis	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 4	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Oesophageal varices	0	0	0	0
Grade 2	0	0	0	0
Varices oesophageal	0	0	0	0
Grade 2	0	0	0	0
Oral soft tissue haemorrhages	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
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SAF-Anemic Analysis Set

(Continued)	Female			
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Gastrointestinal disorders (cont)				
Gastrointestinal vascular occlusion and infarction	0	0	0	0
Grade 4	0	0	0	0
Visceral venous thrombosis	0	0	0	0
Grade 4	0	0	0	0
Oesophageal varices	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Varices oesophageal	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Oral soft tissue haemorrhages	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Oral soft tissue haemorrhages (cont)				
Mouth haemorrhage	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Oral soft tissue pain and paraesthesia	0	0	0	0
Grade 1	0	0	0	0
Oral pain	0	0	0	0
Grade 1	0	0	0	0
Umbilical hernias	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Umbilical hernia	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
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Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Gastrointestinal disorders (cont)				
Oral soft tissue haemorrhages (cont)				
Mouth haemorrhage	0	0	0	0
Grade 2	0	0	0	0
Oral soft tissue pain and paraesthesia	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Oral pain	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Umbilical hernias	0	0	0	0
Grade 1	0	0	0	0
Umbilical hernia	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions	17 (50.0%)	6 (54.5%)	23 (51.1%)	40 (63.5%)
Grade 1	8 (23.5%)	1 (9.1%)	9 (20.0%)	14 (22.2%)
Grade 2	6 (17.6%)	3 (27.3%)	9 (20.0%)	14 (22.2%)
Grade 3	2 (5.9%)	2 (18.2%)	4 (8.9%)	11 (17.5%)
Grade 5	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Asthenic conditions	7 (20.6%)	4 (36.4%)	11 (24.4%)	26 (41.3%)
Grade 1	4 (11.8%)	1 (9.1%)	5 (11.1%)	9 (14.3%)
Grade 2	2 (5.9%)	2 (18.2%)	4 (8.9%)	12 (19.0%)
Grade 3	1 (2.9%)	1 (9.1%)	2 (4.4%)	5 (7.9%)
Asthenia	4 (11.8%)	3 (27.3%)	7 (15.6%)	16 (25.4%)
Grade 1	3 (8.8%)	0	3 (6.7%)	4 (6.3%)
Grade 2	0	2 (18.2%)	2 (4.4%)	7 (11.1%)
Grade 3	1 (2.9%)	1 (9.1%)	2 (4.4%)	5 (7.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions	8 (88.9%)	13 (68.4%)	21 (75.0%)	24 (72.7%)
Grade 1	1 (11.1%)	5 (26.3%)	6 (21.4%)	5 (15.2%)
Grade 2	5 (55.6%)	6 (31.6%)	11 (39.3%)	14 (42.4%)
Grade 3	2 (22.2%)	2 (10.5%)	4 (14.3%)	5 (15.2%)
Grade 5	0	0	0	0
Asthenic conditions	3 (33.3%)	9 (47.4%)	12 (42.9%)	15 (45.5%)
Grade 1	0	2 (10.5%)	2 (7.1%)	3 (9.1%)
Grade 2	2 (22.2%)	5 (26.3%)	7 (25.0%)	8 (24.2%)
Grade 3	1 (11.1%)	2 (10.5%)	3 (10.7%)	4 (12.1%)
Asthenia	2 (22.2%)	6 (31.6%)	8 (28.6%)	9 (27.3%)
Grade 1	0	1 (5.3%)	1 (3.6%)	2 (6.1%)
Grade 2	2 (22.2%)	3 (15.8%)	5 (17.9%)	4 (12.1%)
Grade 3	0	2 (10.5%)	2 (7.1%)	3 (9.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-et.pdf 24AUG2023:15:00

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Asthenic conditions (cont)				
Fatigue	3 (8.8%)	1 (9.1%)	4 (8.9%)	10 (15.9%)
Grade 1	1 (2.9%)	1 (9.1%)	2 (4.4%)	5 (7.9%)
Grade 2	2 (5.9%)	0	2 (4.4%)	5 (7.9%)
Grade 3	0	0	0	0
Febrile disorders	7 (20.6%)	3 (27.3%)	10 (22.2%)	15 (23.8%)
Grade 1	5 (14.7%)	2 (18.2%)	7 (15.6%)	10 (15.9%)
Grade 2	2 (5.9%)	1 (9.1%)	3 (6.7%)	3 (4.8%)
Grade 3	0	0	0	2 (3.2%)
Pyrexia	7 (20.6%)	3 (27.3%)	10 (22.2%)	15 (23.8%)
Grade 1	5 (14.7%)	2 (18.2%)	7 (15.6%)	10 (15.9%)
Grade 2	2 (5.9%)	1 (9.1%)	3 (6.7%)	3 (4.8%)
Grade 3	0	0	0	2 (3.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Asthenic conditions (cont)				
Fatigue	1 (11.1%)	4 (21.1%)	5 (17.9%)	8 (24.2%)
Grade 1	0	1 (5.3%)	1 (3.6%)	2 (6.1%)
Grade 2	0	2 (10.5%)	2 (7.1%)	4 (12.1%)
Grade 3	1 (11.1%)	1 (5.3%)	2 (7.1%)	2 (6.1%)
Febrile disorders	4 (44.4%)	6 (31.6%)	10 (35.7%)	11 (33.3%)
Grade 1	2 (22.2%)	4 (21.1%)	6 (21.4%)	6 (18.2%)
Grade 2	1 (11.1%)	2 (10.5%)	3 (10.7%)	4 (12.1%)
Grade 3	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Pyrexia	4 (44.4%)	6 (31.6%)	10 (35.7%)	11 (33.3%)
Grade 1	2 (22.2%)	4 (21.1%)	6 (21.4%)	6 (18.2%)
Grade 2	1 (11.1%)	2 (10.5%)	3 (10.7%)	4 (12.1%)
Grade 3	1 (11.1%)	0	1 (3.6%)	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Oedema NEC	8 (23.5%)	1 (9.1%)	9 (20.0%)	17 (27.0%)
Grade 1	3 (8.8%)	0	3 (6.7%)	7 (11.1%)
Grade 2	4 (11.8%)	0	4 (8.9%)	8 (12.7%)
Grade 3	1 (2.9%)	1 (9.1%)	2 (4.4%)	2 (3.2%)
Oedema peripheral	6 (17.6%)	1 (9.1%)	7 (15.6%)	15 (23.8%)
Grade 1	2 (5.9%)	0	2 (4.4%)	6 (9.5%)
Grade 2	3 (8.8%)	0	3 (6.7%)	7 (11.1%)
Grade 3	1 (2.9%)	1 (9.1%)	2 (4.4%)	2 (3.2%)
Generalised oedema	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Oedema	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Oedema NEC	2 (22.2%)	2 (10.5%)	4 (14.3%)	4 (12.1%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	2 (22.2%)	1 (5.3%)	3 (10.7%)	3 (9.1%)
Grade 3	0	0	0	0
Oedema peripheral	2 (22.2%)	2 (10.5%)	4 (14.3%)	4 (12.1%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	2 (22.2%)	1 (5.3%)	3 (10.7%)	3 (9.1%)
Grade 3	0	0	0	0
Generalised oedema	0	0	0	0
Grade 2	0	0	0	0
Oedema	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-et.pdf 24AUG2023:15:00

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Feelings and sensations NEC	3 (8.8%)	0	3 (6.7%)	6 (9.5%)
Grade 1	2 (5.9%)	0	2 (4.4%)	4 (6.3%)
Grade 2	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Early satiety	1 (2.9%)	0	1 (2.2%)	3 (4.8%)
Grade 1	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 2	0	0	0	1 (1.6%)
Chills	2 (5.9%)	0	2 (4.4%)	2 (3.2%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Feeling hot	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 1	1 (2.9%)	0	1 (2.2%)	2 (3.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Feelings and sensations NEC	0	2 (10.5%)	2 (7.1%)	2 (6.1%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Early satiety	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	0	0	0
Chills	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	0	0	0
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Feeling hot	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Pain and discomfort NEC	2 (5.9%)	0	2 (4.4%)	4 (6.3%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	3 (4.8%)
Chest pain	2 (5.9%)	0	2 (4.4%)	2 (3.2%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Chest discomfort	0	0	0	0
Grade 1	0	0	0	0
Facial pain	0	0	0	0
Grade 1	0	0	0	0
Non-cardiac chest pain	0	0	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Pain and discomfort NEC	1 (11.1%)	0	1 (3.6%)	2 (6.1%)
Grade 1	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 2	0	0	0	1 (3.0%)
Chest pain	0	0	0	1 (3.0%)
Grade 1	0	0	0	0
Grade 2	0	0	0	1 (3.0%)
Chest discomfort	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 1	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Facial pain	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 1	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Non-cardiac chest pain	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Pain and discomfort NEC (cont)				
Non-cardiac chest pain (cont)				
Grade 2	0	0	0	1 (1.6%)
Pain	0	0	0	1 (1.6%)
Grade 2	0	0	0	1 (1.6%)
General signs and symptoms NEC	1 (2.9%)	0	1 (2.2%)	3 (4.8%)
Grade 1	0	0	0	0
Grade 3	0	0	0	2 (3.2%)
Grade 5	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Disease progression	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 3	0	0	0	1 (1.6%)
Grade 5	1 (2.9%)	0	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Pain and discomfort NEC (cont)				
Non-cardiac chest pain (cont)				
Grade 2	0	0	0	0
Pain	0	0	0	0
Grade 2	0	0	0	0
General signs and symptoms NEC	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 1	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 3	0	0	0	0
Grade 5	0	0	0	0
Disease progression	0	0	0	0
Grade 3	0	0	0	0
Grade 5	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
General signs and symptoms NEC (cont)				
General physical health deterioration	0	0	0	1 (1.6%)
Grade 3	0	0	0	1 (1.6%)
Peripheral swelling	0	0	0	0
Grade 1	0	0	0	0
Gait disturbances	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	0	0	0	1 (1.6%)
Gait disturbance	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	0	0	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
General signs and symptoms NEC (cont)				
General physical health deterioration	0	0	0	0
Grade 3	0	0	0	0
Peripheral swelling	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 1	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Gait disturbances	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 1	1 (11.1%)	0	1 (3.6%)	0
Grade 2	0	0	0	1 (3.0%)
Gait disturbance	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 1	1 (11.1%)	0	1 (3.6%)	0
Grade 2	0	0	0	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Inflammations	0	0	0	0
Grade 2	0	0	0	0
Inflammation	0	0	0	0
Grade 2	0	0	0	0
Injection site reactions	0	0	0	1 (1.6%)
Grade 1	0	0	0	1 (1.6%)
Injection site pain	0	0	0	1 (1.6%)
Grade 1	0	0	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
General disorders and administration site conditions (cont)				
Inflammations	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Inflammation	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Injection site reactions	0	0	0	0
Grade 1	0	0	0	0
Injection site pain	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations	19 (55.9%)	7 (63.6%)	26 (57.8%)	41 (65.1%)
Grade 1	2 (5.9%)	3 (27.3%)	5 (11.1%)	5 (7.9%)
Grade 2	6 (17.6%)	1 (9.1%)	7 (15.6%)	14 (22.2%)
Grade 3	5 (14.7%)	2 (18.2%)	7 (15.6%)	13 (20.6%)
Grade 4	3 (8.8%)	0	3 (6.7%)	4 (6.3%)
Grade 5	3 (8.8%)	1 (9.1%)	4 (8.9%)	5 (7.9%)
Lower respiratory tract and lung infections	10 (29.4%)	4 (36.4%)	14 (31.1%)	19 (30.2%)
Grade 1	2 (5.9%)	1 (9.1%)	3 (6.7%)	3 (4.8%)
Grade 2	3 (8.8%)	0	3 (6.7%)	6 (9.5%)
Grade 3	4 (11.8%)	2 (18.2%)	6 (13.3%)	7 (11.1%)
Grade 4	0	0	0	1 (1.6%)
Grade 5	1 (2.9%)	1 (9.1%)	2 (4.4%)	2 (3.2%)
Pneumonia	5 (14.7%)	2 (18.2%)	7 (15.6%)	10 (15.9%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	0	0	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations	8 (88.9%)	11 (57.9%)	19 (67.9%)	23 (69.7%)
Grade 1	1 (11.1%)	3 (15.8%)	4 (14.3%)	5 (15.2%)
Grade 2	6 (66.7%)	7 (36.8%)	13 (46.4%)	16 (48.5%)
Grade 3	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 4	0	0	0	0
Grade 5	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Lower respiratory tract and lung infections	4 (44.4%)	3 (15.8%)	7 (25.0%)	9 (27.3%)
Grade 1	0	0	0	0
Grade 2	3 (33.3%)	3 (15.8%)	6 (21.4%)	8 (24.2%)
Grade 3	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 4	0	0	0	0
Grade 5	0	0	0	0
Pneumonia	2 (22.2%)	1 (5.3%)	3 (10.7%)	3 (9.1%)
Grade 1	0	0	0	0
Grade 2	1 (11.1%)	1 (5.3%)	2 (7.1%)	2 (6.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Lower respiratory tract and lung infections (cont)				
Pneumonia (cont)				
Grade 3	3 (8.8%)	1 (9.1%)	4 (8.9%)	5 (7.9%)
Grade 4	0	0	0	1 (1.6%)
Grade 5	1 (2.9%)	1 (9.1%)	2 (4.4%)	2 (3.2%)
Bronchitis	3 (8.8%)	1 (9.1%)	4 (8.9%)	4 (6.3%)
Grade 1	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 2	3 (8.8%)	0	3 (6.7%)	3 (4.8%)
Lung infection	1 (2.9%)	1 (9.1%)	2 (4.4%)	4 (6.3%)
Grade 2	0	0	0	2 (3.2%)
Grade 3	1 (2.9%)	1 (9.1%)	2 (4.4%)	2 (3.2%)
Atypical pneumonia	1 (2.9%)	0	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Lower respiratory tract and lung infections (cont)				
Pneumonia (cont)				
Grade 3	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 4	0	0	0	0
Grade 5	0	0	0	0
Bronchitis	3 (33.3%)	2 (10.5%)	5 (17.9%)	7 (21.2%)
Grade 1	0	0	0	0
Grade 2	3 (33.3%)	2 (10.5%)	5 (17.9%)	7 (21.2%)
Lung infection	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 3	0	0	0	0
Atypical pneumonia	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Lower respiratory tract and lung infections (cont)				
Atypical pneumonia (cont)				
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Lower respiratory tract infection	0	0	0	0
Grade 2	0	0	0	0
Upper respiratory tract infections	8 (23.5%)	3 (27.3%)	11 (24.4%)	19 (30.2%)
Grade 1	2 (5.9%)	2 (18.2%)	4 (8.9%)	6 (9.5%)
Grade 2	5 (14.7%)	1 (9.1%)	6 (13.3%)	11 (17.5%)
Grade 3	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 4	0	0	0	1 (1.6%)
Upper respiratory tract infection	5 (14.7%)	2 (18.2%)	7 (15.6%)	13 (20.6%)
Grade 1	1 (2.9%)	1 (9.1%)	2 (4.4%)	4 (6.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Lower respiratory tract and lung infections (cont)				
Atypical pneumonia (cont)				
Grade 1	0	0	0	0
Lower respiratory tract infection	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Upper respiratory tract infections	4 (44.4%)	4 (21.1%)	8 (28.6%)	9 (27.3%)
Grade 1	1 (11.1%)	3 (15.8%)	4 (14.3%)	5 (15.2%)
Grade 2	3 (33.3%)	1 (5.3%)	4 (14.3%)	4 (12.1%)
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Upper respiratory tract infection	3 (33.3%)	3 (15.8%)	6 (21.4%)	6 (18.2%)
Grade 1	1 (11.1%)	3 (15.8%)	4 (14.3%)	4 (12.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Upper respiratory tract infections (cont)				
Upper respiratory tract infection (cont)				
Grade 2	3 (8.8%)	1 (9.1%)	4 (8.9%)	7 (11.1%)
Grade 3	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 4	0	0	0	1 (1.6%)
Nasopharyngitis	2 (5.9%)	1 (9.1%)	3 (6.7%)	4 (6.3%)
Grade 1	1 (2.9%)	1 (9.1%)	2 (4.4%)	3 (4.8%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Sinusitis	1 (2.9%)	0	1 (2.2%)	3 (4.8%)
Grade 2	1 (2.9%)	0	1 (2.2%)	3 (4.8%)
Tracheitis	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Upper respiratory tract infections (cont)				
Upper respiratory tract infection (cont)				
Grade 2	2 (22.2%)	0	2 (7.1%)	2 (6.1%)
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Nasopharyngitis	1 (11.1%)	1 (5.3%)	2 (7.1%)	3 (9.1%)
Grade 1	1 (11.1%)	1 (5.3%)	2 (7.1%)	3 (9.1%)
Grade 2	0	0	0	0
Sinusitis	2 (22.2%)	0	2 (7.1%)	2 (6.1%)
Grade 2	2 (22.2%)	0	2 (7.1%)	2 (6.1%)
Tracheitis	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Urinary tract infections	4 (11.8%)	0	4 (8.9%)	7 (11.1%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	0	0	0	2 (3.2%)
Grade 3	3 (8.8%)	0	3 (6.7%)	4 (6.3%)
Urinary tract infection	3 (8.8%)	0	3 (6.7%)	6 (9.5%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	0	0	0	2 (3.2%)
Grade 3	2 (5.9%)	0	2 (4.4%)	3 (4.8%)
Cystitis	0	0	0	0
Grade 2	0	0	0	0
Kidney infection	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 3	1 (2.9%)	0	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Urinary tract infections	4 (44.4%)	6 (31.6%)	10 (35.7%)	11 (33.3%)
Grade 1	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 2	3 (33.3%)	6 (31.6%)	9 (32.1%)	10 (30.3%)
Grade 3	0	0	0	0
Urinary tract infection	3 (33.3%)	6 (31.6%)	9 (32.1%)	9 (27.3%)
Grade 1	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 2	2 (22.2%)	6 (31.6%)	8 (28.6%)	8 (24.2%)
Grade 3	0	0	0	0
Cystitis	1 (11.1%)	0	1 (3.6%)	2 (6.1%)
Grade 2	1 (11.1%)	0	1 (3.6%)	2 (6.1%)
Kidney infection	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Herpes viral infections	3 (8.8%)	2 (18.2%)	5 (11.1%)	8 (12.7%)
Grade 1	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 2	2 (5.9%)	2 (18.2%)	4 (8.9%)	5 (7.9%)
Grade 3	0	0	0	1 (1.6%)
Oral herpes	1 (2.9%)	1 (9.1%)	2 (4.4%)	4 (6.3%)
Grade 1	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 2	0	1 (9.1%)	1 (2.2%)	2 (3.2%)
Herpes zoster	1 (2.9%)	1 (9.1%)	2 (4.4%)	3 (4.8%)
Grade 1	0	0	0	0
Grade 2	1 (2.9%)	1 (9.1%)	2 (4.4%)	3 (4.8%)
Herpes simplex	1 (2.9%)	1 (9.1%)	2 (4.4%)	2 (3.2%)
Grade 2	1 (2.9%)	1 (9.1%)	2 (4.4%)	2 (3.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Herpes viral infections	1 (11.1%)	0	1 (3.6%)	2 (6.1%)
Grade 1	1 (11.1%)	0	1 (3.6%)	2 (6.1%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Oral herpes	0	0	0	1 (3.0%)
Grade 1	0	0	0	1 (3.0%)
Grade 2	0	0	0	0
Herpes zoster	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 1	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 2	0	0	0	0
Herpes simplex	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Herpes viral infections (cont)				
Ophthalmic herpes zoster	0	0	0	1 (1.6%)
Grade 3	0	0	0	1 (1.6%)
Bacterial infections NEC	3 (8.8%)	0	3 (6.7%)	7 (11.1%)
Grade 2	0	0	0	1 (1.6%)
Grade 3	3 (8.8%)	0	3 (6.7%)	5 (7.9%)
Grade 5	0	0	0	1 (1.6%)
Cellulitis	2 (5.9%)	0	2 (4.4%)	3 (4.8%)
Grade 3	2 (5.9%)	0	2 (4.4%)	3 (4.8%)
Urinary tract infection bacterial	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Bacterial rhinitis	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Herpes viral infections (cont)				
Ophthalmic herpes zoster	0	0	0	0
Grade 3	0	0	0	0
Bacterial infections NEC	2 (22.2%)	0	2 (7.1%)	2 (6.1%)
Grade 2	2 (22.2%)	0	2 (7.1%)	2 (6.1%)
Grade 3	0	0	0	0
Grade 5	0	0	0	0
Cellulitis	0	0	0	0
Grade 3	0	0	0	0
Urinary tract infection bacterial	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Bacterial rhinitis	1 (11.1%)	0	1 (3.6%)	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-et.pdf 24AUG2023:15:00

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Bacterial infections NEC (cont)				
Bacterial rhinitis (cont)				
Grade 2	0	0	0	0
Bacterial sepsis	0	0	0	1 (1.6%)
Grade 5	0	0	0	1 (1.6%)
Citrobacter infection	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 3	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Peritonitis bacterial	0	0	0	1 (1.6%)
Grade 3	0	0	0	1 (1.6%)
Propionibacterium infection	0	0	0	1 (1.6%)
Grade 2	0	0	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Bacterial infections NEC (cont)				
Bacterial rhinitis (cont)				
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Bacterial sepsis	0	0	0	0
Grade 5	0	0	0	0
Citrobacter infection	0	0	0	0
Grade 3	0	0	0	0
Peritonitis bacterial	0	0	0	0
Grade 3	0	0	0	0
Propionibacterium infection	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Sepsis, bacteraemia, viraemia and fungaemia NEC	5 (14.7%)	0	5 (11.1%)	7 (11.1%)
Grade 3	0	0	0	1 (1.6%)
Grade 4	3 (8.8%)	0	3 (6.7%)	4 (6.3%)
Grade 5	2 (5.9%)	0	2 (4.4%)	2 (3.2%)
Sepsis	4 (11.8%)	0	4 (8.9%)	6 (9.5%)
Grade 3	0	0	0	1 (1.6%)
Grade 4	3 (8.8%)	0	3 (6.7%)	4 (6.3%)
Grade 5	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Bacteraemia	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 5	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Urosepsis	0	0	0	0
Grade 4	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Sepsis, bacteraemia, viraemia and fungaemia NEC	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Grade 5	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Sepsis	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Grade 5	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Bacteraemia	0	0	0	0
Grade 5	0	0	0	0
Urosepsis	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 4	0	1 (5.3%)	1 (3.6%)	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Infections NEC	3 (8.8%)	0	3 (6.7%)	4 (6.3%)
Grade 1	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 2	2 (5.9%)	0	2 (4.4%)	2 (3.2%)
Respiratory tract infection	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 1	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 2	0	0	0	0
Infection	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Localised infection	0	0	0	0
Grade 2	0	0	0	0
Wound infection	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Infections NEC	0	2 (10.5%)	2 (7.1%)	2 (6.1%)
Grade 1	0	0	0	0
Grade 2	0	2 (10.5%)	2 (7.1%)	2 (6.1%)
Respiratory tract infection	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	0	0	0
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Infection	0	0	0	0
Grade 2	0	0	0	0
Localised infection	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Wound infection	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-et.pdf 24AUG2023:15:00

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Candida infections	0	0	0	2 (3.2%)
Grade 1	0	0	0	1 (1.6%)
Grade 2	0	0	0	1 (1.6%)
Grade 3	0	0	0	0
Oral candidiasis	0	0	0	2 (3.2%)
Grade 1	0	0	0	1 (1.6%)
Grade 2	0	0	0	1 (1.6%)
Grade 3	0	0	0	0
Oropharyngeal candidiasis	0	0	0	0
Grade 1	0	0	0	0
Abdominal and gastrointestinal infections	2 (5.9%)	0	2 (4.4%)	3 (4.8%)
Grade 1	2 (5.9%)	0	2 (4.4%)	2 (3.2%)
Grade 3	0	0	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-et.pdf 24AUG2023:15:00

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Candida infections	0	1 (5.3%)	1 (3.6%)	2 (6.1%)
Grade 1	0	0	0	1 (3.0%)
Grade 2	0	0	0	0
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Oral candidiasis	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Oropharyngeal candidiasis	0	0	0	1 (3.0%)
Grade 1	0	0	0	1 (3.0%)
Abdominal and gastrointestinal infections	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Abdominal and gastrointestinal infections (cont)				
Gastroenteritis	2 (5.9%)	0	2 (4.4%)	2 (3.2%)
Grade 1	2 (5.9%)	0	2 (4.4%)	2 (3.2%)
Diverticulitis	0	0	0	1 (1.6%)
Grade 3	0	0	0	1 (1.6%)
Ear infections	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Ear infection	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Otitis media	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Abdominal and gastrointestinal infections (cont)				
Gastroenteritis	0	0	0	0
Grade 1	0	0	0	0
Diverticulitis	0	0	0	0
Grade 3	0	0	0	0
Ear infections	2 (22.2%)	0	2 (7.1%)	2 (6.1%)
Grade 2	2 (22.2%)	0	2 (7.1%)	2 (6.1%)
Ear infection	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Otitis media	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Fungal infections NEC	1 (2.9%)	1 (9.1%)	2 (4.4%)	2 (3.2%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 3	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Oral fungal infection	1 (2.9%)	1 (9.1%)	2 (4.4%)	2 (3.2%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 3	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Fungal skin infection	0	0	0	0
Grade 1	0	0	0	0
Dental and oral soft tissue infections	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Dental fistula	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Fungal infections NEC	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 1	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 3	0	0	0	0
Oral fungal infection	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Fungal skin infection	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 1	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Dental and oral soft tissue infections	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Dental fistula	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Dental and oral soft tissue infections (cont)				
Tooth abscess	0	0	0	0
Grade 2	0	0	0	0
Escherichia infections	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	0
Grade 3	0	0	0	1 (1.6%)
Escherichia bacteraemia	0	0	0	0
Grade 3	0	0	0	0
Escherichia infection	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Escherichia urinary tract infection	1 (2.9%)	0	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Dental and oral soft tissue infections (cont)				
Tooth abscess	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Escherichia infections	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	0	0	0
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Escherichia bacteraemia	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Escherichia infection	0	0	0	0
Grade 1	0	0	0	0
Escherichia urinary tract infection	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
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	Male			
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Escherichia infections (cont)				
Escherichia urinary tract infection (cont)				
Grade 2	1 (2.9%)	0	1 (2.2%)	0
Grade 3	0	0	0	1 (1.6%)
Eye and eyelid infections	0	0	0	1 (1.6%)
Grade 1	0	0	0	0
Grade 2	0	0	0	1 (1.6%)
Conjunctivitis	0	0	0	1 (1.6%)
Grade 1	0	0	0	0
Grade 2	0	0	0	1 (1.6%)
Influenza viral infections	0	1 (9.1%)	1 (2.2%)	2 (3.2%)
Grade 1	0	0	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Escherichia infections (cont)				
Escherichia urinary tract infection (cont)				
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Eye and eyelid infections	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 1	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 2	0	0	0	0
Conjunctivitis	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 1	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 2	0	0	0	0
Influenza viral infections	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Influenza viral infections (cont) (cont)				
Grade 2	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Influenza	0	1 (9.1%)	1 (2.2%)	2 (3.2%)
Grade 1	0	0	0	1 (1.6%)
Grade 2	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Skin structures and soft tissue infections	0	0	0	2 (3.2%)
Grade 1	0	0	0	1 (1.6%)
Grade 2	0	0	0	1 (1.6%)
Folliculitis	0	0	0	1 (1.6%)
Grade 1	0	0	0	1 (1.6%)
Skin infection	0	0	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Influenza viral infections (cont)				
(cont)				
Grade 2	0	0	0	0
Influenza	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Skin structures and soft tissue infections	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Folliculitis	0	0	0	0
Grade 1	0	0	0	0
Skin infection	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
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	Male			
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Skin structures and soft tissue infections (cont)				
Skin infection (cont)				
Grade 2	0	0	0	1 (1.6%)
Viral infections NEC	1 (2.9%)	1 (9.1%)	2 (4.4%)	2 (3.2%)
Grade 1	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 3	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Pneumonia viral	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 3	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Viral rash	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 1	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Clostridia infections	1 (2.9%)	0	1 (2.2%)	1 (1.6%)

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Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
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Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Skin structures and soft tissue infections (cont)				
Skin infection (cont)				
Grade 2	0	0	0	0
Viral infections NEC	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Pneumonia viral	0	0	0	0
Grade 3	0	0	0	0
Viral rash	0	0	0	0
Grade 1	0	0	0	0
Clostridia infections	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
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Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Clostridia infections (cont)				
(cont)				
Grade 3	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Clostridium difficile infection	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 3	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Enterococcal infections	0	0	0	1 (1.6%)
Grade 2	0	0	0	1 (1.6%)
Urinary tract infection enterococcal	0	0	0	1 (1.6%)
Grade 2	0	0	0	1 (1.6%)
Muscle and soft tissue infections	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Clostridia infections (cont)				
(cont)				
Grade 3	0	0	0	0
Clostridium difficile infection	0	0	0	0
Grade 3	0	0	0	0
Enterococcal infections	0	0	0	0
Grade 2	0	0	0	0
Urinary tract infection enterococcal	0	0	0	0
Grade 2	0	0	0	0
Muscle and soft tissue infections	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
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SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Muscle and soft tissue infections (cont)				
Soft tissue infection	0	0	0	0
Grade 3	0	0	0	0
Staphylococcal infections	0	0	0	1 (1.6%)
Grade 2	0	0	0	1 (1.6%)
Staphylococcal infection	0	0	0	1 (1.6%)
Grade 2	0	0	0	1 (1.6%)
Streptococcal infections	0	0	0	1 (1.6%)
Grade 2	0	0	0	1 (1.6%)
Erysipelas	0	0	0	1 (1.6%)
Grade 2	0	0	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Muscle and soft tissue infections (cont)				
Soft tissue infection	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Staphylococcal infections	0	0	0	0
Grade 2	0	0	0	0
Staphylococcal infection	0	0	0	0
Grade 2	0	0	0	0
Streptococcal infections	0	0	0	0
Grade 2	0	0	0	0
Erysipelas	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Vascular infections	0	0	0	0
Grade 2	0	0	0	0
Haematoma infection	0	0	0	0
Grade 2	0	0	0	0
Nervous system disorders	13 (38.2%)	8 (72.7%)	21 (46.7%)	40 (63.5%)
Grade 1	7 (20.6%)	5 (45.5%)	12 (26.7%)	24 (38.1%)
Grade 2	3 (8.8%)	2 (18.2%)	5 (11.1%)	10 (15.9%)
Grade 3	2 (5.9%)	1 (9.1%)	3 (6.7%)	5 (7.9%)
Grade 4	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Neurological signs and symptoms NEC	5 (14.7%)	1 (9.1%)	6 (13.3%)	15 (23.8%)
Grade 1	4 (11.8%)	1 (9.1%)	5 (11.1%)	10 (15.9%)
Grade 2	0	0	0	3 (4.8%)
Grade 3	1 (2.9%)	0	1 (2.2%)	2 (3.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Infections and infestations (cont)				
Vascular infections	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Haematoma infection	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Nervous system disorders	5 (55.6%)	9 (47.4%)	14 (50.0%)	17 (51.5%)
Grade 1	2 (22.2%)	5 (26.3%)	7 (25.0%)	9 (27.3%)
Grade 2	1 (11.1%)	3 (15.8%)	4 (14.3%)	5 (15.2%)
Grade 3	1 (11.1%)	1 (5.3%)	2 (7.1%)	2 (6.1%)
Grade 4	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Neurological signs and symptoms NEC	2 (22.2%)	2 (10.5%)	4 (14.3%)	6 (18.2%)
Grade 1	1 (11.1%)	2 (10.5%)	3 (10.7%)	5 (15.2%)
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Neurological signs and symptoms NEC (cont)				
Dizziness	5 (14.7%)	1 (9.1%)	6 (13.3%)	12 (19.0%)
Grade 1	4 (11.8%)	1 (9.1%)	5 (11.1%)	9 (14.3%)
Grade 2	0	0	0	2 (3.2%)
Grade 3	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Presyncope	0	0	0	3 (4.8%)
Grade 1	0	0	0	1 (1.6%)
Grade 2	0	0	0	1 (1.6%)
Grade 3	0	0	0	1 (1.6%)
Dizziness exertional	0	0	0	1 (1.6%)
Grade 1	0	0	0	1 (1.6%)
Dizziness postural	0	0	0	1 (1.6%)
Grade 1	0	0	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Neurological signs and symptoms NEC (cont)				
Dizziness	1 (11.1%)	2 (10.5%)	3 (10.7%)	5 (15.2%)
Grade 1	1 (11.1%)	2 (10.5%)	3 (10.7%)	5 (15.2%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Presyncope	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 1	0	0	0	0
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 3	0	0	0	0
Dizziness exertional	0	0	0	0
Grade 1	0	0	0	0
Dizziness postural	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Peripheral neuropathies NEC	2 (5.9%)	5 (45.5%)	7 (15.6%)	12 (19.0%)
Grade 1	0	3 (27.3%)	3 (6.7%)	7 (11.1%)
Grade 2	2 (5.9%)	1 (9.1%)	3 (6.7%)	4 (6.3%)
Grade 3	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Peripheral sensory neuropathy	2 (5.9%)	4 (36.4%)	6 (13.3%)	10 (15.9%)
Grade 1	0	3 (27.3%)	3 (6.7%)	6 (9.5%)
Grade 2	2 (5.9%)	0	2 (4.4%)	3 (4.8%)
Grade 3	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Neuropathy peripheral	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 2	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Peripheral motor neuropathy	0	0	0	1 (1.6%)
Grade 1	0	0	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Peripheral neuropathies NEC	3 (33.3%)	2 (10.5%)	5 (17.9%)	6 (18.2%)
Grade 1	2 (22.2%)	2 (10.5%)	4 (14.3%)	5 (15.2%)
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 3	0	0	0	0
Peripheral sensory neuropathy	2 (22.2%)	2 (10.5%)	4 (14.3%)	5 (15.2%)
Grade 1	2 (22.2%)	2 (10.5%)	4 (14.3%)	5 (15.2%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Neuropathy peripheral	0	0	0	0
Grade 2	0	0	0	0
Peripheral motor neuropathy	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Peripheral neuropathies NEC (cont)				
Peripheral sensorimotor neuropathy	0	0	0	0
Grade 2	0	0	0	0
Headaches NEC	0	1 (9.1%)	1 (2.2%)	8 (12.7%)
Grade 1	0	1 (9.1%)	1 (2.2%)	6 (9.5%)
Grade 2	0	0	0	2 (3.2%)
Grade 3	0	0	0	0
Headache	0	1 (9.1%)	1 (2.2%)	8 (12.7%)
Grade 1	0	1 (9.1%)	1 (2.2%)	6 (9.5%)
Grade 2	0	0	0	2 (3.2%)
Grade 3	0	0	0	0
Paraesthesias and dysaesthesias	2 (5.9%)	2 (18.2%)	4 (8.9%)	6 (9.5%)
Grade 1	2 (5.9%)	2 (18.2%)	4 (8.9%)	5 (7.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Peripheral neuropathies NEC (cont)				
Peripheral sensorimotor neuropathy	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Headaches NEC	0	5 (26.3%)	5 (17.9%)	6 (18.2%)
Grade 1	0	2 (10.5%)	2 (7.1%)	3 (9.1%)
Grade 2	0	2 (10.5%)	2 (7.1%)	2 (6.1%)
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Headache	0	5 (26.3%)	5 (17.9%)	6 (18.2%)
Grade 1	0	2 (10.5%)	2 (7.1%)	3 (9.1%)
Grade 2	0	2 (10.5%)	2 (7.1%)	2 (6.1%)
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Paraesthesias and dysaesthesias	0	1 (5.3%)	1 (3.6%)	2 (6.1%)
Grade 1	0	1 (5.3%)	1 (3.6%)	2 (6.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Paraesthesias and dysaesthesias (cont)				
(cont)				
Grade 2	0	0	0	1 (1.6%)
Paraesthesia	1 (2.9%)	2 (18.2%)	3 (6.7%)	6 (9.5%)
Grade 1	1 (2.9%)	2 (18.2%)	3 (6.7%)	5 (7.9%)
Grade 2	0	0	0	1 (1.6%)
Hypoaesthesia	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Disturbances in consciousness NEC	1 (2.9%)	2 (18.2%)	3 (6.7%)	5 (7.9%)
Grade 1	0	2 (18.2%)	2 (4.4%)	3 (4.8%)
Grade 3	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Somnolence	0	2 (18.2%)	2 (4.4%)	3 (4.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Paraesthesias and dysaesthesias (cont)				
(cont)				
Grade 2	0	0	0	0
Paraesthesia	0	1 (5.3%)	1 (3.6%)	2 (6.1%)
Grade 1	0	1 (5.3%)	1 (3.6%)	2 (6.1%)
Grade 2	0	0	0	0
Hypoaesthesia	0	0	0	0
Grade 1	0	0	0	0
Disturbances in consciousness NEC	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 1	0	0	0	0
Grade 3	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Somnolence	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Disturbances in consciousness NEC (cont)				
Somnolence (cont)				
Grade 1	0	2 (18.2%)	2 (4.4%)	3 (4.8%)
Syncope	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 3	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Loss of consciousness	0	0	0	1 (1.6%)
Grade 3	0	0	0	1 (1.6%)
Sensory abnormalities NEC	1 (2.9%)	1 (9.1%)	2 (4.4%)	4 (6.3%)
Grade 1	1 (2.9%)	0	1 (2.2%)	3 (4.8%)
Grade 2	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Restless legs syndrome	0	0	0	1 (1.6%)
Grade 1	0	0	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Disturbances in consciousness NEC (cont)				
Somnolence (cont)				
Grade 1	0	0	0	0
Syncope	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 3	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Loss of consciousness	0	0	0	0
Grade 3	0	0	0	0
Sensory abnormalities NEC	1 (11.1%)	0	1 (3.6%)	2 (6.1%)
Grade 1	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 2	0	0	0	1 (3.0%)
Restless legs syndrome	1 (11.1%)	0	1 (3.6%)	2 (6.1%)
Grade 1	1 (11.1%)	0	1 (3.6%)	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Sensory abnormalities NEC (cont)				
Restless legs syndrome (cont)				
Grade 2	0	0	0	0
Allodynia	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 2	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Hypogeusia	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Neuralgia	0	0	0	0
Grade 1	0	0	0	0
Post herpetic neuralgia	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 2	0	1 (9.1%)	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Sensory abnormalities NEC (cont)				
Restless legs syndrome (cont)				
Grade 2	0	0	0	1 (3.0%)
Allodynia	0	0	0	0
Grade 2	0	0	0	0
Hypogeusia	0	0	0	0
Grade 1	0	0	0	0
Neuralgia	0	0	0	1 (3.0%)
Grade 1	0	0	0	1 (3.0%)
Post herpetic neuralgia	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Sensory abnormalities NEC (cont)				
Taste disorder	0	0	0	1 (1.6%)
Grade 1	0	0	0	1 (1.6%)
Mental impairment (excl dementia and memory loss)	2 (5.9%)	1 (9.1%)	3 (6.7%)	4 (6.3%)
Grade 1	2 (5.9%)	1 (9.1%)	3 (6.7%)	4 (6.3%)
Disturbance in attention	1 (2.9%)	1 (9.1%)	2 (4.4%)	3 (4.8%)
Grade 1	1 (2.9%)	1 (9.1%)	2 (4.4%)	3 (4.8%)
Cognitive disorder	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Sensory abnormalities NEC (cont)				
Taste disorder	0	0	0	0
Grade 1	0	0	0	0
Mental impairment (excl dementia and memory loss)	0	0	0	0
Grade 1	0	0	0	0
Disturbance in attention	0	0	0	0
Grade 1	0	0	0	0
Cognitive disorder	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Central nervous system haemorrhages and cerebrovascular accidents	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	0	0	0	0
Grade 4	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Cerebrovascular accident	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	0	0	0	0
Grade 4	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Cerebral infarction	0	0	0	0
Grade 1	0	0	0	0
Subarachnoid haemorrhage	0	0	0	0
Grade 4	0	0	0	0
Tremor (excl congenital)	1 (2.9%)	0	1 (2.2%)	3 (4.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Central nervous system haemorrhages and cerebrovascular accidents	1 (11.1%)	1 (5.3%)	2 (7.1%)	2 (6.1%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 4	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Cerebrovascular accident	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 4	0	0	0	0
Cerebral infarction	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Subarachnoid haemorrhage	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 4	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Tremor (excl congenital)	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Tremor (excl congenital) (cont)				
(cont)				
Grade 1	0	0	0	2 (3.2%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Tremor	1 (2.9%)	0	1 (2.2%)	3 (4.8%)
Grade 1	0	0	0	2 (3.2%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Coordination and balance disturbances	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Balance disorder	0	0	0	0
Grade 1	0	0	0	0
Coordination abnormal	1 (2.9%)	0	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Tremor (excl congenital) (cont)				
(cont)				
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Tremor	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Coordination and balance disturbances	0	0	0	1 (3.0%)
Grade 1	0	0	0	1 (3.0%)
Balance disorder	0	0	0	1 (3.0%)
Grade 1	0	0	0	1 (3.0%)
Coordination abnormal	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Coordination and balance disturbances (cont)				
Coordination abnormal (cont)				
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Memory loss (excl dementia)	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 1	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Amnesia	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Memory impairment	0	0	0	1 (1.6%)
Grade 1	0	0	0	1 (1.6%)
Central nervous system aneurysms and dissections	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Coordination and balance disturbances (cont)				
Coordination abnormal (cont)				
Grade 1	0	0	0	0
Memory loss (excl dementia)	0	0	0	0
Grade 1	0	0	0	0
Amnesia	0	0	0	0
Grade 1	0	0	0	0
Memory impairment	0	0	0	0
Grade 1	0	0	0	0
Central nervous system aneurysms and dissections	1 (11.1%)	0	1 (3.6%)	1 (3.6%)
Grade 3	1 (11.1%)	0	1 (3.6%)	1 (3.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Central nervous system aneurysms and dissections (cont)				
Carotid artery aneurysm	0	0	0	0
Grade 3	0	0	0	0
Cervical spinal cord and nerve root disorders	0	0	0	0
Grade 1	0	0	0	0
Cervical radiculopathy	0	0	0	0
Grade 1	0	0	0	0
Dementia (excl Alzheimer's type)	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 1	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Dementia	0	1 (9.1%)	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Central nervous system aneurysms and dissections (cont)				
Carotid artery aneurysm	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 3	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Cervical spinal cord and nerve root disorders	0	0	0	1 (3.0%)
Grade 1	0	0	0	1 (3.0%)
Cervical radiculopathy	0	0	0	1 (3.0%)
Grade 1	0	0	0	1 (3.0%)
Dementia (excl Alzheimer's type)	0	0	0	0
Grade 1	0	0	0	0
Dementia	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Dementia (excl Alzheimer's type) (cont)				
Dementia (cont)				
Grade 1	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Hypoglossal nerve disorders	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 2	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Tongue paralysis	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 2	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Lumbar spinal cord and nerve root disorders	0	0	0	0
Grade 2	0	0	0	0
Sciatica	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Dementia (excl Alzheimer's type) (cont)				
Dementia (cont)				
Grade 1	0	0	0	0
Hypoglossal nerve disorders	0	0	0	0
Grade 2	0	0	0	0
Tongue paralysis	0	0	0	0
Grade 2	0	0	0	0
Lumbar spinal cord and nerve root disorders	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Sciatica	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Mononeuropathies	0	0	0	0
Grade 1	0	0	0	0
Nerve compression	0	0	0	0
Grade 1	0	0	0	0
Nervous system cysts and polyps	0	0	0	0
Grade 1	0	0	0	0
Arachnoid cyst	0	0	0	0
Grade 1	0	0	0	0
Neurologic visual problems NEC	0	0	0	1 (1.6%)
Grade 2	0	0	0	1 (1.6%)
Visual field defect	0	0	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Mononeuropathies	0	0	0	1 (3.0%)
Grade 1	0	0	0	1 (3.0%)
Nerve compression	0	0	0	1 (3.0%)
Grade 1	0	0	0	1 (3.0%)
Nervous system cysts and polyps	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Arachnoid cyst	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Neurologic visual problems NEC	0	0	0	0
Grade 2	0	0	0	0
Visual field defect	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Neurologic visual problems NEC (cont)				
Visual field defect (cont)				
Grade 2	0	0	0	1 (1.6%)
Neuromuscular disorders NEC	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Muscle contractions involuntary	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Olfactory nerve disorders	0	0	0	1 (1.6%)
Grade 1	0	0	0	1 (1.6%)
Parosmia	0	0	0	1 (1.6%)
Grade 1	0	0	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Neurologic visual problems NEC (cont)				
Visual field defect (cont)				
Grade 2	0	0	0	0
Neuromuscular disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Muscle contractions involuntary	0	0	0	0
Grade 1	0	0	0	0
Olfactory nerve disorders	0	0	0	0
Grade 1	0	0	0	0
Parosmia	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Speech and language abnormalities	0	0	0	1 (1.6%)
Grade 1	0	0	0	1 (1.6%)
Speech disorder	0	0	0	1 (1.6%)
Grade 1	0	0	0	1 (1.6%)
Blood and lymphatic system disorders	12 (35.3%)	7 (63.6%)	19 (42.2%)	32 (50.8%)
Grade 1	2 (5.9%)	0	2 (4.4%)	3 (4.8%)
Grade 2	1 (2.9%)	1 (9.1%)	2 (4.4%)	5 (7.9%)
Grade 3	5 (14.7%)	4 (36.4%)	9 (20.0%)	16 (25.4%)
Grade 4	4 (11.8%)	2 (18.2%)	6 (13.3%)	8 (12.7%)
Anaemias NEC	6 (17.6%)	4 (36.4%)	10 (22.2%)	18 (28.6%)
Grade 2	0	0	0	0
Grade 3	6 (17.6%)	4 (36.4%)	10 (22.2%)	18 (28.6%)
Grade 4	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Nervous system disorders (cont)				
Speech and language abnormalities	0	0	0	0
Grade 1	0	0	0	0
Speech disorder	0	0	0	0
Grade 1	0	0	0	0
Blood and lymphatic system disorders	5 (55.6%)	13 (68.4%)	18 (64.3%)	22 (66.7%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	4 (21.1%)	4 (14.3%)	4 (12.1%)
Grade 3	5 (55.6%)	6 (31.6%)	11 (39.3%)	13 (39.4%)
Grade 4	0	2 (10.5%)	2 (7.1%)	4 (12.1%)
Anaemias NEC	4 (44.4%)	5 (26.3%)	9 (32.1%)	11 (33.3%)
Grade 2	0	1 (5.3%)	1 (3.6%)	2 (6.1%)
Grade 3	4 (44.4%)	4 (21.1%)	8 (28.6%)	8 (24.2%)
Grade 4	0	0	0	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Anaemias NEC (cont)				
Anaemia	6 (17.6%)	4 (36.4%)	10 (22.2%)	18 (28.6%)
Grade 2	0	0	0	0
Grade 3	6 (17.6%)	4 (36.4%)	10 (22.2%)	18 (28.6%)
Grade 4	0	0	0	0
Thrombocytopenias	5 (14.7%)	4 (36.4%)	9 (20.0%)	16 (25.4%)
Grade 1	0	0	0	1 (1.6%)
Grade 2	2 (5.9%)	1 (9.1%)	3 (6.7%)	6 (9.5%)
Grade 3	1 (2.9%)	2 (18.2%)	3 (6.7%)	4 (6.3%)
Grade 4	2 (5.9%)	1 (9.1%)	3 (6.7%)	5 (7.9%)
Thrombocytopenia	5 (14.7%)	4 (36.4%)	9 (20.0%)	16 (25.4%)
Grade 1	0	0	0	1 (1.6%)
Grade 2	2 (5.9%)	1 (9.1%)	3 (6.7%)	6 (9.5%)
Grade 3	1 (2.9%)	2 (18.2%)	3 (6.7%)	4 (6.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-et.pdf 24AUG2023:15:00

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Anaemias NEC (cont)				
Anaemia	4 (44.4%)	5 (26.3%)	9 (32.1%)	11 (33.3%)
Grade 2	0	1 (5.3%)	1 (3.6%)	2 (6.1%)
Grade 3	4 (44.4%)	4 (21.1%)	8 (28.6%)	8 (24.2%)
Grade 4	0	0	0	1 (3.0%)
Thrombocytopenias	1 (11.1%)	4 (21.1%)	5 (17.9%)	7 (21.2%)
Grade 1	0	0	0	0
Grade 2	0	2 (10.5%)	2 (7.1%)	2 (6.1%)
Grade 3	1 (11.1%)	0	1 (3.6%)	2 (6.1%)
Grade 4	0	2 (10.5%)	2 (7.1%)	3 (9.1%)
Thrombocytopenia	1 (11.1%)	4 (21.1%)	5 (17.9%)	7 (21.2%)
Grade 1	0	0	0	0
Grade 2	0	2 (10.5%)	2 (7.1%)	2 (6.1%)
Grade 3	1 (11.1%)	0	1 (3.6%)	2 (6.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Thrombocytopenias (cont)				
Thrombocytopenia (cont)				
Grade 4	2 (5.9%)	1 (9.1%)	3 (6.7%)	5 (7.9%)
Neutropenias	2 (5.9%)	1 (9.1%)	3 (6.7%)	5 (7.9%)
Grade 1	0	0	0	1 (1.6%)
Grade 2	0	0	0	0
Grade 3	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 4	2 (5.9%)	0	2 (4.4%)	3 (4.8%)
Neutropenia	2 (5.9%)	1 (9.1%)	3 (6.7%)	5 (7.9%)
Grade 1	0	0	0	1 (1.6%)
Grade 2	0	0	0	0
Grade 3	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 4	2 (5.9%)	0	2 (4.4%)	3 (4.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Thrombocytopenias (cont)				
Thrombocytopenia (cont)				
Grade 4	0	2 (10.5%)	2 (7.1%)	3 (9.1%)
Neutropenias	0	1 (5.3%)	1 (3.6%)	5 (15.2%)
Grade 1	0	0	0	0
Grade 2	0	0	0	1 (3.0%)
Grade 3	0	1 (5.3%)	1 (3.6%)	2 (6.1%)
Grade 4	0	0	0	2 (6.1%)
Neutropenia	0	1 (5.3%)	1 (3.6%)	5 (15.2%)
Grade 1	0	0	0	0
Grade 2	0	0	0	1 (3.0%)
Grade 3	0	1 (5.3%)	1 (3.6%)	2 (6.1%)
Grade 4	0	0	0	2 (6.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Spleen disorders	0	1 (9.1%)	1 (2.2%)	2 (3.2%)
Grade 2	0	0	0	1 (1.6%)
Grade 3	0	0	0	0
Grade 4	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Splenic infarction	0	1 (9.1%)	1 (2.2%)	2 (3.2%)
Grade 2	0	0	0	1 (1.6%)
Grade 3	0	0	0	0
Grade 4	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Splenomegaly	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Leukocytoses NEC	4 (11.8%)	0	4 (8.9%)	5 (7.9%)
Grade 1	3 (8.8%)	0	3 (6.7%)	4 (6.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Spleen disorders	0	3 (15.8%)	3 (10.7%)	4 (12.1%)
Grade 2	0	2 (10.5%)	2 (7.1%)	2 (6.1%)
Grade 3	0	1 (5.3%)	1 (3.6%)	2 (6.1%)
Grade 4	0	0	0	0
Splenic infarction	0	2 (10.5%)	2 (7.1%)	2 (6.1%)
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 4	0	0	0	0
Splenomegaly	0	1 (5.3%)	1 (3.6%)	2 (6.1%)
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 3	0	0	0	1 (3.0%)
Leukocytoses NEC	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Leukocytoses NEC (cont)				
(cont)				
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Leukocytosis	4 (11.8%)	0	4 (8.9%)	4 (6.3%)
Grade 1	3 (8.8%)	0	3 (6.7%)	3 (4.8%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Neutrophilia	0	0	0	1 (1.6%)
Grade 1	0	0	0	1 (1.6%)
Leukopenias NEC	1 (2.9%)	1 (9.1%)	2 (4.4%)	2 (3.2%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 3	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Leukopenia	1 (2.9%)	1 (9.1%)	2 (4.4%)	2 (3.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Leukocytoses NEC (cont)				
(cont)				
Grade 2	0	0	0	0
Leukocytosis	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Neutrophilia	0	0	0	0
Grade 1	0	0	0	0
Leukopenias NEC	0	0	0	1 (3.0%)
Grade 2	0	0	0	0
Grade 3	0	0	0	1 (3.0%)
Leukopenia	0	0	0	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Leukopenias NEC (cont)				
Leukopenia (cont)				
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 3	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Bleeding tendencies	0	0	0	1 (1.6%)
Grade 1	0	0	0	1 (1.6%)
Increased tendency to bruise	0	0	0	1 (1.6%)
Grade 1	0	0	0	1 (1.6%)
Anaemias haemolytic NEC	0	0	0	0
Grade 3	0	0	0	0
Haemolytic anaemia	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Leukopenias NEC (cont)				
Leukopenia (cont)				
Grade 2	0	0	0	0
Grade 3	0	0	0	1 (3.0%)
Bleeding tendencies	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Increased tendency to bruise	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Anaemias haemolytic NEC	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Haemolytic anaemia	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Coagulopathies	0	0	0	1 (1.6%)
Grade 1	0	0	0	1 (1.6%)
Hyperfibrinogenaemia	0	0	0	1 (1.6%)
Grade 1	0	0	0	1 (1.6%)
Lymphatic system disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Lymphadenopathy	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Blood and lymphatic system disorders (cont)				
Coagulopathies	0	0	0	0
Grade 1	0	0	0	0
Hyperfibrinogenaemia	0	0	0	0
Grade 1	0	0	0	0
Lymphatic system disorders NEC	0	0	0	1 (3.0%)
Grade 1	0	0	0	1 (3.0%)
Lymphadenopathy	0	0	0	1 (3.0%)
Grade 1	0	0	0	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders	20 (58.8%)	6 (54.5%)	26 (57.8%)	40 (63.5%)
Grade 1	7 (20.6%)	1 (9.1%)	8 (17.8%)	13 (20.6%)
Grade 2	4 (11.8%)	3 (27.3%)	7 (15.6%)	11 (17.5%)
Grade 3	5 (14.7%)	1 (9.1%)	6 (13.3%)	8 (12.7%)
Grade 4	2 (5.9%)	1 (9.1%)	3 (6.7%)	4 (6.3%)
Grade 5	2 (5.9%)	0	2 (4.4%)	4 (6.3%)
Coughing and associated symptoms	10 (29.4%)	3 (27.3%)	13 (28.9%)	20 (31.7%)
Grade 1	4 (11.8%)	1 (9.1%)	5 (11.1%)	11 (17.5%)
Grade 2	4 (11.8%)	2 (18.2%)	6 (13.3%)	7 (11.1%)
Grade 3	2 (5.9%)	0	2 (4.4%)	2 (3.2%)
Cough	10 (29.4%)	3 (27.3%)	13 (28.9%)	18 (28.6%)
Grade 1	4 (11.8%)	1 (9.1%)	5 (11.1%)	10 (15.9%)
Grade 2	4 (11.8%)	2 (18.2%)	6 (13.3%)	6 (9.5%)
Grade 3	2 (5.9%)	0	2 (4.4%)	2 (3.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders	4 (44.4%)	9 (47.4%)	13 (46.4%)	14 (42.4%)
Grade 1	1 (11.1%)	3 (15.8%)	4 (14.3%)	4 (12.1%)
Grade 2	2 (22.2%)	2 (10.5%)	4 (14.3%)	5 (15.2%)
Grade 3	1 (11.1%)	4 (21.1%)	5 (17.9%)	5 (15.2%)
Grade 4	0	0	0	0
Grade 5	0	0	0	0
Coughing and associated symptoms	3 (33.3%)	3 (15.8%)	6 (21.4%)	7 (21.2%)
Grade 1	1 (11.1%)	1 (5.3%)	2 (7.1%)	2 (6.1%)
Grade 2	2 (22.2%)	1 (5.3%)	3 (10.7%)	4 (12.1%)
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Cough	3 (33.3%)	3 (15.8%)	6 (21.4%)	7 (21.2%)
Grade 1	1 (11.1%)	1 (5.3%)	2 (7.1%)	2 (6.1%)
Grade 2	2 (22.2%)	1 (5.3%)	3 (10.7%)	4 (12.1%)
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Coughing and associated symptoms (cont)				
Haemoptysis	0	0	0	2 (3.2%)
Grade 1	0	0	0	1 (1.6%)
Grade 2	0	0	0	1 (1.6%)
Productive cough	0	1 (9.1%)	1 (2.2%)	2 (3.2%)
Grade 1	0	1 (9.1%)	1 (2.2%)	2 (3.2%)
Sputum discoloured	0	0	0	0
Grade 2	0	0	0	0
Breathing abnormalities	7 (20.6%)	2 (18.2%)	9 (20.0%)	14 (22.2%)
Grade 1	3 (8.8%)	0	3 (6.7%)	4 (6.3%)
Grade 2	2 (5.9%)	1 (9.1%)	3 (6.7%)	5 (7.9%)
Grade 3	0	1 (9.1%)	1 (2.2%)	3 (4.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-et.pdf 24AUG2023:15:00

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Coughing and associated symptoms (cont)				
Haemoptysis	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Productive cough	0	0	0	0
Grade 1	0	0	0	0
Sputum discoloured	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Breathing abnormalities	0	5 (26.3%)	5 (17.9%)	6 (18.2%)
Grade 1	0	3 (15.8%)	3 (10.7%)	4 (12.1%)
Grade 2	0	2 (10.5%)	2 (7.1%)	2 (6.1%)
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Breathing abnormalities (cont) (cont)				
Grade 4	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 5	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Dyspnoea	4 (11.8%)	1 (9.1%)	5 (11.1%)	11 (17.5%)
Grade 1	2 (5.9%)	0	2 (4.4%)	3 (4.8%)
Grade 2	2 (5.9%)	1 (9.1%)	3 (6.7%)	6 (9.5%)
Grade 3	0	0	0	2 (3.2%)
Dyspnoea exertional	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 1	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Respiratory distress	2 (5.9%)	0	2 (4.4%)	2 (3.2%)
Grade 4	1 (2.9%)	0	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Breathing abnormalities (cont) (cont)				
Grade 4	0	0	0	0
Grade 5	0	0	0	0
Dyspnoea	0	5 (26.3%)	5 (17.9%)	6 (18.2%)
Grade 1	0	3 (15.8%)	3 (10.7%)	4 (12.1%)
Grade 2	0	2 (10.5%)	2 (7.1%)	2 (6.1%)
Grade 3	0	0	0	0
Dyspnoea exertional	0	0	0	0
Grade 1	0	0	0	0
Respiratory distress	0	0	0	0
Grade 4	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Breathing abnormalities (cont)				
Respiratory distress (cont)				
Grade 5	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Sleep apnoea syndrome	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 3	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Nasal disorders NEC	2 (5.9%)	1 (9.1%)	3 (6.7%)	7 (11.1%)
Grade 1	2 (5.9%)	0	2 (4.4%)	4 (6.3%)
Grade 2	0	1 (9.1%)	1 (2.2%)	3 (4.8%)
Epistaxis	1 (2.9%)	1 (9.1%)	2 (4.4%)	6 (9.5%)
Grade 1	1 (2.9%)	0	1 (2.2%)	3 (4.8%)
Grade 2	0	1 (9.1%)	1 (2.2%)	3 (4.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-et.pdf 24AUG2023:15:00

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Breathing abnormalities (cont)				
Respiratory distress (cont)				
Grade 5	0	0	0	0
Sleep apnoea syndrome	0	0	0	0
Grade 3	0	0	0	0
Nasal disorders NEC	0	1 (5.3%)	1 (3.6%)	3 (9.1%)
Grade 1	0	1 (5.3%)	1 (3.6%)	3 (9.1%)
Grade 2	0	0	0	0
Epistaxis	0	1 (5.3%)	1 (3.6%)	3 (9.1%)
Grade 1	0	1 (5.3%)	1 (3.6%)	3 (9.1%)
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Nasal disorders NEC (cont)				
Nasal septum ulceration	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Upper respiratory tract signs and symptoms	3 (8.8%)	0	3 (6.7%)	5 (7.9%)
Grade 1	3 (8.8%)	0	3 (6.7%)	5 (7.9%)
Oropharyngeal pain	2 (5.9%)	0	2 (4.4%)	3 (4.8%)
Grade 1	2 (5.9%)	0	2 (4.4%)	3 (4.8%)
Rhinorrhoea	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 1	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Dysphonia	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Nasal disorders NEC (cont)				
Nasal septum ulceration	0	0	0	0
Grade 1	0	0	0	0
Upper respiratory tract signs and symptoms	1 (11.1%)	1 (5.3%)	2 (7.1%)	3 (9.1%)
Grade 1	1 (11.1%)	1 (5.3%)	2 (7.1%)	3 (9.1%)
Oropharyngeal pain	0	0	0	0
Grade 1	0	0	0	0
Rhinorrhoea	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Dysphonia	0	0	0	1 (3.0%)
Grade 1	0	0	0	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Upper respiratory tract signs and symptoms (cont)				
Upper-airway cough syndrome	0	0	0	0
Grade 1	0	0	0	0
Lower respiratory tract inflammatory and immunologic conditions	4 (11.8%)	0	4 (8.9%)	4 (6.3%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 3	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 4	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 5	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Pneumonitis	2 (5.9%)	0	2 (4.4%)	2 (3.2%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 3	1 (2.9%)	0	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Upper respiratory tract signs and symptoms (cont)				
Upper-airway cough syndrome	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 1	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Lower respiratory tract inflammatory and immunologic conditions	1 (11.1%)	1 (5.3%)	2 (7.1%)	2 (6.1%)
Grade 2	0	0	0	0
Grade 3	1 (11.1%)	1 (5.3%)	2 (7.1%)	2 (6.1%)
Grade 4	0	0	0	0
Grade 5	0	0	0	0
Pneumonitis	1 (11.1%)	1 (5.3%)	2 (7.1%)	2 (6.1%)
Grade 2	0	0	0	0
Grade 3	1 (11.1%)	1 (5.3%)	2 (7.1%)	2 (6.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-et.pdf 24AUG2023:15:00

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Lower respiratory tract inflammatory and immunologic conditions (cont)				
Pneumonia aspiration	2 (5.9%)	0	2 (4.4%)	2 (3.2%)
Grade 4	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 5	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Pulmonary oedemas	0	1 (9.1%)	1 (2.2%)	2 (3.2%)
Grade 3	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 4	0	0	0	1 (1.6%)
Pulmonary oedema	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 3	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Acute respiratory distress syndrome	0	0	0	1 (1.6%)
Grade 4	0	0	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Lower respiratory tract inflammatory and immunologic conditions (cont)				
Pneumonia aspiration	0	0	0	0
Grade 4	0	0	0	0
Grade 5	0	0	0	0
Pulmonary oedemas	0	2 (10.5%)	2 (7.1%)	2 (6.1%)
Grade 3	0	2 (10.5%)	2 (7.1%)	2 (6.1%)
Grade 4	0	0	0	0
Pulmonary oedema	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Acute respiratory distress syndrome	0	0	0	0
Grade 4	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Pulmonary oedemas (cont)				
Pulmonary congestion	0	0	0	0
Grade 3	0	0	0	0
Parenchymal lung disorders NEC	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 2	0	0	0	1 (1.6%)
Grade 3	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Atelectasis	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 2	0	0	0	1 (1.6%)
Grade 3	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Interstitial lung disease	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Pulmonary oedemas (cont)				
Pulmonary congestion	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Parenchymal lung disorders NEC	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	0	0	0
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Atelectasis	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Interstitial lung disease	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Respiratory failures (excl neonatal)	1 (2.9%)	0	1 (2.2%)	3 (4.8%)
Grade 3	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 5	0	0	0	2 (3.2%)
Respiratory failure	1 (2.9%)	0	1 (2.2%)	3 (4.8%)
Grade 3	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 5	0	0	0	2 (3.2%)
Bronchospasm and obstruction	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	0	0	0	0
Asthma	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Respiratory failures (excl neonatal)	0	0	0	0
Grade 3	0	0	0	0
Grade 5	0	0	0	0
Respiratory failure	0	0	0	0
Grade 3	0	0	0	0
Grade 5	0	0	0	0
Bronchospasm and obstruction	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 1	0	0	0	0
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Asthma	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

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Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Bronchospasm and obstruction (cont)				
Bronchial hyperreactivity	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Pneumothorax and pleural effusions NEC	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 3	0	0	0	1 (1.6%)
Pleural effusion	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 3	0	0	0	1 (1.6%)
Pulmonary hypertensions	0	0	0	1 (1.6%)
Grade 2	0	0	0	0
Grade 3	0	0	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Bronchospasm and obstruction (cont)				
Bronchial hyperreactivity	0	0	0	0
Grade 1	0	0	0	0
Pneumothorax and pleural effusions NEC	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Pleural effusion	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Pulmonary hypertensions	0	0	0	1 (3.0%)
Grade 2	0	0	0	1 (3.0%)
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Pulmonary hypertensions (cont)				
Pulmonary hypertension	0	0	0	1 (1.6%)
Grade 2	0	0	0	0
Grade 3	0	0	0	1 (1.6%)
Respiratory tract disorders NEC	1 (2.9%)	1 (9.1%)	2 (4.4%)	2 (3.2%)
Grade 2	1 (2.9%)	1 (9.1%)	2 (4.4%)	2 (3.2%)
Lung disorder	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Respiratory tract inflammation	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 2	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Bronchial conditions NEC	1 (2.9%)	0	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Pulmonary hypertensions (cont)				
Pulmonary hypertension	0	0	0	1 (3.0%)
Grade 2	0	0	0	1 (3.0%)
Grade 3	0	0	0	0
Respiratory tract disorders NEC	0	0	0	0
Grade 2	0	0	0	0
Lung disorder	0	0	0	0
Grade 2	0	0	0	0
Respiratory tract inflammation	0	0	0	0
Grade 2	0	0	0	0
Bronchial conditions NEC	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Bronchial conditions NEC (cont) (cont)				
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Bronchial wall thickening	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Conditions associated with abnormal gas exchange	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 4	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Hypoxia	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 4	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Pulmonary thrombotic and embolic conditions	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Bronchial conditions NEC (cont) (cont)				
Grade 1	0	0	0	0
Bronchial wall thickening	0	0	0	0
Grade 1	0	0	0	0
Conditions associated with abnormal gas exchange	0	0	0	0
Grade 4	0	0	0	0
Hypoxia	0	0	0	0
Grade 4	0	0	0	0
Pulmonary thrombotic and embolic conditions	0	1 (5.3%)	1 (3.6%)	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Pulmonary thrombotic and embolic conditions (cont) (cont)				
Grade 3	0	0	0	0
Pulmonary embolism	0	0	0	0
Grade 3	0	0	0	0
Metabolism and nutrition disorders	16 (47.1%)	2 (18.2%)	18 (40.0%)	33 (52.4%)
Grade 1	7 (20.6%)	1 (9.1%)	8 (17.8%)	16 (25.4%)
Grade 2	6 (17.6%)	0	6 (13.3%)	8 (12.7%)
Grade 3	2 (5.9%)	1 (9.1%)	3 (6.7%)	8 (12.7%)
Grade 4	1 (2.9%)	0	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Respiratory, thoracic and mediastinal disorders (cont)				
Pulmonary thrombotic and embolic conditions (cont)				
(cont)				
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Pulmonary embolism	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Metabolism and nutrition disorders	4 (44.4%)	7 (36.8%)	11 (39.3%)	14 (42.4%)
Grade 1	2 (22.2%)	1 (5.3%)	3 (10.7%)	6 (18.2%)
Grade 2	1 (11.1%)	4 (21.1%)	5 (17.9%)	5 (15.2%)
Grade 3	1 (11.1%)	2 (10.5%)	3 (10.7%)	3 (9.1%)
Grade 4	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Potassium imbalance	4 (11.8%)	1 (9.1%)	5 (11.1%)	10 (15.9%)
Grade 1	1 (2.9%)	0	1 (2.2%)	4 (6.3%)
Grade 2	2 (5.9%)	0	2 (4.4%)	3 (4.8%)
Grade 3	1 (2.9%)	1 (9.1%)	2 (4.4%)	3 (4.8%)
Hyperkalaemia	3 (8.8%)	0	3 (6.7%)	8 (12.7%)
Grade 1	0	0	0	4 (6.3%)
Grade 2	3 (8.8%)	0	3 (6.7%)	4 (6.3%)
Grade 3	0	0	0	0
Hypokalaemia	2 (5.9%)	1 (9.1%)	3 (6.7%)	5 (7.9%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	0	0	0	1 (1.6%)
Grade 3	1 (2.9%)	1 (9.1%)	2 (4.4%)	3 (4.8%)
Water soluble vitamin deficiencies	5 (14.7%)	1 (9.1%)	6 (13.3%)	11 (17.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Potassium imbalance	1 (11.1%)	4 (21.1%)	5 (17.9%)	5 (15.2%)
Grade 1	0	0	0	0
Grade 2	0	3 (15.8%)	3 (10.7%)	3 (9.1%)
Grade 3	1 (11.1%)	1 (5.3%)	2 (7.1%)	2 (6.1%)
Hyperkalaemia	1 (11.1%)	2 (10.5%)	3 (10.7%)	3 (9.1%)
Grade 1	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Hypokalaemia	1 (11.1%)	2 (10.5%)	3 (10.7%)	3 (9.1%)
Grade 1	0	0	0	0
Grade 2	0	2 (10.5%)	2 (7.1%)	2 (6.1%)
Grade 3	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Water soluble vitamin deficiencies	1 (11.1%)	0	1 (3.6%)	3 (9.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Water soluble vitamin deficiencies (cont) (cont)				
Grade 1	2 (5.9%)	1 (9.1%)	3 (6.7%)	6 (9.5%)
Grade 2	3 (8.8%)	0	3 (6.7%)	5 (7.9%)
Vitamin B1 deficiency	4 (11.8%)	1 (9.1%)	5 (11.1%)	8 (12.7%)
Grade 1	2 (5.9%)	1 (9.1%)	3 (6.7%)	4 (6.3%)
Grade 2	2 (5.9%)	0	2 (4.4%)	4 (6.3%)
Vitamin B complex deficiency	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 1	0	0	0	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Vitamin B6 deficiency	0	0	0	1 (1.6%)
Grade 1	0	0	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Water soluble vitamin deficiencies (cont)				
(cont)				
Grade 1	1 (11.1%)	0	1 (3.6%)	3 (9.1%)
Grade 2	0	0	0	0
Vitamin B1 deficiency	1 (11.1%)	0	1 (3.6%)	3 (9.1%)
Grade 1	1 (11.1%)	0	1 (3.6%)	3 (9.1%)
Grade 2	0	0	0	0
Vitamin B complex deficiency	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Vitamin B6 deficiency	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Disorders of purine metabolism	5 (14.7%)	1 (9.1%)	6 (13.3%)	10 (15.9%)
Grade 1	3 (8.8%)	0	3 (6.7%)	6 (9.5%)
Grade 2	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 3	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 4	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Hyperuricaemia	4 (11.8%)	1 (9.1%)	5 (11.1%)	9 (14.3%)
Grade 1	3 (8.8%)	0	3 (6.7%)	6 (9.5%)
Grade 2	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 3	0	0	0	1 (1.6%)
Grade 4	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Gout	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 3	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Appetite disorders	2 (5.9%)	0	2 (4.4%)	7 (11.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Disorders of purine metabolism	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Hyperuricaemia	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Gout	0	0	0	0
Grade 3	0	0	0	0
Appetite disorders	0	2 (10.5%)	2 (7.1%)	2 (6.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Appetite disorders (cont)				
(cont)				
Grade 1	1 (2.9%)	0	1 (2.2%)	5 (7.9%)
Grade 2	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Decreased appetite	2 (5.9%)	0	2 (4.4%)	6 (9.5%)
Grade 1	1 (2.9%)	0	1 (2.2%)	4 (6.3%)
Grade 2	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Appetite disorder	0	0	0	1 (1.6%)
Grade 1	0	0	0	1 (1.6%)
Calcium metabolism disorders	2 (5.9%)	1 (9.1%)	3 (6.7%)	5 (7.9%)
Grade 1	2 (5.9%)	0	2 (4.4%)	4 (6.3%)
Grade 3	0	1 (9.1%)	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Appetite disorders (cont)				
(cont)				
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Decreased appetite	0	2 (10.5%)	2 (7.1%)	2 (6.1%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Appetite disorder	0	0	0	0
Grade 1	0	0	0	0
Calcium metabolism disorders	0	1 (5.3%)	1 (3.6%)	2 (6.1%)
Grade 1	0	1 (5.3%)	1 (3.6%)	2 (6.1%)
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Calcium metabolism disorders (cont)				
Hypocalcaemia	2 (5.9%)	1 (9.1%)	3 (6.7%)	5 (7.9%)
Grade 1	2 (5.9%)	0	2 (4.4%)	4 (6.3%)
Grade 3	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Sodium imbalance	2 (5.9%)	0	2 (4.4%)	3 (4.8%)
Grade 1	2 (5.9%)	0	2 (4.4%)	3 (4.8%)
Grade 3	0	0	0	0
Hyponatraemia	2 (5.9%)	0	2 (4.4%)	3 (4.8%)
Grade 1	2 (5.9%)	0	2 (4.4%)	3 (4.8%)
Grade 3	0	0	0	0
Hypernatraemia	0	0	0	1 (1.6%)
Grade 1	0	0	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Calcium metabolism disorders (cont)				
Hypocalcaemia	0	1 (5.3%)	1 (3.6%)	2 (6.1%)
Grade 1	0	1 (5.3%)	1 (3.6%)	2 (6.1%)
Grade 3	0	0	0	0
Sodium imbalance	0	3 (15.8%)	3 (10.7%)	4 (12.1%)
Grade 1	0	1 (5.3%)	1 (3.6%)	2 (6.1%)
Grade 3	0	2 (10.5%)	2 (7.1%)	2 (6.1%)
Hyponatraemia	0	3 (15.8%)	3 (10.7%)	4 (12.1%)
Grade 1	0	1 (5.3%)	1 (3.6%)	2 (6.1%)
Grade 3	0	2 (10.5%)	2 (7.1%)	2 (6.1%)
Hypernatraemia	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Phosphorus metabolism disorders	1 (2.9%)	1 (9.1%)	2 (4.4%)	4 (6.3%)
Grade 1	0	0	0	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 3	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Hypophosphataemia	1 (2.9%)	1 (9.1%)	2 (4.4%)	3 (4.8%)
Grade 2	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 3	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Hyperphosphataemia	0	0	0	1 (1.6%)
Grade 1	0	0	0	1 (1.6%)
Hyperglycaemic conditions NEC	0	0	0	3 (4.8%)
Grade 1	0	0	0	1 (1.6%)
Grade 2	0	0	0	0
Grade 3	0	0	0	2 (3.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Phosphorus metabolism disorders	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	0	0	0
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 3	0	0	0	0
Hypophosphataemia	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 3	0	0	0	0
Hyperphosphataemia	0	0	0	0
Grade 1	0	0	0	0
Hyperglycaemic conditions NEC	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	0	0	0
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Hyperglycaemic conditions NEC (cont)				
Hyperglycaemia	0	0	0	3 (4.8%)
Grade 1	0	0	0	1 (1.6%)
Grade 2	0	0	0	0
Grade 3	0	0	0	2 (3.2%)
Magnesium metabolism disorders	1 (2.9%)	1 (9.1%)	2 (4.4%)	2 (3.2%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	0	0	0	0
Grade 3	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Hypomagnesaemia	1 (2.9%)	1 (9.1%)	2 (4.4%)	2 (3.2%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	0	0	0	0
Grade 3	0	1 (9.1%)	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Hyperglycaemic conditions NEC (cont)				
Hyperglycaemia	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	0	0	0
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 3	0	0	0	0
Magnesium metabolism disorders	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 1	0	0	0	0
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 3	0	0	0	0
Hypomagnesaemia	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 1	0	0	0	0
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Protein metabolism disorders NEC	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 2	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Hypoalbuminaemia	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 2	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Total fluid volume decreased	0	0	0	1 (1.6%)
Grade 1	0	0	0	1 (1.6%)
Dehydration	0	0	0	0
Grade 1	0	0	0	0
Hypovolaemia	0	0	0	1 (1.6%)
Grade 1	0	0	0	1 (1.6%)
Diabetes mellitus (incl subtypes)	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Protein metabolism disorders NEC	0	0	0	0
Grade 2	0	0	0	0
Hypoalbuminaemia	0	0	0	0
Grade 2	0	0	0	0
Total fluid volume decreased	0	0	0	1 (3.0%)
Grade 1	0	0	0	1 (3.0%)
Dehydration	0	0	0	1 (3.0%)
Grade 1	0	0	0	1 (3.0%)
Hypovolaemia	0	0	0	0
Grade 1	0	0	0	0
Diabetes mellitus (incl subtypes)	0	1 (5.3%)	1 (3.6%)	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Diabetes mellitus (incl subtypes) (cont) (cont)				
Grade 2	0	0	0	0
Diabetes mellitus	0	0	0	0
Grade 2	0	0	0	0
Electrolyte imbalance NEC	0	0	0	1 (1.6%)
Grade 3	0	0	0	1 (1.6%)
Tumour lysis syndrome	0	0	0	1 (1.6%)
Grade 3	0	0	0	1 (1.6%)
Elevated cholesterol	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Diabetes mellitus (incl subtypes) (cont) (cont)				
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Diabetes mellitus	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Electrolyte imbalance NEC	0	0	0	0
Grade 3	0	0	0	0
Tumour lysis syndrome	0	0	0	0
Grade 3	0	0	0	0
Elevated cholesterol	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 1	1 (11.1%)	0	1 (3.6%)	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Elevated cholesterol (cont)				
Hypercholesterolaemia	0	0	0	0
Grade 1	0	0	0	0
Total fluid volume increased	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Fluid overload	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Musculoskeletal and connective tissue disorders	14 (41.2%)	4 (36.4%)	18 (40.0%)	31 (49.2%)
Grade 1	7 (20.6%)	4 (36.4%)	11 (24.4%)	18 (28.6%)
Grade 2	7 (20.6%)	0	7 (15.6%)	11 (17.5%)
Grade 3	0	0	0	2 (3.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Metabolism and nutrition disorders (cont)				
Elevated cholesterol (cont)				
Hypercholesterolaemia	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 1	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Total fluid volume increased	0	0	0	0
Grade 2	0	0	0	0
Fluid overload	0	0	0	0
Grade 2	0	0	0	0
Musculoskeletal and connective tissue disorders	4 (44.4%)	7 (36.8%)	11 (39.3%)	12 (36.4%)
Grade 1	2 (22.2%)	3 (15.8%)	5 (17.9%)	6 (18.2%)
Grade 2	2 (22.2%)	4 (21.1%)	6 (21.4%)	6 (18.2%)
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Musculoskeletal and connective tissue pain and discomfort	8 (23.5%)	2 (18.2%)	10 (22.2%)	13 (20.6%)
Grade 1	5 (14.7%)	2 (18.2%)	7 (15.6%)	10 (15.9%)
Grade 2	3 (8.8%)	0	3 (6.7%)	3 (4.8%)
Pain in extremity	5 (14.7%)	0	5 (11.1%)	7 (11.1%)
Grade 1	3 (8.8%)	0	3 (6.7%)	5 (7.9%)
Grade 2	2 (5.9%)	0	2 (4.4%)	2 (3.2%)
Back pain	4 (11.8%)	1 (9.1%)	5 (11.1%)	6 (9.5%)
Grade 1	2 (5.9%)	1 (9.1%)	3 (6.7%)	4 (6.3%)
Grade 2	2 (5.9%)	0	2 (4.4%)	2 (3.2%)
Limb discomfort	0	1 (9.1%)	1 (2.2%)	2 (3.2%)
Grade 1	0	1 (9.1%)	1 (2.2%)	2 (3.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Musculoskeletal and connective tissue pain and discomfort	3 (33.3%)	2 (10.5%)	5 (17.9%)	6 (18.2%)
Grade 1	1 (11.1%)	1 (5.3%)	2 (7.1%)	3 (9.1%)
Grade 2	2 (22.2%)	1 (5.3%)	3 (10.7%)	3 (9.1%)
Pain in extremity	1 (11.1%)	1 (5.3%)	2 (7.1%)	3 (9.1%)
Grade 1	1 (11.1%)	1 (5.3%)	2 (7.1%)	3 (9.1%)
Grade 2	0	0	0	0
Back pain	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 1	0	0	0	0
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Limb discomfort	0	0	0	1 (3.0%)
Grade 1	0	0	0	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Musculoskeletal and connective tissue pain and discomfort (cont)				
Flank pain	0	0	0	0
Grade 1	0	0	0	0
Musculoskeletal chest pain	0	0	0	0
Grade 1	0	0	0	0
Musculoskeletal pain	0	0	0	0
Grade 2	0	0	0	0
Neck pain	0	0	0	0
Grade 2	0	0	0	0
Joint related signs and symptoms	2 (5.9%)	0	2 (4.4%)	4 (6.3%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Musculoskeletal and connective tissue pain and discomfort (cont)				
Flank pain	0	0	0	1 (3.0%)
Grade 1	0	0	0	1 (3.0%)
Musculoskeletal chest pain	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 1	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Musculoskeletal pain	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Neck pain	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Joint related signs and symptoms	1 (11.1%)	0	1 (3.6%)	5 (15.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-et.pdf 24AUG2023:15:00

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Joint related signs and symptoms (cont) (cont)				
Grade 1	2 (5.9%)	0	2 (4.4%)	4 (6.3%)
Grade 2	0	0	0	0
Arthralgia	2 (5.9%)	0	2 (4.4%)	4 (6.3%)
Grade 1	2 (5.9%)	0	2 (4.4%)	4 (6.3%)
Grade 2	0	0	0	0
Bone related signs and symptoms	2 (5.9%)	2 (18.2%)	4 (8.9%)	7 (11.1%)
Grade 1	1 (2.9%)	2 (18.2%)	3 (6.7%)	3 (4.8%)
Grade 2	1 (2.9%)	0	1 (2.2%)	4 (6.3%)
Bone pain	1 (2.9%)	2 (18.2%)	3 (6.7%)	5 (7.9%)
Grade 1	0	2 (18.2%)	2 (4.4%)	2 (3.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Joint related signs and symptoms (cont) (cont)				
Grade 1	1 (11.1%)	0	1 (3.6%)	4 (12.1%)
Grade 2	0	0	0	1 (3.0%)
Arthralgia	1 (11.1%)	0	1 (3.6%)	5 (15.2%)
Grade 1	1 (11.1%)	0	1 (3.6%)	4 (12.1%)
Grade 2	0	0	0	1 (3.0%)
Bone related signs and symptoms	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	0	0	0
Bone pain	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Bone related signs and symptoms (cont)				
Bone pain (cont)				
Grade 2	1 (2.9%)	0	1 (2.2%)	3 (4.8%)
Metatarsalgia	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Spinal pain	0	0	0	1 (1.6%)
Grade 2	0	0	0	1 (1.6%)
Muscle related signs and symptoms NEC	2 (5.9%)	1 (9.1%)	3 (6.7%)	5 (7.9%)
Grade 1	2 (5.9%)	1 (9.1%)	3 (6.7%)	5 (7.9%)
Grade 2	0	0	0	0
Muscle spasms	2 (5.9%)	1 (9.1%)	3 (6.7%)	5 (7.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Bone related signs and symptoms (cont)				
Bone pain (cont)				
Grade 2	0	0	0	0
Metatarsalgia	0	0	0	0
Grade 1	0	0	0	0
Spinal pain	0	0	0	0
Grade 2	0	0	0	0
Muscle related signs and symptoms NEC	1 (11.1%)	1 (5.3%)	2 (7.1%)	3 (9.1%)
Grade 1	0	1 (5.3%)	1 (3.6%)	2 (6.1%)
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Muscle spasms	1 (11.1%)	1 (5.3%)	2 (7.1%)	3 (9.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Muscle related signs and symptoms NEC (cont)				
Muscle spasms (cont)				
Grade 1	2 (5.9%)	1 (9.1%)	3 (6.7%)	5 (7.9%)
Grade 2	0	0	0	0
Muscle pains	2 (5.9%)	1 (9.1%)	3 (6.7%)	5 (7.9%)
Grade 1	2 (5.9%)	1 (9.1%)	3 (6.7%)	4 (6.3%)
Grade 2	0	0	0	1 (1.6%)
Myalgia	2 (5.9%)	1 (9.1%)	3 (6.7%)	5 (7.9%)
Grade 1	2 (5.9%)	1 (9.1%)	3 (6.7%)	4 (6.3%)
Grade 2	0	0	0	1 (1.6%)
Bone disorders NEC	2 (5.9%)	0	2 (4.4%)	2 (3.2%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Muscle related signs and symptoms NEC (cont)				
Muscle spasms (cont)				
Grade 1	0	1 (5.3%)	1 (3.6%)	2 (6.1%)
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Muscle pains	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Myalgia	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Bone disorders NEC	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Bone disorders NEC (cont)				
(cont)				
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Osteonecrosis	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Osteosis	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Crystal arthropathic disorders	0	0	0	1 (1.6%)
Grade 2	0	0	0	0
Grade 3	0	0	0	1 (1.6%)
Chondrocalcinosis pyrophosphate	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Bone disorders NEC (cont) (cont)				
Grade 2	0	0	0	0
Osteonecrosis	0	0	0	0
Grade 2	0	0	0	0
Osteosis	0	0	0	0
Grade 1	0	0	0	0
Crystal arthropathic disorders	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 3	0	0	0	0
Chondrocalcinosis pyrophosphate	0	1 (5.3%)	1 (3.6%)	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Crystal arthropathic disorders (cont)				
Chondrocalcinosis pyrophosphate (cont)				
Grade 2	0	0	0	0
Gouty arthritis	0	0	0	1 (1.6%)
Grade 3	0	0	0	1 (1.6%)
Muscle weakness conditions	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Muscular weakness	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Bursal disorders	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Crystal arthropathic disorders (cont)				
Chondrocalcinosis pyrophosphate (cont)				
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Gouty arthritis	0	0	0	0
Grade 3	0	0	0	0
Muscle weakness conditions	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Muscular weakness	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Bursal disorders	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Bursal disorders (cont)				
Bursitis	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Extremity deformities	0	0	0	0
Grade 2	0	0	0	0
Foot deformity	0	0	0	0
Grade 2	0	0	0	0
Musculoskeletal and connective tissue conditions NEC	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Muscle contracture	1 (2.9%)	0	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Bursal disorders (cont)				
Bursitis	0	0	0	0
Grade 2	0	0	0	0
Extremity deformities	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Foot deformity	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Musculoskeletal and connective tissue conditions NEC	0	0	0	0
Grade 1	0	0	0	0
Muscle contracture	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Musculoskeletal and connective tissue conditions NEC (cont)				
Muscle contracture (cont)				
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Soft tissue disorders NEC	0	0	0	1 (1.6%)
Grade 3	0	0	0	1 (1.6%)
Groin pain	0	0	0	1 (1.6%)
Grade 3	0	0	0	1 (1.6%)
Spine and neck deformities	0	0	0	0
Grade 2	0	0	0	0
Spinal stenosis	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Musculoskeletal and connective tissue conditions NEC (cont)				
Muscle contracture (cont)				
Grade 1	0	0	0	0
Soft tissue disorders NEC	0	0	0	0
Grade 3	0	0	0	0
Groin pain	0	0	0	0
Grade 3	0	0	0	0
Spine and neck deformities	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Spinal stenosis	1 (11.1%)	0	1 (3.6%)	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Spine and neck deformities (cont)				
Spinal stenosis (cont)				
Grade 2	0	0	0	0
Tendon disorders	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Tendonitis	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Investigations	14 (41.2%)	2 (18.2%)	16 (35.6%)	29 (46.0%)
Grade 1	5 (14.7%)	1 (9.1%)	6 (13.3%)	14 (22.2%)
Grade 2	5 (14.7%)	1 (9.1%)	6 (13.3%)	9 (14.3%)
Grade 3	4 (11.8%)	0	4 (8.9%)	6 (9.5%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Musculoskeletal and connective tissue disorders (cont)				
Spine and neck deformities (cont)				
Spinal stenosis (cont)				
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Tendon disorders	0	0	0	0
Grade 1	0	0	0	0
Tendonitis	0	0	0	0
Grade 1	0	0	0	0
Investigations	4 (44.4%)	7 (36.8%)	11 (39.3%)	11 (33.3%)
Grade 1	2 (22.2%)	2 (10.5%)	4 (14.3%)	4 (12.1%)
Grade 2	2 (22.2%)	3 (15.8%)	5 (17.9%)	5 (15.2%)
Grade 3	0	2 (10.5%)	2 (7.1%)	2 (6.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Physical examination procedures and organ system status	8 (23.5%)	1 (9.1%)	9 (20.0%)	17 (27.0%)
Grade 1	6 (17.6%)	1 (9.1%)	7 (15.6%)	13 (20.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	3 (4.8%)
Grade 3	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Weight decreased	3 (8.8%)	1 (9.1%)	4 (8.9%)	10 (15.9%)
Grade 1	2 (5.9%)	1 (9.1%)	3 (6.7%)	7 (11.1%)
Grade 2	1 (2.9%)	0	1 (2.2%)	3 (4.8%)
Weight increased	2 (5.9%)	0	2 (4.4%)	3 (4.8%)
Grade 1	2 (5.9%)	0	2 (4.4%)	3 (4.8%)
Eastern Cooperative Oncology Group performance status worsened	2 (5.9%)	0	2 (4.4%)	2 (3.2%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Physical examination procedures and organ system status	1 (11.1%)	4 (21.1%)	5 (17.9%)	5 (15.2%)
Grade 1	0	2 (10.5%)	2 (7.1%)	2 (6.1%)
Grade 2	1 (11.1%)	2 (10.5%)	3 (10.7%)	3 (9.1%)
Grade 3	0	0	0	0
Weight decreased	1 (11.1%)	3 (15.8%)	4 (14.3%)	4 (12.1%)
Grade 1	0	2 (10.5%)	2 (7.1%)	2 (6.1%)
Grade 2	1 (11.1%)	1 (5.3%)	2 (7.1%)	2 (6.1%)
Weight increased	0	0	0	0
Grade 1	0	0	0	0
Eastern Cooperative Oncology Group performance status worsened	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Physical examination procedures and organ system status (cont)				
Eastern Cooperative Oncology Group performance status worsened (cont)				
Grade 3	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Body temperature increased	0	0	0	1 (1.6%)
Grade 1	0	0	0	1 (1.6%)
Breath sounds abnormal	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
General physical condition abnormal	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Physical examination procedures and organ system status (cont)				
Eastern Cooperative Oncology Group performance status worsened (cont)				
Grade 3	0	0	0	0
Body temperature increased	0	0	0	0
Grade 1	0	0	0	0
Breath sounds abnormal	0	0	0	0
Grade 1	0	0	0	0
General physical condition abnormal	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Liver function analyses	4 (11.8%)	0	4 (8.9%)	9 (14.3%)
Grade 1	2 (5.9%)	0	2 (4.4%)	4 (6.3%)
Grade 2	1 (2.9%)	0	1 (2.2%)	3 (4.8%)
Grade 3	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Alanine aminotransferase increased	1 (2.9%)	0	1 (2.2%)	3 (4.8%)
Grade 1	0	0	0	1 (1.6%)
Grade 3	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Blood bilirubin increased	2 (5.9%)	0	2 (4.4%)	5 (7.9%)
Grade 1	2 (5.9%)	0	2 (4.4%)	3 (4.8%)
Grade 2	0	0	0	2 (3.2%)
Aspartate aminotransferase increased	0	0	0	2 (3.2%)
Grade 1	0	0	0	1 (1.6%)
Grade 2	0	0	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Liver function analyses	1 (11.1%)	2 (10.5%)	3 (10.7%)	3 (9.1%)
Grade 1	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 2	0	0	0	0
Grade 3	0	2 (10.5%)	2 (7.1%)	2 (6.1%)
Alanine aminotransferase increased	1 (11.1%)	1 (5.3%)	2 (7.1%)	2 (6.1%)
Grade 1	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Blood bilirubin increased	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Aspartate aminotransferase increased	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Liver function analyses (cont)				
Aspartate aminotransferase increased (cont)				
Grade 3	0	0	0	0
Gamma-glutamyltransferase increased	0	0	0	1 (1.6%)
Grade 1	0	0	0	0
Grade 3	0	0	0	1 (1.6%)
Hepatic enzyme increased	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Liver function test increased	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Liver function analyses (cont)				
Aspartate aminotransferase increased (cont)				
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Gamma-glutamyltransferase increased	1 (11.1%)	1 (5.3%)	2 (7.1%)	2 (6.1%)
Grade 1	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Hepatic enzyme increased	0	0	0	0
Grade 2	0	0	0	0
Liver function test increased	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Renal function analyses	4 (11.8%)	1 (9.1%)	5 (11.1%)	8 (12.7%)
Grade 1	1 (2.9%)	0	1 (2.2%)	3 (4.8%)
Grade 2	3 (8.8%)	1 (9.1%)	4 (8.9%)	4 (6.3%)
Grade 3	0	0	0	1 (1.6%)
Blood creatinine increased	3 (8.8%)	1 (9.1%)	4 (8.9%)	7 (11.1%)
Grade 1	1 (2.9%)	0	1 (2.2%)	3 (4.8%)
Grade 2	2 (5.9%)	1 (9.1%)	3 (6.7%)	3 (4.8%)
Grade 3	0	0	0	1 (1.6%)
Creatinine renal clearance decreased	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Tissue enzyme analyses NEC	2 (5.9%)	0	2 (4.4%)	5 (7.9%)
Grade 1	0	0	0	2 (3.2%)
Grade 2	1 (2.9%)	0	1 (2.2%)	2 (3.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Renal function analyses	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 1	0	0	0	0
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 3	0	0	0	0
Blood creatinine increased	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 1	0	0	0	0
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 3	0	0	0	0
Creatinine renal clearance decreased	0	0	0	0
Grade 2	0	0	0	0
Tissue enzyme analyses NEC	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 1	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Tissue enzyme analyses NEC (cont)				
(cont)				
Grade 3	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Blood alkaline phosphatase increased	1 (2.9%)	0	1 (2.2%)	3 (4.8%)
Grade 1	0	0	0	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Blood lactate dehydrogenase increased	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 1	0	0	0	1 (1.6%)
Grade 3	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Cardiac auscultatory investigations	1 (2.9%)	0	1 (2.2%)	3 (4.8%)
Grade 1	1 (2.9%)	0	1 (2.2%)	3 (4.8%)
Cardiac murmur	1 (2.9%)	0	1 (2.2%)	3 (4.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Tissue enzyme analyses NEC (cont)				
(cont)				
Grade 3	0	0	0	0
Blood alkaline phosphatase increased	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 1	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 2	0	0	0	0
Blood lactate dehydrogenase increased	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Cardiac auscultatory investigations	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 1	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Cardiac murmur	1 (11.1%)	0	1 (3.6%)	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Cardiac auscultatory investigations (cont)				
Cardiac murmur (cont)				
Grade 1	1 (2.9%)	0	1 (2.2%)	3 (4.8%)
Coagulation and bleeding analyses	2 (5.9%)	0	2 (4.4%)	3 (4.8%)
Grade 1	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
International normalised ratio increased	2 (5.9%)	0	2 (4.4%)	3 (4.8%)
Grade 1	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Mineral and electrolyte analyses	2 (5.9%)	0	2 (4.4%)	2 (3.2%)
Grade 1	2 (5.9%)	0	2 (4.4%)	2 (3.2%)
Blood bicarbonate decreased	1 (2.9%)	0	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Cardiac auscultatory investigations (cont)				
Cardiac murmur (cont)				
Grade 1	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Coagulation and bleeding analyses	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	0	0	0
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
International normalised ratio increased	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	0	0	0
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Mineral and electrolyte analyses	0	0	0	0
Grade 1	0	0	0	0
Blood bicarbonate decreased	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Mineral and electrolyte analyses (cont)				
Blood bicarbonate decreased (cont)				
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Blood chloride increased	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Cardiac function diagnostic procedures	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 2	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Ejection fraction decreased	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 2	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Haematological analyses NEC	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Mineral and electrolyte analyses (cont)				
Blood bicarbonate decreased (cont)				
Grade 1	0	0	0	0
Blood chloride increased	0	0	0	0
Grade 1	0	0	0	0
Cardiac function diagnostic procedures	0	0	0	0
Grade 2	0	0	0	0
Ejection fraction decreased	0	0	0	0
Grade 2	0	0	0	0
Haematological analyses NEC	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Haematological analyses NEC (cont)				
Blast cell count increased	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Skeletal and cardiac muscle analyses	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Troponin increased	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
White blood cell analyses	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 3	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Neutrophil count decreased	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 3	1 (2.9%)	0	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Investigations (cont)				
Haematological analyses NEC (cont)				
Blast cell count increased	0	0	0	0
Grade 2	0	0	0	0
Skeletal and cardiac muscle analyses	0	0	0	0
Grade 1	0	0	0	0
Troponin increased	0	0	0	0
Grade 1	0	0	0	0
White blood cell analyses	0	0	0	0
Grade 3	0	0	0	0
Neutrophil count decreased	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders	11 (32.4%)	4 (36.4%)	15 (33.3%)	30 (47.6%)
Grade 1	7 (20.6%)	1 (9.1%)	8 (17.8%)	20 (31.7%)
Grade 2	3 (8.8%)	2 (18.2%)	5 (11.1%)	8 (12.7%)
Grade 3	1 (2.9%)	1 (9.1%)	2 (4.4%)	2 (3.2%)
Pruritus NEC	4 (11.8%)	1 (9.1%)	5 (11.1%)	16 (25.4%)
Grade 1	3 (8.8%)	0	3 (6.7%)	10 (15.9%)
Grade 2	1 (2.9%)	1 (9.1%)	2 (4.4%)	6 (9.5%)
Grade 3	0	0	0	0
Pruritus	3 (8.8%)	0	3 (6.7%)	12 (19.0%)
Grade 1	2 (5.9%)	0	2 (4.4%)	8 (12.7%)
Grade 2	1 (2.9%)	0	1 (2.2%)	4 (6.3%)
Grade 3	0	0	0	0
Pruritus generalised	1 (2.9%)	1 (9.1%)	2 (4.4%)	4 (6.3%)
Grade 1	1 (2.9%)	0	1 (2.2%)	2 (3.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders	2 (22.2%)	6 (31.6%)	8 (28.6%)	10 (30.3%)
Grade 1	1 (11.1%)	3 (15.8%)	4 (14.3%)	6 (18.2%)
Grade 2	1 (11.1%)	2 (10.5%)	3 (10.7%)	3 (9.1%)
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Pruritus NEC	1 (11.1%)	2 (10.5%)	3 (10.7%)	3 (9.1%)
Grade 1	1 (11.1%)	1 (5.3%)	2 (7.1%)	2 (6.1%)
Grade 2	0	0	0	0
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Pruritus	1 (11.1%)	2 (10.5%)	3 (10.7%)	3 (9.1%)
Grade 1	1 (11.1%)	1 (5.3%)	2 (7.1%)	2 (6.1%)
Grade 2	0	0	0	0
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Pruritus generalised	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Pruritus NEC (cont)				
Pruritus generalised (cont)				
Grade 2	0	1 (9.1%)	1 (2.2%)	2 (3.2%)
Aquagenic pruritus	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Apocrine and eccrine gland disorders	3 (8.8%)	2 (18.2%)	5 (11.1%)	10 (15.9%)
Grade 1	1 (2.9%)	0	1 (2.2%)	5 (7.9%)
Grade 2	1 (2.9%)	1 (9.1%)	2 (4.4%)	3 (4.8%)
Grade 3	1 (2.9%)	1 (9.1%)	2 (4.4%)	2 (3.2%)
Night sweats	2 (5.9%)	2 (18.2%)	4 (8.9%)	8 (12.7%)
Grade 1	0	0	0	3 (4.8%)
Grade 2	1 (2.9%)	1 (9.1%)	2 (4.4%)	3 (4.8%)
Grade 3	1 (2.9%)	1 (9.1%)	2 (4.4%)	2 (3.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Pruritus NEC (cont)				
Pruritus generalised (cont)				
Grade 2	0	0	0	0
Aquagenic pruritus	0	0	0	0
Grade 1	0	0	0	0
Apocrine and eccrine gland disorders	0	4 (21.1%)	4 (14.3%)	5 (15.2%)
Grade 1	0	3 (15.8%)	3 (10.7%)	4 (12.1%)
Grade 2	0	0	0	0
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Night sweats	0	2 (10.5%)	2 (7.1%)	3 (9.1%)
Grade 1	0	2 (10.5%)	2 (7.1%)	3 (9.1%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Apocrine and eccrine gland disorders (cont)				
Hyperhidrosis	1 (2.9%)	0	1 (2.2%)	3 (4.8%)
Grade 1	1 (2.9%)	0	1 (2.2%)	3 (4.8%)
Grade 3	0	0	0	0
Rashes, eruptions and exanthems NEC	2 (5.9%)	1 (9.1%)	3 (6.7%)	5 (7.9%)
Grade 1	2 (5.9%)	1 (9.1%)	3 (6.7%)	5 (7.9%)
Grade 2	0	0	0	0
Rash	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 1	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Rash maculo-papular	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 1	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Apocrine and eccrine gland disorders (cont)				
Hyperhidrosis	0	2 (10.5%)	2 (7.1%)	2 (6.1%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Rashes, eruptions and exanthems NEC	0	1 (5.3%)	1 (3.6%)	2 (6.1%)
Grade 1	0	0	0	1 (3.0%)
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Rash	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Rash maculo-papular	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	0	0	0
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-et.pdf 24AUG2023:15:00

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Rashes, eruptions and exanthems NEC (cont)				
Rash generalised	0	0	0	0
Grade 1	0	0	0	0
Rash macular	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 1	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Dermal and epidermal conditions NEC	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Dry skin	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Skin lesion	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Rashes, eruptions and exanthems NEC (cont)				
Rash generalised	0	0	0	1 (3.0%)
Grade 1	0	0	0	1 (3.0%)
Rash macular	0	0	0	0
Grade 1	0	0	0	0
Dermal and epidermal conditions NEC	1 (11.1%)	2 (10.5%)	3 (10.7%)	4 (12.1%)
Grade 1	1 (11.1%)	2 (10.5%)	3 (10.7%)	4 (12.1%)
Dry skin	0	2 (10.5%)	2 (7.1%)	3 (9.1%)
Grade 1	0	2 (10.5%)	2 (7.1%)	3 (9.1%)
Skin lesion	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 1	1 (11.1%)	0	1 (3.6%)	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Purpura and related conditions	1 (2.9%)	1 (9.1%)	2 (4.4%)	4 (6.3%)
Grade 1	1 (2.9%)	0	1 (2.2%)	3 (4.8%)
Grade 2	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Petechiae	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Ecchymosis	0	0	0	1 (1.6%)
Grade 1	0	0	0	1 (1.6%)
Purpura	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 2	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Purpura senile	0	0	0	1 (1.6%)
Grade 1	0	0	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Purpura and related conditions	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	0	0	0
Petechiae	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Ecchymosis	0	0	0	0
Grade 1	0	0	0	0
Purpura	0	0	0	0
Grade 2	0	0	0	0
Purpura senile	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Erythemas	2 (5.9%)	1 (9.1%)	3 (6.7%)	3 (4.8%)
Grade 1	2 (5.9%)	1 (9.1%)	3 (6.7%)	3 (4.8%)
Erythema	2 (5.9%)	1 (9.1%)	3 (6.7%)	3 (4.8%)
Grade 1	2 (5.9%)	1 (9.1%)	3 (6.7%)	3 (4.8%)
Alopecias	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Alopecia	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Angioedemas	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Swelling face	1 (2.9%)	0	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Erythemas	0	0	0	0
Grade 1	0	0	0	0
Erythema	0	0	0	0
Grade 1	0	0	0	0
Alopecias	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Alopecia	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Angioedemas	0	0	0	0
Grade 1	0	0	0	0
Swelling face	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Angioedemas (cont)				
Swelling face (cont)				
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Bullous conditions	0	0	0	0
Grade 2	0	0	0	0
Erythema multiforme	0	0	0	0
Grade 2	0	0	0	0
Dermatitis and eczema	0	0	0	0
Grade 2	0	0	0	0
Dermatitis contact	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Angioedemas (cont)				
Swelling face (cont)				
Grade 1	0	0	0	0
Bullous conditions	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Erythema multiforme	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Dermatitis and eczema	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Dermatitis contact	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Dermatitis ascribed to specific agent	0	0	0	1 (1.6%)
Grade 1	0	0	0	1 (1.6%)
Palmar-plantar erythrodysaesthesia syndrome	0	0	0	1 (1.6%)
Grade 1	0	0	0	1 (1.6%)
Rosaceas	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 1	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Rosacea	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 1	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Skin and subcutaneous tissue ulcerations	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Dermatitis ascribed to specific agent	0	0	0	0
Grade 1	0	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	0	0	0	0
Grade 1	0	0	0	0
Rosaceas	0	0	0	0
Grade 1	0	0	0	0
Rosacea	0	0	0	0
Grade 1	0	0	0	0
Skin and subcutaneous tissue ulcerations	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Skin and subcutaneous tissue ulcerations (cont)				
Skin ulcer	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Skin preneoplastic conditions NEC	0	0	0	0
Grade 2	0	0	0	0
Actinic keratosis	0	0	0	0
Grade 2	0	0	0	0
Renal and urinary disorders	12 (35.3%)	4 (36.4%)	16 (35.6%)	19 (30.2%)
Grade 1	3 (8.8%)	0	3 (6.7%)	4 (6.3%)
Grade 2	4 (11.8%)	3 (27.3%)	7 (15.6%)	9 (14.3%)
Grade 3	3 (8.8%)	1 (9.1%)	4 (8.9%)	4 (6.3%)
Grade 5	2 (5.9%)	0	2 (4.4%)	2 (3.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Skin and subcutaneous tissue disorders (cont)				
Skin and subcutaneous tissue ulcerations (cont)				
Skin ulcer	0	0	0	0
Grade 2	0	0	0	0
Skin preneoplastic conditions NEC	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Actinic keratosis	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Renal and urinary disorders	3 (33.3%)	7 (36.8%)	10 (35.7%)	10 (30.3%)
Grade 1	1 (11.1%)	6 (31.6%)	7 (25.0%)	7 (21.2%)
Grade 2	2 (22.2%)	0	2 (7.1%)	2 (6.1%)
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 5	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal failure and impairment	9 (26.5%)	3 (27.3%)	12 (26.7%)	15 (23.8%)
Grade 1	2 (5.9%)	0	2 (4.4%)	3 (4.8%)
Grade 2	4 (11.8%)	2 (18.2%)	6 (13.3%)	8 (12.7%)
Grade 3	2 (5.9%)	1 (9.1%)	3 (6.7%)	3 (4.8%)
Grade 5	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Acute kidney injury	3 (8.8%)	1 (9.1%)	4 (8.9%)	5 (7.9%)
Grade 1	2 (5.9%)	0	2 (4.4%)	2 (3.2%)
Grade 2	1 (2.9%)	1 (9.1%)	2 (4.4%)	3 (4.8%)
Grade 3	0	0	0	0
Renal failure	3 (8.8%)	1 (9.1%)	4 (8.9%)	5 (7.9%)
Grade 1	0	0	0	0
Grade 2	1 (2.9%)	1 (9.1%)	2 (4.4%)	3 (4.8%)
Grade 3	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 5	1 (2.9%)	0	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal failure and impairment	1 (11.1%)	3 (15.8%)	4 (14.3%)	4 (12.1%)
Grade 1	0	2 (10.5%)	2 (7.1%)	2 (6.1%)
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 5	0	0	0	0
Acute kidney injury	1 (11.1%)	3 (15.8%)	4 (14.3%)	4 (12.1%)
Grade 1	0	2 (10.5%)	2 (7.1%)	2 (6.1%)
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Renal failure	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Grade 5	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal failure and impairment (cont)				
Chronic kidney disease	2 (5.9%)	1 (9.1%)	3 (6.7%)	3 (4.8%)
Grade 2	2 (5.9%)	0	2 (4.4%)	2 (3.2%)
Grade 3	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Renal impairment	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 1	0	0	0	1 (1.6%)
Grade 3	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Bladder and urethral symptoms	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	0	0	0	0
Dysuria	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal failure and impairment (cont)				
Chronic kidney disease	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Renal impairment	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Bladder and urethral symptoms	2 (22.2%)	4 (21.1%)	6 (21.4%)	6 (18.2%)
Grade 1	1 (11.1%)	4 (21.1%)	5 (17.9%)	5 (15.2%)
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Dysuria	2 (22.2%)	1 (5.3%)	3 (10.7%)	3 (9.1%)
Grade 1	1 (11.1%)	1 (5.3%)	2 (7.1%)	2 (6.1%)
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-et.pdf 24AUG2023:15:00

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Bladder and urethral symptoms (cont)				
Urinary incontinence	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Bladder spasm	0	0	0	0
Grade 1	0	0	0	0
Micturition urgency	0	0	0	1 (1.6%)
Grade 1	0	0	0	1 (1.6%)
Renal lithiasis	2 (5.9%)	0	2 (4.4%)	3 (4.8%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 3	0	0	0	1 (1.6%)
Nephrolithiasis	2 (5.9%)	0	2 (4.4%)	3 (4.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Bladder and urethral symptoms (cont)				
Urinary incontinence	0	2 (10.5%)	2 (7.1%)	2 (6.1%)
Grade 1	0	2 (10.5%)	2 (7.1%)	2 (6.1%)
Bladder spasm	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Micturition urgency	0	0	0	0
Grade 1	0	0	0	0
Renal lithiasis	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Nephrolithiasis	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal lithiasis (cont)				
Nephrolithiasis (cont)				
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 3	0	0	0	1 (1.6%)
Urinary abnormalities	2 (5.9%)	0	2 (4.4%)	2 (3.2%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Proteinuria	2 (5.9%)	0	2 (4.4%)	2 (3.2%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Haematuria	0	0	0	1 (1.6%)
Grade 1	0	0	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Renal lithiasis (cont)				
Nephrolithiasis (cont)				
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Urinary abnormalities	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Proteinuria	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Haematuria	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Bladder disorders NEC	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 2	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Urinary bladder haemorrhage	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 2	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Myoneurogenic bladder disorders	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Hypertonic bladder	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Nephritis NEC	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 5	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Nephritis	1 (2.9%)	0	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-et.pdf 24AUG2023:15:00

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Bladder disorders NEC	0	0	0	0
Grade 2	0	0	0	0
Urinary bladder haemorrhage	0	0	0	0
Grade 2	0	0	0	0
Myoneurogenic bladder disorders	0	0	0	0
Grade 2	0	0	0	0
Hypertonic bladder	0	0	0	0
Grade 2	0	0	0	0
Nephritis NEC	0	0	0	0
Grade 5	0	0	0	0
Nephritis	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Nephritis NEC (cont)				
Nephritis (cont)				
Grade 5	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Renal neoplasms	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Renal cyst	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Urinary tract lithiasis (excl renal)	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 3	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Ureterolithiasis	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 3	1 (2.9%)	0	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Nephritis NEC (cont)				
Nephritis (cont)				
Grade 5	0	0	0	0
Renal neoplasms	0	0	0	0
Grade 1	0	0	0	0
Renal cyst	0	0	0	0
Grade 1	0	0	0	0
Urinary tract lithiasis (excl renal)	0	0	0	0
Grade 3	0	0	0	0
Ureterolithiasis	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Urinary tract signs and symptoms NEC	0	0	0	1 (1.6%)
Grade 2	0	0	0	1 (1.6%)
Renal colic	0	0	0	1 (1.6%)
Grade 2	0	0	0	1 (1.6%)
Vascular disorders	7 (20.6%)	3 (27.3%)	10 (22.2%)	15 (23.8%)
Grade 1	2 (5.9%)	2 (18.2%)	4 (8.9%)	5 (7.9%)
Grade 2	2 (5.9%)	1 (9.1%)	3 (6.7%)	4 (6.3%)
Grade 3	3 (8.8%)	0	3 (6.7%)	5 (7.9%)
Grade 4	0	0	0	1 (1.6%)
Vascular hypertensive disorders NEC	2 (5.9%)	0	2 (4.4%)	5 (7.9%)
Grade 2	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 3	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 4	0	0	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Renal and urinary disorders (cont)				
Urinary tract signs and symptoms NEC	0	0	0	0
Grade 2	0	0	0	0
Renal colic	0	0	0	0
Grade 2	0	0	0	0
Vascular disorders	3 (33.3%)	4 (21.1%)	7 (25.0%)	9 (27.3%)
Grade 1	0	1 (5.3%)	1 (3.6%)	2 (6.1%)
Grade 2	3 (33.3%)	2 (10.5%)	5 (17.9%)	6 (18.2%)
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 4	0	0	0	0
Vascular hypertensive disorders NEC	0	1 (5.3%)	1 (3.6%)	3 (9.1%)
Grade 2	0	1 (5.3%)	1 (3.6%)	3 (9.1%)
Grade 3	0	0	0	0
Grade 4	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Vascular hypertensive disorders NEC (cont)				
Hypertension	2 (5.9%)	0	2 (4.4%)	5 (7.9%)
Grade 2	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 3	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 4	0	0	0	1 (1.6%)
Vascular hypotensive disorders	1 (2.9%)	2 (18.2%)	3 (6.7%)	4 (6.3%)
Grade 1	1 (2.9%)	1 (9.1%)	2 (4.4%)	3 (4.8%)
Grade 2	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Hypotension	1 (2.9%)	2 (18.2%)	3 (6.7%)	3 (4.8%)
Grade 1	1 (2.9%)	1 (9.1%)	2 (4.4%)	2 (3.2%)
Grade 2	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Orthostatic hypotension	0	0	0	1 (1.6%)
Grade 1	0	0	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Vascular hypertensive disorders NEC (cont)				
Hypertension	0	1 (5.3%)	1 (3.6%)	3 (9.1%)
Grade 2	0	1 (5.3%)	1 (3.6%)	3 (9.1%)
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Vascular hypotensive disorders	1 (11.1%)	0	1 (3.6%)	2 (6.1%)
Grade 1	0	0	0	1 (3.0%)
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Hypotension	1 (11.1%)	0	1 (3.6%)	2 (6.1%)
Grade 1	0	0	0	1 (3.0%)
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Orthostatic hypotension	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-et.pdf 24AUG2023:15:00

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Haemorrhages NEC	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	0	0	0	0
Grade 3	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Haematoma	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	0	0	0	0
Grade 3	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Peripheral embolism and thrombosis	0	0	0	0
Grade 2	0	0	0	0
Deep vein thrombosis	0	0	0	0
Grade 2	0	0	0	0
Thrombophlebitis	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Haemorrhages NEC	0	2 (10.5%)	2 (7.1%)	2 (6.1%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Haematoma	0	2 (10.5%)	2 (7.1%)	2 (6.1%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Peripheral embolism and thrombosis	2 (22.2%)	1 (5.3%)	3 (10.7%)	3 (9.1%)
Grade 2	2 (22.2%)	1 (5.3%)	3 (10.7%)	3 (9.1%)
Deep vein thrombosis	2 (22.2%)	0	2 (7.1%)	2 (6.1%)
Grade 2	2 (22.2%)	0	2 (7.1%)	2 (6.1%)
Thrombophlebitis	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Peripheral vascular disorders NEC	1 (2.9%)	1 (9.1%)	2 (4.4%)	2 (3.2%)
Grade 1	1 (2.9%)	1 (9.1%)	2 (4.4%)	2 (3.2%)
Hot flush	1 (2.9%)	1 (9.1%)	2 (4.4%)	2 (3.2%)
Grade 1	1 (2.9%)	1 (9.1%)	2 (4.4%)	2 (3.2%)
Non-site specific embolism and thrombosis	2 (5.9%)	0	2 (4.4%)	2 (3.2%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 3	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Embolism	2 (5.9%)	0	2 (4.4%)	2 (3.2%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 3	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Site specific vascular disorders NEC	2 (5.9%)	0	2 (4.4%)	2 (3.2%)
Grade 1	2 (5.9%)	0	2 (4.4%)	2 (3.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Peripheral vascular disorders NEC	0	0	0	1 (3.0%)
Grade 1	0	0	0	1 (3.0%)
Hot flush	0	0	0	1 (3.0%)
Grade 1	0	0	0	1 (3.0%)
Non-site specific embolism and thrombosis	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Embolism	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Site specific vascular disorders NEC	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Site specific vascular disorders NEC (cont)				
Jugular vein distension	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Pallor	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Aortic necrosis and vascular insufficiency	0	0	0	1 (1.6%)
Grade 3	0	0	0	1 (1.6%)
Aortic stenosis	0	0	0	1 (1.6%)
Grade 3	0	0	0	1 (1.6%)
Peripheral vasoconstriction, necrosis and vascular insufficiency	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 1	0	1 (9.1%)	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Site specific vascular disorders NEC (cont)				
Jugular vein distension	0	0	0	0
Grade 1	0	0	0	0
Pallor	0	0	0	0
Grade 1	0	0	0	0
Aortic necrosis and vascular insufficiency	0	0	0	0
Grade 3	0	0	0	0
Aortic stenosis	0	0	0	0
Grade 3	0	0	0	0
Peripheral vasoconstriction, necrosis and vascular insufficiency	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Peripheral vasoconstriction, necrosis and vascular insufficiency (cont)				
Peripheral coldness	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 1	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Psychiatric disorders	10 (29.4%)	1 (9.1%)	11 (24.4%)	14 (22.2%)
Grade 1	5 (14.7%)	0	5 (11.1%)	6 (9.5%)
Grade 2	5 (14.7%)	1 (9.1%)	6 (13.3%)	8 (12.7%)
Disturbances in initiating and maintaining sleep	4 (11.8%)	0	4 (8.9%)	5 (7.9%)
Grade 1	3 (8.8%)	0	3 (6.7%)	3 (4.8%)
Grade 2	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Insomnia	4 (11.8%)	0	4 (8.9%)	5 (7.9%)
Grade 1	3 (8.8%)	0	3 (6.7%)	3 (4.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Vascular disorders (cont)				
Peripheral vasoconstriction, necrosis and vascular insufficiency (cont)				
Peripheral coldness	0	0	0	0
Grade 1	0	0	0	0
Psychiatric disorders	0	6 (31.6%)	6 (21.4%)	9 (27.3%)
Grade 1	0	3 (15.8%)	3 (10.7%)	5 (15.2%)
Grade 2	0	3 (15.8%)	3 (10.7%)	4 (12.1%)
Disturbances in initiating and maintaining sleep	0	3 (15.8%)	3 (10.7%)	4 (12.1%)
Grade 1	0	2 (10.5%)	2 (7.1%)	3 (9.1%)
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Insomnia	0	3 (15.8%)	3 (10.7%)	4 (12.1%)
Grade 1	0	2 (10.5%)	2 (7.1%)	3 (9.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-et.pdf 24AUG2023:15:00

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Disturbances in initiating and maintaining sleep (cont)				
Insomnia (cont)				
Grade 2	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Confusion and disorientation	3 (8.8%)	0	3 (6.7%)	4 (6.3%)
Grade 1	3 (8.8%)	0	3 (6.7%)	3 (4.8%)
Grade 2	0	0	0	1 (1.6%)
Confusional state	3 (8.8%)	0	3 (6.7%)	4 (6.3%)
Grade 1	3 (8.8%)	0	3 (6.7%)	3 (4.8%)
Grade 2	0	0	0	1 (1.6%)
Anxiety symptoms	2 (5.9%)	0	2 (4.4%)	5 (7.9%)
Grade 1	0	0	0	3 (4.8%)
Grade 2	2 (5.9%)	0	2 (4.4%)	2 (3.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-et.pdf 24AUG2023:15:00

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Disturbances in initiating and maintaining sleep (cont)				
Insomnia (cont)				
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Confusion and disorientation	0	2 (10.5%)	2 (7.1%)	2 (6.1%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Confusional state	0	2 (10.5%)	2 (7.1%)	2 (6.1%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Anxiety symptoms	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Anxiety symptoms (cont)				
Anxiety	2 (5.9%)	0	2 (4.4%)	3 (4.8%)
Grade 1	0	0	0	1 (1.6%)
Grade 2	2 (5.9%)	0	2 (4.4%)	2 (3.2%)
Agitation	0	0	0	2 (3.2%)
Grade 1	0	0	0	2 (3.2%)
Depressive disorders	0	0	0	1 (1.6%)
Grade 2	0	0	0	1 (1.6%)
Depression	0	0	0	1 (1.6%)
Grade 2	0	0	0	1 (1.6%)
Increased physical activity levels	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Anxiety symptoms (cont)				
Anxiety	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Agitation	0	0	0	0
Grade 1	0	0	0	0
Depressive disorders	0	1 (5.3%)	1 (3.6%)	2 (6.1%)
Grade 2	0	1 (5.3%)	1 (3.6%)	2 (6.1%)
Depression	0	1 (5.3%)	1 (3.6%)	2 (6.1%)
Grade 2	0	1 (5.3%)	1 (3.6%)	2 (6.1%)
Increased physical activity levels	0	0	0	1 (3.0%)
Grade 1	0	0	0	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Increased physical activity levels (cont)				
Restlessness	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Mood alterations with depressive symptoms	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	0	0	0	0
Depressed mood	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	0	0	0	0
Deliria	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 2	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Delirium	0	1 (9.1%)	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Increased physical activity levels (cont)				
Restlessness	0	0	0	1 (3.0%)
Grade 1	0	0	0	1 (3.0%)
Mood alterations with depressive symptoms	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	0	0	0
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Depressed mood	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	0	0	0
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Deliria	0	0	0	0
Grade 2	0	0	0	0
Delirium	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Deliria (cont)				
Delirium (cont)				
Grade 2	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Emotional and mood disturbances NEC	0	0	0	1 (1.6%)
Grade 1	0	0	0	1 (1.6%)
Irritability	0	0	0	1 (1.6%)
Grade 1	0	0	0	1 (1.6%)
Sexual desire disorders	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Libido increased	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Deliria (cont)				
Delirium (cont)				
Grade 2	0	0	0	0
Emotional and mood disturbances NEC	0	0	0	0
Grade 1	0	0	0	0
Irritability	0	0	0	0
Grade 1	0	0	0	0
Sexual desire disorders	0	0	0	0
Grade 2	0	0	0	0
Libido increased	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Sleep disorders NEC	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Sleep disorder	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Cardiac disorders	6 (17.6%)	2 (18.2%)	8 (17.8%)	13 (20.6%)
Grade 1	1 (2.9%)	1 (9.1%)	2 (4.4%)	2 (3.2%)
Grade 2	2 (5.9%)	0	2 (4.4%)	2 (3.2%)
Grade 3	1 (2.9%)	1 (9.1%)	2 (4.4%)	7 (11.1%)
Grade 4	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 5	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Heart failures NEC	3 (8.8%)	1 (9.1%)	4 (8.9%)	7 (11.1%)
Grade 3	2 (5.9%)	1 (9.1%)	3 (6.7%)	6 (9.5%)
Grade 5	1 (2.9%)	0	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Psychiatric disorders (cont)				
Sleep disorders NEC	0	0	0	0
Grade 2	0	0	0	0
Sleep disorder	0	0	0	0
Grade 2	0	0	0	0
Cardiac disorders	2 (22.2%)	5 (26.3%)	7 (25.0%)	7 (21.2%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	3 (15.8%)	3 (10.7%)	3 (9.1%)
Grade 3	2 (22.2%)	1 (5.3%)	3 (10.7%)	3 (9.1%)
Grade 4	0	0	0	0
Grade 5	0	0	0	0
Heart failures NEC	1 (11.1%)	1 (5.3%)	2 (7.1%)	2 (6.1%)
Grade 3	1 (11.1%)	1 (5.3%)	2 (7.1%)	2 (6.1%)
Grade 5	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Heart failures NEC (cont)				
Cardiac failure	1 (2.9%)	1 (9.1%)	2 (4.4%)	4 (6.3%)
Grade 3	0	1 (9.1%)	1 (2.2%)	3 (4.8%)
Grade 5	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Cardiac failure congestive	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 3	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Cardiac failure acute	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 3	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Supraventricular arrhythmias	3 (8.8%)	0	3 (6.7%)	6 (9.5%)
Grade 2	2 (5.9%)	0	2 (4.4%)	2 (3.2%)
Grade 3	0	0	0	3 (4.8%)
Grade 4	1 (2.9%)	0	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Heart failures NEC (cont)				
Cardiac failure	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 3	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 5	0	0	0	0
Cardiac failure congestive	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Cardiac failure acute	0	0	0	0
Grade 3	0	0	0	0
Supraventricular arrhythmias	1 (11.1%)	1 (5.3%)	2 (7.1%)	2 (6.1%)
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 3	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 4	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Supraventricular arrhythmias (cont)				
Atrial fibrillation	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 2	0	0	0	0
Grade 3	0	0	0	1 (1.6%)
Grade 4	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Sinus tachycardia	2 (5.9%)	0	2 (4.4%)	3 (4.8%)
Grade 2	2 (5.9%)	0	2 (4.4%)	2 (3.2%)
Grade 3	0	0	0	1 (1.6%)
Supraventricular tachycardia	0	0	0	1 (1.6%)
Grade 3	0	0	0	1 (1.6%)
Cardiac signs and symptoms NEC	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Supraventricular arrhythmias (cont)				
Atrial fibrillation	1 (11.1%)	1 (5.3%)	2 (7.1%)	2 (6.1%)
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 3	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 4	0	0	0	0
Sinus tachycardia	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Supraventricular tachycardia	0	0	0	0
Grade 3	0	0	0	0
Cardiac signs and symptoms NEC	0	1 (5.3%)	1 (3.6%)	2 (6.1%)
Grade 1	0	1 (5.3%)	1 (3.6%)	2 (6.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Cardiac signs and symptoms NEC (cont)				
Palpitations	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Left ventricular failures	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 3	0	0	0	0
Left ventricular failure	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 3	0	0	0	0
Ischaemic coronary artery disorders	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	0	0	0	0
Grade 3	1 (2.9%)	0	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Cardiac signs and symptoms NEC (cont)				
Palpitations	0	1 (5.3%)	1 (3.6%)	2 (6.1%)
Grade 1	0	1 (5.3%)	1 (3.6%)	2 (6.1%)
Left ventricular failures	1 (11.1%)	1 (5.3%)	2 (7.1%)	2 (6.1%)
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Left ventricular failure	1 (11.1%)	1 (5.3%)	2 (7.1%)	2 (6.1%)
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Ischaemic coronary artery disorders	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Ischaemic coronary artery disorders (cont)				
Acute myocardial infarction	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 3	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Myocardial ischaemia	0	0	0	0
Grade 2	0	0	0	0
Pericardial disorders NEC	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	0	0	0	0
Pericardial effusion	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	0	0	0	0
Rate and rhythm disorders NEC	1 (2.9%)	1 (9.1%)	2 (4.4%)	2 (3.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Ischaemic coronary artery disorders (cont)				
Acute myocardial infarction	0	0	0	0
Grade 3	0	0	0	0
Myocardial ischaemia	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Pericardial disorders NEC	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	0	0	0
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Pericardial effusion	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	0	0	0
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Rate and rhythm disorders NEC	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Rate and rhythm disorders NEC (cont) (cont)				
Grade 1	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 3	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Extrasystoles	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 1	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Tachycardia	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 3	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Aortic valvular disorders	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Aortic valve calcification	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Rate and rhythm disorders NEC (cont)				
(cont)				
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Extrasystoles	0	0	0	0
Grade 1	0	0	0	0
Tachycardia	0	0	0	0
Grade 3	0	0	0	0
Aortic valvular disorders	0	0	0	0
Grade 1	0	0	0	0
Aortic valve calcification	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Cardiomyopathies	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Cardiomyopathy	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Coronary artery disorders NEC	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Arteriosclerosis coronary artery	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Myocardial disorders NEC	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Cardiomegaly	1 (2.9%)	0	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Cardiomyopathies	0	0	0	0
Grade 1	0	0	0	0
Cardiomyopathy	0	0	0	0
Grade 1	0	0	0	0
Coronary artery disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Arteriosclerosis coronary artery	0	0	0	0
Grade 1	0	0	0	0
Myocardial disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Cardiomegaly	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Myocardial disorders NEC (cont)				
Cardiomegaly (cont)				
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Injury, poisoning and procedural complications	4 (11.8%)	2 (18.2%)	6 (13.3%)	9 (14.3%)
Grade 1	2 (5.9%)	1 (9.1%)	3 (6.7%)	5 (7.9%)
Grade 2	0	1 (9.1%)	1 (2.2%)	2 (3.2%)
Grade 3	2 (5.9%)	0	2 (4.4%)	2 (3.2%)
Skin injuries NEC	0	1 (9.1%)	1 (2.2%)	3 (4.8%)
Grade 1	0	1 (9.1%)	1 (2.2%)	3 (4.8%)
Contusion	0	1 (9.1%)	1 (2.2%)	3 (4.8%)
Grade 1	0	1 (9.1%)	1 (2.2%)	3 (4.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Cardiac disorders (cont)				
Myocardial disorders NEC (cont)				
Cardiomegaly (cont)				
Grade 1	0	0	0	0
Injury, poisoning and procedural complications	3 (33.3%)	1 (5.3%)	4 (14.3%)	7 (21.2%)
Grade 1	0	1 (5.3%)	1 (3.6%)	3 (9.1%)
Grade 2	2 (22.2%)	0	2 (7.1%)	2 (6.1%)
Grade 3	1 (11.1%)	0	1 (3.6%)	2 (6.1%)
Skin injuries NEC	0	0	0	3 (9.1%)
Grade 1	0	0	0	3 (9.1%)
Contusion	0	0	0	3 (9.1%)
Grade 1	0	0	0	3 (9.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Non-site specific injuries NEC	2 (5.9%)	0	2 (4.4%)	3 (4.8%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	0	0	0	1 (1.6%)
Grade 3	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Fall	2 (5.9%)	0	2 (4.4%)	3 (4.8%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	0	0	0	1 (1.6%)
Grade 3	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Limb fractures and dislocations	0	0	0	1 (1.6%)
Grade 2	0	0	0	1 (1.6%)
Grade 3	0	0	0	0
Femur fracture	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Non-site specific injuries NEC	1 (11.1%)	1 (5.3%)	2 (7.1%)	2 (6.1%)
Grade 1	1 (11.1%)	1 (5.3%)	2 (7.1%)	2 (6.1%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Fall	1 (11.1%)	1 (5.3%)	2 (7.1%)	2 (6.1%)
Grade 1	1 (11.1%)	1 (5.3%)	2 (7.1%)	2 (6.1%)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Limb fractures and dislocations	0	0	0	1 (3.0%)
Grade 2	0	0	0	0
Grade 3	0	0	0	1 (3.0%)
Femur fracture	0	0	0	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Limb fractures and dislocations (cont)				
Femur fracture (cont)				
Grade 3	0	0	0	0
Radius fracture	0	0	0	1 (1.6%)
Grade 2	0	0	0	1 (1.6%)
Muscle, tendon and ligament injuries	1 (2.9%)	1 (9.1%)	2 (4.4%)	2 (3.2%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Ligament sprain	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Muscle rupture	0	1 (9.1%)	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Limb fractures and dislocations (cont)				
Femur fracture (cont)				
Grade 3	0	0	0	1 (3.0%)
Radius fracture	0	0	0	0
Grade 2	0	0	0	0
Muscle, tendon and ligament injuries	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Ligament sprain	0	0	0	0
Grade 1	0	0	0	0
Muscle rupture	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Muscle, tendon and ligament injuries (cont)				
Muscle rupture (cont)				
Grade 2	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Non-site specific procedural complications	1 (2.9%)	1 (9.1%)	2 (4.4%)	2 (3.2%)
Grade 1	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 3	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Procedural pain	1 (2.9%)	1 (9.1%)	2 (4.4%)	2 (3.2%)
Grade 1	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 3	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Cerebral injuries NEC	0	0	0	0
Grade 3	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Muscle, tendon and ligament injuries (cont)				
Muscle rupture (cont)				
Grade 2	0	0	0	0
Non-site specific procedural complications	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Procedural pain	0	0	0	0
Grade 1	0	0	0	0
Grade 3	0	0	0	0
Cerebral injuries NEC	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 3	1 (11.1%)	0	1 (3.6%)	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Cerebral injuries NEC (cont)				
Subdural haematoma	0	0	0	0
Grade 3	0	0	0	0
Fractures and dislocations NEC	0	0	0	0
Grade 2	0	0	0	0
Joint dislocation	0	0	0	0
Grade 2	0	0	0	0
Site specific injuries NEC	0	0	0	0
Grade 2	0	0	0	0
Tooth fracture	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Injury, poisoning and procedural complications (cont)				
Cerebral injuries NEC (cont)				
Subdural haematoma	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 3	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Fractures and dislocations NEC	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Joint dislocation	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Site specific injuries NEC	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Tooth fracture	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders	3 (8.8%)	2 (18.2%)	5 (11.1%)	10 (15.9%)
Grade 1	2 (5.9%)	1 (9.1%)	3 (6.7%)	6 (9.5%)
Grade 2	1 (2.9%)	1 (9.1%)	2 (4.4%)	4 (6.3%)
Grade 3	0	0	0	0
Visual disorders NEC	1 (2.9%)	0	1 (2.2%)	3 (4.8%)
Grade 1	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 2	0	0	0	1 (1.6%)
Vision blurred	1 (2.9%)	0	1 (2.2%)	3 (4.8%)
Grade 1	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 2	0	0	0	1 (1.6%)
Photopsia	0	0	0	1 (1.6%)
Grade 1	0	0	0	0
Grade 2	0	0	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders	1 (11.1%)	3 (15.8%)	4 (14.3%)	5 (15.2%)
Grade 1	1 (11.1%)	1 (5.3%)	2 (7.1%)	3 (9.1%)
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Visual disorders NEC	1 (11.1%)	1 (5.3%)	2 (7.1%)	2 (6.1%)
Grade 1	1 (11.1%)	1 (5.3%)	2 (7.1%)	2 (6.1%)
Grade 2	0	0	0	0
Vision blurred	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 1	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 2	0	0	0	0
Photopsia	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Cataract conditions	1 (2.9%)	0	1 (2.2%)	4 (6.3%)
Grade 1	0	0	0	2 (3.2%)
Grade 2	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Cataract subcapsular	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 1	0	0	0	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Cataract	0	0	0	1 (1.6%)
Grade 2	0	0	0	1 (1.6%)
Cataract nuclear	0	0	0	1 (1.6%)
Grade 1	0	0	0	1 (1.6%)
Lacrimation disorders	0	1 (9.1%)	1 (2.2%)	2 (3.2%)
Grade 1	0	0	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Cataract conditions	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Cataract subcapsular	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Cataract	0	0	0	0
Grade 2	0	0	0	0
Cataract nuclear	0	0	0	0
Grade 1	0	0	0	0
Lacrimation disorders	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

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Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Lacrimation disorders (cont) (cont)				
Grade 2	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Dry eye	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 1	0	0	0	0
Grade 2	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Lacrimation increased	0	0	0	1 (1.6%)
Grade 1	0	0	0	1 (1.6%)
Conjunctival and corneal bleeding and vascular disorders	0	0	0	1 (1.6%)
Grade 1	0	0	0	0
Grade 2	0	0	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Lacrimation disorders (cont)				
(cont)				
Grade 2	0	0	0	0
Dry eye	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	0	0	0
Lacrimation increased	0	0	0	0
Grade 1	0	0	0	0
Conjunctival and corneal bleeding and vascular disorders	0	0	0	1 (3.0%)
Grade 1	0	0	0	1 (3.0%)
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

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Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
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SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Conjunctival and corneal bleeding and vascular disorders (cont)				
Conjunctival haemorrhage	0	0	0	1 (1.6%)
Grade 1	0	0	0	0
Grade 2	0	0	0	1 (1.6%)
Visual impairment and blindness (excl colour blindness)	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	0	0	0	0
Visual acuity reduced	0	0	0	0
Grade 2	0	0	0	0
Visual impairment	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

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Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Conjunctival and corneal bleeding and vascular disorders (cont)				
Conjunctival haemorrhage	0	0	0	1 (3.0%)
Grade 1	0	0	0	1 (3.0%)
Grade 2	0	0	0	0
Visual impairment and blindness (excl colour blindness)	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	0	0	0
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Visual acuity reduced	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Visual impairment	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

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Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Choroid and vitreous structural change, deposit and degeneration	0	0	0	0
Grade 3	0	0	0	0
Vitreous detachment	0	0	0	0
Grade 3	0	0	0	0
Conjunctival infections, irritations and inflammations	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 1	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Conjunctival hyperaemia	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 1	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Retinal structural change, deposit and degeneration	1 (2.9%)	0	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Choroid and vitreous structural change, deposit and degeneration	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Vitreous detachment	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Conjunctival infections, irritations and inflammations	0	0	0	0
Grade 1	0	0	0	0
Conjunctival hyperaemia	0	0	0	0
Grade 1	0	0	0	0
Retinal structural change, deposit and degeneration	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Retinal structural change, deposit and degeneration (cont) (cont)				
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Retinal drusen	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	7 (20.6%)	1 (9.1%)	8 (17.8%)	9 (14.3%)
Grade 1	0	0	0	0
Grade 2	3 (8.8%)	1 (9.1%)	4 (8.9%)	4 (6.3%)
Grade 3	2 (5.9%)	0	2 (4.4%)	2 (3.2%)
Grade 4	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 5	1 (2.9%)	0	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Eye disorders (cont)				
Retinal structural change, deposit and degeneration (cont) (cont)				
Grade 1	0	0	0	0
Retinal drusen	0	0	0	0
Grade 1	0	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (22.2%)	2 (10.5%)	4 (14.3%)	6 (18.2%)
Grade 1	0	0	0	1 (3.0%)
Grade 2	1 (11.1%)	1 (5.3%)	2 (7.1%)	2 (6.1%)
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 4	0	0	0	0
Grade 5	1 (11.1%)	0	1 (3.6%)	2 (6.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Skin neoplasms malignant and unspecified (excl melanoma)	2 (5.9%)	1 (9.1%)	3 (6.7%)	3 (4.8%)
Grade 2	2 (5.9%)	1 (9.1%)	3 (6.7%)	3 (4.8%)
Basal cell carcinoma	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Squamous cell carcinoma of skin	1 (2.9%)	1 (9.1%)	2 (4.4%)	2 (3.2%)
Grade 2	1 (2.9%)	1 (9.1%)	2 (4.4%)	2 (3.2%)
Bowen's disease	0	0	0	0
Grade 2	0	0	0	0
Carcinoma in situ of skin	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Skin neoplasms malignant and unspecified (excl melanoma)	1 (11.1%)	0	1 (3.6%)	2 (6.1%)
Grade 2	1 (11.1%)	0	1 (3.6%)	2 (6.1%)
Basal cell carcinoma	1 (11.1%)	0	1 (3.6%)	2 (6.1%)
Grade 2	1 (11.1%)	0	1 (3.6%)	2 (6.1%)
Squamous cell carcinoma of skin	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Bowen's disease	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Carcinoma in situ of skin	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Skin neoplasms malignant and unspecified (excl melanoma) (cont)				
Keratoacanthoma	0	0	0	0
Grade 2	0	0	0	0
Leukaemias NEC	2 (5.9%)	0	2 (4.4%)	3 (4.8%)
Grade 3	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 4	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Leukaemia	2 (5.9%)	0	2 (4.4%)	3 (4.8%)
Grade 3	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 4	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Leukaemias acute myeloid	0	0	0	0
Grade 5	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Skin neoplasms malignant and unspecified (excl melanoma) (cont)				
Keratoacanthoma	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Leukaemias NEC	0	0	0	0
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Leukaemia	0	0	0	0
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Leukaemias acute myeloid	1 (11.1%)	0	1 (3.6%)	2 (6.1%)
Grade 5	1 (11.1%)	0	1 (3.6%)	2 (6.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Leukaemias acute myeloid (cont)				
Acute myeloid leukaemia	0	0	0	0
Grade 5	0	0	0	0
Urinary tract neoplasms unspecified malignancy NEC	2 (5.9%)	0	2 (4.4%)	2 (3.2%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 3	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Bladder neoplasm	2 (5.9%)	0	2 (4.4%)	2 (3.2%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 3	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Bladder neoplasms malignant	0	0	0	1 (1.6%)
Grade 2	0	0	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Leukaemias acute myeloid (cont)				
Acute myeloid leukaemia	1 (11.1%)	0	1 (3.6%)	2 (6.1%)
Grade 5	1 (11.1%)	0	1 (3.6%)	2 (6.1%)
Urinary tract neoplasms unspecified malignancy NEC	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Bladder neoplasm	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Bladder neoplasms malignant	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

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Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Bladder neoplasms malignant (cont)				
Bladder cancer	0	0	0	1 (1.6%)
Grade 2	0	0	0	1 (1.6%)
Gastric neoplasms malignant	0	0	0	0
Grade 2	0	0	0	0
Adenocarcinoma gastric	0	0	0	0
Grade 2	0	0	0	0
Myeloproliferative disorders (excl leukaemias)	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 5	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Myelofibrosis	1 (2.9%)	0	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

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Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Bladder neoplasms malignant (cont)				
Bladder cancer	0	0	0	0
Grade 2	0	0	0	0
Gastric neoplasms malignant	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Adenocarcinoma gastric	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Myeloproliferative disorders (excl leukaemias)	0	0	0	0
Grade 5	0	0	0	0
Myelofibrosis	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Myeloproliferative disorders (excl leukaemias) (cont)				
Myelofibrosis (cont)				
Grade 5	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Plasma cell neoplasms NEC	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Hypergammaglobulinaemia benign monoclonal	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Thyroid neoplasms malignant	0	0	0	0
Grade 3	0	0	0	0
Papillary thyroid cancer	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
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Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Myeloproliferative disorders (excl leukaemias) (cont)				
Myelofibrosis (cont)				
Grade 5	0	0	0	0
Plasma cell neoplasms NEC	0	0	0	0
Grade 1	0	0	0	0
Hypergammaglobulinaemia benign monoclonal	0	0	0	0
Grade 1	0	0	0	0
Thyroid neoplasms malignant	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Papillary thyroid cancer	0	1 (5.3%)	1 (3.6%)	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
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SAF-Anemic Analysis Set

	Male			
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Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Thyroid neoplasms malignant (cont)				
Papillary thyroid cancer (cont)				
Grade 3	0	0	0	0
Upper gastrointestinal neoplasms benign	0	0	0	0
Grade 1	0	0	0	0
Oesophageal papilloma	0	0	0	0
Grade 1	0	0	0	0
Urinary tract neoplasms malignant NEC	0	0	0	1 (1.6%)
Grade 2	0	0	0	1 (1.6%)
Transitional cell carcinoma	0	0	0	1 (1.6%)
Grade 2	0	0	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)				
Thyroid neoplasms malignant (cont)				
Papillary thyroid cancer (cont)				
Grade 3	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Upper gastrointestinal neoplasms benign	0	0	0	1 (3.0%)
Grade 1	0	0	0	1 (3.0%)
Oesophageal papilloma	0	0	0	1 (3.0%)
Grade 1	0	0	0	1 (3.0%)
Urinary tract neoplasms malignant NEC	0	0	0	0
Grade 2	0	0	0	0
Transitional cell carcinoma	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Ear and labyrinth disorders	2 (5.9%)	0	2 (4.4%)	3 (4.8%)
Grade 1	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Inner ear signs and symptoms	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 1	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 2	0	0	0	0
Vertigo	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 1	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Tinnitus	0	0	0	0
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Hearing losses	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Ear and labyrinth disorders	1 (11.1%)	2 (10.5%)	3 (10.7%)	5 (15.2%)
Grade 1	0	2 (10.5%)	2 (7.1%)	3 (9.1%)
Grade 2	1 (11.1%)	0	1 (3.6%)	2 (6.1%)
Inner ear signs and symptoms	0	1 (5.3%)	1 (3.6%)	3 (9.1%)
Grade 1	0	1 (5.3%)	1 (3.6%)	2 (6.1%)
Grade 2	0	0	0	1 (3.0%)
Vertigo	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Tinnitus	0	0	0	2 (6.1%)
Grade 1	0	0	0	1 (3.0%)
Grade 2	0	0	0	1 (3.0%)
Hearing losses	1 (11.1%)	1 (5.3%)	2 (7.1%)	2 (6.1%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-et.pdf 24AUG2023:15:00

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Ear and labyrinth disorders (cont)				
Hearing losses (cont)				
(cont)				
Grade 2	0	0	0	0
Deafness bilateral	0	0	0	0
Grade 1	0	0	0	0
Hypoacusis	0	0	0	0
Grade 2	0	0	0	0
Inner ear disorders NEC	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Vestibular disorder	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Ear and labyrinth disorders (cont)				
Hearing losses (cont)				
(cont)				
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Deafness bilateral	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Hypoacusis	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 2	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Inner ear disorders NEC	0	0	0	0
Grade 2	0	0	0	0
Vestibular disorder	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Hepatobiliary disorders	4 (11.8%)	0	4 (8.9%)	5 (7.9%)
Grade 1	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 2	2 (5.9%)	0	2 (4.4%)	2 (3.2%)
Grade 5	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Cholecystitis and cholelithiasis	2 (5.9%)	0	2 (4.4%)	2 (3.2%)
Grade 2	2 (5.9%)	0	2 (4.4%)	2 (3.2%)
Cholecystitis	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Cholecystitis acute	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Cholestasis and jaundice	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Hepatobiliary disorders	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	0	0	0
Grade 5	0	0	0	0
Cholecystitis and cholelithiasis	0	0	0	0
Grade 2	0	0	0	0
Cholecystitis	0	0	0	0
Grade 2	0	0	0	0
Cholecystitis acute	0	0	0	0
Grade 2	0	0	0	0
Cholestasis and jaundice	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-et.pdf 24AUG2023:15:00

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Hepatobiliary disorders (cont)				
Cholestasis and jaundice (cont)				
Jaundice	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Hepatic failure and associated disorders	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 5	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Hepatic failure	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 5	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Hepatic vascular disorders	0	0	0	1 (1.6%)
Grade 1	0	0	0	1 (1.6%)
Portal hypertension	0	0	0	1 (1.6%)
Grade 1	0	0	0	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Hepatobiliary disorders (cont)				
Cholestasis and jaundice (cont)				
Jaundice	0	0	0	0
Grade 1	0	0	0	0
Hepatic failure and associated disorders	0	0	0	0
Grade 5	0	0	0	0
Hepatic failure	0	0	0	0
Grade 5	0	0	0	0
Hepatic vascular disorders	0	0	0	0
Grade 1	0	0	0	0
Portal hypertension	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Hepatobiliary disorders (cont)				
Hepatobiliary signs and symptoms	0	0	0	0
Grade 1	0	0	0	0
Hepatic pain	0	0	0	0
Grade 1	0	0	0	0
Endocrine disorders	2 (5.9%)	1 (9.1%)	3 (6.7%)	4 (6.3%)
Grade 1	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 2	2 (5.9%)	0	2 (4.4%)	3 (4.8%)
Thyroid hypofunction disorders	2 (5.9%)	0	2 (4.4%)	3 (4.8%)
Grade 2	2 (5.9%)	0	2 (4.4%)	3 (4.8%)
Hypothyroidism	2 (5.9%)	0	2 (4.4%)	3 (4.8%)
Grade 2	2 (5.9%)	0	2 (4.4%)	3 (4.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Hepatobiliary disorders (cont)				
Hepatobiliary signs and symptoms	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Hepatic pain	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Endocrine disorders	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 2	0	0	0	0
Thyroid hypofunction disorders	0	0	0	0
Grade 2	0	0	0	0
Hypothyroidism	0	0	0	0
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Endocrine disorders (cont)				
Acute and chronic thyroiditis	0	0	0	0
Grade 1	0	0	0	0
Autoimmune thyroiditis	0	0	0	0
Grade 1	0	0	0	0
Thyroid disorders NEC	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 1	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Thyroid mass	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Grade 1	0	1 (9.1%)	1 (2.2%)	1 (1.6%)
Reproductive system and breast disorders	2 (5.9%)	0	2 (4.4%)	3 (4.8%)
Grade 1	0	0	0	0
Grade 2	2 (5.9%)	0	2 (4.4%)	3 (4.8%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
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Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Endocrine disorders (cont)				
Acute and chronic thyroiditis	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Autoimmune thyroiditis	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Thyroid disorders NEC	0	0	0	0
Grade 1	0	0	0	0
Thyroid mass	0	0	0	0
Grade 1	0	0	0	0
Reproductive system and breast disorders	0	0	0	1 (3.0%)
Grade 1	0	0	0	1 (3.0%)
Grade 2	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Reproductive system and breast disorders (cont)				
Prostatic neoplasms and hypertrophy	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 2	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Benign prostatic hyperplasia	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Grade 2	1 (2.9%)	0	1 (2.2%)	2 (3.2%)
Breast signs and symptoms	0	0	0	0
Grade 1	0	0	0	0
Breast pain	0	0	0	0
Grade 1	0	0	0	0
Scrotal disorders NEC	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Scrotal pain	1 (2.9%)	0	1 (2.2%)	1 (1.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Reproductive system and breast disorders (cont)				
Prostatic neoplasms and hypertrophy	0	0	0	0
Grade 2	0	0	0	0
Benign prostatic hyperplasia	0	0	0	0
Grade 2	0	0	0	0
Breast signs and symptoms	0	0	0	1 (3.0%)
Grade 1	0	0	0	1 (3.0%)
Breast pain	0	0	0	1 (3.0%)
Grade 1	0	0	0	1 (3.0%)
Scrotal disorders NEC	0	0	0	0
Grade 2	0	0	0	0
Scrotal pain	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Reproductive system and breast disorders (cont)				
Scrotal disorders NEC (cont)				
Scrotal pain (cont)				
Grade 2	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Immune system disorders	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Allergic conditions NEC	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Allergic oedema	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Grade 1	1 (2.9%)	0	1 (2.2%)	1 (1.6%)
Allergies to foods, food additives, drugs and other chemicals	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Reproductive system and breast disorders (cont)				
Scrotal disorders NEC (cont)				
Scrotal pain (cont)				
Grade 2	0	0	0	0
Immune system disorders	1 (11.1%)	1 (5.3%)	2 (7.1%)	2 (6.1%)
Grade 1	1 (11.1%)	1 (5.3%)	2 (7.1%)	2 (6.1%)
Allergic conditions NEC	0	0	0	0
Grade 1	0	0	0	0
Allergic oedema	0	0	0	0
Grade 1	0	0	0	0
Allergies to foods, food additives, drugs and other chemicals	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

	Male			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 Onward) Total (N=45)	Overall Exposed to MMB Total (N=63)
Number of Subjects with Any Treatment-Emergent AE	33 (97.1%)	11 (100.0%)	44 (97.8%)	63 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Immune system disorders (cont)				
Allergies to foods, food additives, drugs and other chemicals (cont)				
Drug hypersensitivity	0	0	0	0
Grade 1	0	0	0	0
Atopic disorders	0	0	0	0
Grade 1	0	0	0	0
Seasonal allergy	0	0	0	0
Grade 1	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0402: TEAEs by SOC, HLT, PT and Severity by Gender
Extended Treatment Phase (Week 24 Onward) and Overall Exposed to MMB
SAF-Anemic Analysis Set

(Continued)	Female			
	ET Phase (Week 24 Onward) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 Onward) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 Onward) Total (N=28)	Overall Exposed to MMB Total (N=33)
Number of Subjects with Any Treatment-Emergent AE	9 (100.0%)	19 (100.0%)	28 (100.0%)	33 (100.0%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade				
Immune system disorders (cont)				
Allergies to foods, food additives, drugs and other chemicals (cont)				
Drug hypersensitivity	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Grade 1	0	1 (5.3%)	1 (3.6%)	1 (3.0%)
Atopic disorders	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 1	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Seasonal allergy	1 (11.1%)	0	1 (3.6%)	1 (3.0%)
Grade 1	1 (11.1%)	0	1 (3.6%)	1 (3.0%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under the last column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders	30 (57.7%)	7 (38.9%)	37 (52.9%)	11 (32.4%)	7 (63.6%)	18 (40.0%)
Grade 1	14 (26.9%)	3 (16.7%)	17 (24.3%)	5 (14.7%)	5 (45.5%)	10 (22.2%)
Grade 2	11 (21.2%)	2 (11.1%)	13 (18.6%)	4 (11.8%)	1 (9.1%)	5 (11.1%)
Grade 3	5 (9.6%)	2 (11.1%)	7 (10.0%)	2 (5.9%)	1 (9.1%)	3 (6.7%)
Diarrhoea (excl infective)	16 (30.8%)	2 (11.1%)	18 (25.7%)	7 (20.6%)	2 (18.2%)	9 (20.0%)
Grade 1	10 (19.2%)	1 (5.6%)	11 (15.7%)	5 (14.7%)	2 (18.2%)	7 (15.6%)
Grade 2	5 (9.6%)	1 (5.6%)	6 (8.6%)	2 (5.9%)	0	2 (4.4%)
Grade 3	1 (1.9%)	0	1 (1.4%)	0	0	0
Diarrhoea	16 (30.8%)	2 (11.1%)	18 (25.7%)	7 (20.6%)	2 (18.2%)	9 (20.0%)
Grade 1	10 (19.2%)	1 (5.6%)	11 (15.7%)	5 (14.7%)	2 (18.2%)	7 (15.6%)
Grade 2	5 (9.6%)	1 (5.6%)	6 (8.6%)	2 (5.9%)	0	2 (4.4%)
Grade 3	1 (1.9%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders	10 (71.4%)	10 (47.6%)	20 (57.1%)	2 (22.2%)	8 (42.1%)	10 (35.7%)
Grade 1	3 (21.4%)	3 (14.3%)	6 (17.1%)	0	2 (10.5%)	2 (7.1%)
Grade 2	7 (50.0%)	6 (28.6%)	13 (37.1%)	1 (11.1%)	4 (21.1%)	5 (17.9%)
Grade 3	0	1 (4.8%)	1 (2.9%)	1 (11.1%)	2 (10.5%)	3 (10.7%)
Diarrhoea (excl infective)	5 (35.7%)	3 (14.3%)	8 (22.9%)	2 (22.2%)	4 (21.1%)	6 (21.4%)
Grade 1	4 (28.6%)	1 (4.8%)	5 (14.3%)	1 (11.1%)	0	1 (3.6%)
Grade 2	1 (7.1%)	2 (9.5%)	3 (8.6%)	0	2 (10.5%)	2 (7.1%)
Grade 3	0	0	0	1 (11.1%)	2 (10.5%)	3 (10.7%)
Diarrhoea	5 (35.7%)	3 (14.3%)	8 (22.9%)	2 (22.2%)	4 (21.1%)	6 (21.4%)
Grade 1	4 (28.6%)	1 (4.8%)	5 (14.3%)	1 (11.1%)	0	1 (3.6%)
Grade 2	1 (7.1%)	2 (9.5%)	3 (8.6%)	0	2 (10.5%)	2 (7.1%)
Grade 3	0	0	0	1 (11.1%)	2 (10.5%)	3 (10.7%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal and abdominal pains (excl oral and throat)	12 (23.1%)	2 (11.1%)	14 (20.0%)	2 (5.9%)	3 (27.3%)	5 (11.1%)
Grade 1	5 (9.6%)	0	5 (7.1%)	0	2 (18.2%)	2 (4.4%)
Grade 2	5 (9.6%)	0	5 (7.1%)	1 (2.9%)	1 (9.1%)	2 (4.4%)
Grade 3	2 (3.8%)	2 (11.1%)	4 (5.7%)	1 (2.9%)	0	1 (2.2%)
Abdominal pain	8 (15.4%)	2 (11.1%)	10 (14.3%)	2 (5.9%)	1 (9.1%)	3 (6.7%)
Grade 1	4 (7.7%)	0	4 (5.7%)	0	0	0
Grade 2	3 (5.8%)	0	3 (4.3%)	1 (2.9%)	1 (9.1%)	2 (4.4%)
Grade 3	1 (1.9%)	2 (11.1%)	3 (4.3%)	1 (2.9%)	0	1 (2.2%)
Abdominal pain upper	4 (7.7%)	0	4 (5.7%)	0	2 (18.2%)	2 (4.4%)
Grade 1	1 (1.9%)	0	1 (1.4%)	0	2 (18.2%)	2 (4.4%)
Grade 2	2 (3.8%)	0	2 (2.9%)	0	0	0
Grade 3	1 (1.9%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal and abdominal pains (excl oral and throat)	4 (28.6%)	5 (23.8%)	9 (25.7%)	1 (11.1%)	1 (5.3%)	2 (7.1%)
Grade 1	2 (14.3%)	1 (4.8%)	3 (8.6%)	0	1 (5.3%)	1 (3.6%)
Grade 2	2 (14.3%)	3 (14.3%)	5 (14.3%)	1 (11.1%)	0	1 (3.6%)
Grade 3	0	1 (4.8%)	1 (2.9%)	0	0	0
Abdominal pain	2 (14.3%)	3 (14.3%)	5 (14.3%)	1 (11.1%)	0	1 (3.6%)
Grade 1	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	0	0
Grade 2	1 (7.1%)	1 (4.8%)	2 (5.7%)	1 (11.1%)	0	1 (3.6%)
Grade 3	0	1 (4.8%)	1 (2.9%)	0	0	0
Abdominal pain upper	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	1 (5.3%)	1 (3.6%)
Grade 1	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 2	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal and abdominal pains (excl oral and throat) (cont)						
Abdominal pain lower	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Abdominal tenderness	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Nausea and vomiting symptoms	9 (17.3%)	2 (11.1%)	11 (15.7%)	3 (8.8%)	0	3 (6.7%)
Grade 1	8 (15.4%)	2 (11.1%)	10 (14.3%)	3 (8.8%)	0	3 (6.7%)
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 3	0	0	0	0	0	0
Nausea	9 (17.3%)	2 (11.1%)	11 (15.7%)	3 (8.8%)	0	3 (6.7%)
Grade 1	8 (15.4%)	2 (11.1%)	10 (14.3%)	3 (8.8%)	0	3 (6.7%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal and abdominal pains (excl oral and throat) (cont)						
Abdominal pain lower	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 1	1 (7.1%)	0	1 (2.9%)	0	0	0
Abdominal tenderness	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 2	0	1 (4.8%)	1 (2.9%)	0	0	0
Nausea and vomiting symptoms	3 (21.4%)	2 (9.5%)	5 (14.3%)	2 (22.2%)	4 (21.1%)	6 (21.4%)
Grade 1	3 (21.4%)	1 (4.8%)	4 (11.4%)	2 (22.2%)	1 (5.3%)	3 (10.7%)
Grade 2	0	0	0	0	2 (10.5%)	2 (7.1%)
Grade 3	0	1 (4.8%)	1 (2.9%)	0	1 (5.3%)	1 (3.6%)
Nausea	3 (21.4%)	1 (4.8%)	4 (11.4%)	2 (22.2%)	3 (15.8%)	5 (17.9%)
Grade 1	3 (21.4%)	0	3 (8.6%)	2 (22.2%)	1 (5.3%)	3 (10.7%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Nausea and vomiting symptoms (cont)						
Nausea (cont)						
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 3	0	0	0	0	0	0
Vomiting	2 (3.8%)	0	2 (2.9%)	1 (2.9%)	0	1 (2.2%)
Grade 1	2 (3.8%)	0	2 (2.9%)	1 (2.9%)	0	1 (2.2%)
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Gastrointestinal atonic and hypomotility disorders NEC	9 (17.3%)	1 (5.6%)	10 (14.3%)	2 (5.9%)	0	2 (4.4%)
Grade 1	8 (15.4%)	1 (5.6%)	9 (12.9%)	2 (5.9%)	0	2 (4.4%)
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Nausea and vomiting symptoms (cont)						
Nausea (cont)						
Grade 2	0	0	0	0	2 (10.5%)	2 (7.1%)
Grade 3	0	1 (4.8%)	1 (2.9%)	0	0	0
Vomiting	1 (7.1%)	1 (4.8%)	2 (5.7%)	1 (11.1%)	3 (15.8%)	4 (14.3%)
Grade 1	1 (7.1%)	1 (4.8%)	2 (5.7%)	1 (11.1%)	1 (5.3%)	2 (7.1%)
Grade 2	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 3	0	0	0	0	1 (5.3%)	1 (3.6%)
Gastrointestinal atonic and hypomotility disorders NEC	1 (7.1%)	2 (9.5%)	3 (8.6%)	0	1 (5.3%)	1 (3.6%)
Grade 1	0	2 (9.5%)	2 (5.7%)	0	1 (5.3%)	1 (3.6%)
Grade 2	1 (7.1%)	0	1 (2.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal atonic and hypomotility disorders NEC (cont)						
Constipation	6 (11.5%)	1 (5.6%)	7 (10.0%)	2 (5.9%)	0	2 (4.4%)
Grade 1	6 (11.5%)	1 (5.6%)	7 (10.0%)	2 (5.9%)	0	2 (4.4%)
Gastrooesophageal reflux disease	3 (5.8%)	0	3 (4.3%)	0	0	0
Grade 1	2 (3.8%)	0	2 (2.9%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Impaired gastric emptying	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 1	0	0	0	1 (2.9%)	0	1 (2.2%)
Dyspeptic signs and symptoms	4 (7.7%)	0	4 (5.7%)	0	0	0
Grade 1	2 (3.8%)	0	2 (2.9%)	0	0	0
Grade 2	2 (3.8%)	0	2 (2.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal atonic and hypomotility disorders NEC (cont)						
Constipation	0	1 (4.8%)	1 (2.9%)	0	1 (5.3%)	1 (3.6%)
Grade 1	0	1 (4.8%)	1 (2.9%)	0	1 (5.3%)	1 (3.6%)
Gastrooesophageal reflux disease	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	0	0
Grade 1	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 2	1 (7.1%)	0	1 (2.9%)	0	0	0
Impaired gastric emptying	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dyspeptic signs and symptoms	4 (28.6%)	0	4 (11.4%)	0	0	0
Grade 1	2 (14.3%)	0	2 (5.7%)	0	0	0
Grade 2	2 (14.3%)	0	2 (5.7%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Dyspeptic signs and symptoms (cont)						
Dyspepsia	3 (5.8%)	0	3 (4.3%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	2 (3.8%)	0	2 (2.9%)	0	0	0
Epigastric discomfort	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Non-site specific gastrointestinal haemorrhages	3 (5.8%)	1 (5.6%)	4 (5.7%)	2 (5.9%)	1 (9.1%)	3 (6.7%)
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (5.6%)	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Grade 3	3 (5.8%)	0	3 (4.3%)	1 (2.9%)	1 (9.1%)	2 (4.4%)
Gastrointestinal haemorrhage	2 (3.8%)	0	2 (2.9%)	2 (5.9%)	1 (9.1%)	3 (6.7%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Dyspeptic signs and symptoms (cont)						
Dyspepsia	4 (28.6%)	0	4 (11.4%)	0	0	0
Grade 1	2 (14.3%)	0	2 (5.7%)	0	0	0
Grade 2	2 (14.3%)	0	2 (5.7%)	0	0	0
Epigastric discomfort	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Non-site specific gastrointestinal haemorrhages	0	1 (4.8%)	1 (2.9%)	0	2 (10.5%)	2 (7.1%)
Grade 1	0	1 (4.8%)	1 (2.9%)	0	2 (10.5%)	2 (7.1%)
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Gastrointestinal haemorrhage	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Non-site specific gastrointestinal haemorrhages (cont)						
Gastrointestinal haemorrhage (cont)						
Grade 2	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Grade 3	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	1 (9.1%)	2 (4.4%)
Haematemesis	2 (3.8%)	0	2 (2.9%)	0	0	0
Grade 3	2 (3.8%)	0	2 (2.9%)	0	0	0
Upper gastrointestinal haemorrhage	2 (3.8%)	1 (5.6%)	3 (4.3%)	0	0	0
Grade 2	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 3	2 (3.8%)	0	2 (2.9%)	0	0	0
Melaena	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Non-site specific gastrointestinal haemorrhages (cont)						
Gastrointestinal haemorrhage (cont)						
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Haematemesis	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Upper gastrointestinal haemorrhage	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Melaena	0	1 (4.8%)	1 (2.9%)	0	2 (10.5%)	2 (7.1%)
Grade 1	0	1 (4.8%)	1 (2.9%)	0	2 (10.5%)	2 (7.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Non-site specific gastrointestinal haemorrhages (cont)						
Melaena (cont)						
Grade 3	1 (1.9%)	0	1 (1.4%)	0	0	0
Peritoneal and retroperitoneal disorders	2 (3.8%)	1 (5.6%)	3 (4.3%)	1 (2.9%)	0	1 (2.2%)
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Grade 3	0	1 (5.6%)	1 (1.4%)	0	0	0
Ascites	2 (3.8%)	1 (5.6%)	3 (4.3%)	1 (2.9%)	0	1 (2.2%)
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Grade 3	0	1 (5.6%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Non-site specific gastrointestinal haemorrhages (cont)						
Melaena (cont)						
Grade 3	0	0	0	0	0	0
Peritoneal and retroperitoneal disorders	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	2 (10.5%)	2 (7.1%)
Grade 1	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	0	0
Grade 2	0	0	0	0	2 (10.5%)	2 (7.1%)
Grade 3	0	0	0	0	0	0
Ascites	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	2 (10.5%)	2 (7.1%)
Grade 1	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	0	0
Grade 2	0	0	0	0	2 (10.5%)	2 (7.1%)
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Flatulence, bloating and distension	2 (3.8%)	0	2 (2.9%)	1 (2.9%)	0	1 (2.2%)
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Flatulence	2 (3.8%)	0	2 (2.9%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Abdominal distension	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	1 (2.9%)	0	1 (2.2%)
Gastrointestinal spastic and hypermotility disorders	2 (3.8%)	0	2 (2.9%)	0	0	0
Grade 1	2 (3.8%)	0	2 (2.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Flatulence, bloating and distension	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 1	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Flatulence	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Abdominal distension	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 1	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Gastrointestinal spastic and hypermotility disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal spastic and hypermotility disorders (cont)						
Defaecation urgency	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Frequent bowel movements	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Anal and rectal signs and symptoms	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Anorectal discomfort	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Dental pain and sensation disorders	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase	RT Phase	RT Phase	ET Phase (Week 24 - 48) Continuing	ET Phase (Week 24 - 48) Switch	ET Phase (Week 24 - 48)
	MMB (N=14)	BAT (N=21)	Total (N=35)	(MMB->MMB) (N=9)	(BAT->MMB) (N=19)	Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal spastic and hypermotility disorders (cont)						
Defaecation urgency	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Frequent bowel movements	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Anal and rectal signs and symptoms	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Anorectal discomfort	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dental pain and sensation disorders	1 (7.1%)	0	1 (2.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Dental pain and sensation disorders (cont)						
(cont)						
Grade 2	0	0	0	0	0	0
Toothache	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Gastric and oesophageal haemorrhages	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Oesophageal haemorrhage	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Gastric ulcers and perforation	1 (1.9%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Dental pain and sensation disorders (cont)						
(cont)						
Grade 2	1 (7.1%)	0	1 (2.9%)	0	0	0
Toothache	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 2	1 (7.1%)	0	1 (2.9%)	0	0	0
Gastric and oesophageal haemorrhages	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 2	1 (7.1%)	0	1 (2.9%)	0	0	0
Oesophageal haemorrhage	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 2	1 (7.1%)	0	1 (2.9%)	0	0	0
Gastric ulcers and perforation	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastric ulcers and perforation (cont) (cont)						
Grade 3	1 (1.9%)	0	1 (1.4%)	0	0	0
Gastric ulcer	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 3	1 (1.9%)	0	1 (1.4%)	0	0	0
Gastritis (excl infective)	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Gastritis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Gastrointestinal mucosal dystrophies and secretion disorders	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastric ulcers and perforation (cont) (cont)						
Grade 3	0	0	0	0	0	0
Gastric ulcer	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Gastritis (excl infective)	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 1	1 (7.1%)	0	1 (2.9%)	0	0	0
Gastritis	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 1	1 (7.1%)	0	1 (2.9%)	0	0	0
Gastrointestinal mucosal dystrophies and secretion disorders	1 (7.1%)	0	1 (2.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal mucosal dystrophies and secretion disorders (cont) (cont)						
Grade 1	0	0	0	0	0	0
Gastrointestinal melanosis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Gastrointestinal signs and symptoms NEC	0	0	0	0	1 (9.1%)	1 (2.2%)
Grade 1	0	0	0	0	1 (9.1%)	1 (2.2%)
Abdominal discomfort	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dysphagia	0	0	0	0	1 (9.1%)	1 (2.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal mucosal dystrophies and secretion disorders (cont) (cont)						
Grade 1	1 (7.1%)	0	1 (2.9%)	0	0	0
Gastrointestinal melanosis	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 1	1 (7.1%)	0	1 (2.9%)	0	0	0
Gastrointestinal signs and symptoms NEC	1 (7.1%)	0	1 (2.9%)	0	1 (5.3%)	1 (3.6%)
Grade 1	1 (7.1%)	0	1 (2.9%)	0	1 (5.3%)	1 (3.6%)
Abdominal discomfort	1 (7.1%)	0	1 (2.9%)	0	1 (5.3%)	1 (3.6%)
Grade 1	1 (7.1%)	0	1 (2.9%)	0	1 (5.3%)	1 (3.6%)
Dysphagia	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal signs and symptoms NEC (cont)						
Dysphagia (cont)						
Grade 1	0	0	0	0	1 (9.1%)	1 (2.2%)
Intestinal haemorrhages	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Anal haemorrhage	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Stomatitis and ulceration	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	1 (9.1%)	2 (4.4%)
Grade 1	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	1 (9.1%)	2 (4.4%)
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Gastrointestinal signs and symptoms NEC (cont)						
Dysphagia (cont)						
Grade 1	0	0	0	0	0	0
Intestinal haemorrhages	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Anal haemorrhage	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Stomatitis and ulceration	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (4.8%)	1 (2.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Stomatitis and ulceration (cont)						
Mouth ulceration	1 (1.9%)	0	1 (1.4%)	0	1 (9.1%)	1 (2.2%)
Grade 1	1 (1.9%)	0	1 (1.4%)	0	1 (9.1%)	1 (2.2%)
Palatal ulcer	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 1	0	0	0	1 (2.9%)	0	1 (2.2%)
Stomatitis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Anal and rectal disorders NEC	0	0	0	0	1 (9.1%)	1 (2.2%)
Grade 2	0	0	0	0	1 (9.1%)	1 (2.2%)
Anal fissure	0	0	0	0	1 (9.1%)	1 (2.2%)
Grade 2	0	0	0	0	1 (9.1%)	1 (2.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Stomatitis and ulceration (cont)						
Mouth ulceration	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Palatal ulcer	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Stomatitis	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 2	0	1 (4.8%)	1 (2.9%)	0	0	0
Anal and rectal disorders NEC	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Anal fissure	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
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Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Dental and periodontal infections and inflammations	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 2	0	1 (5.6%)	1 (1.4%)	0	0	0
Dental caries	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 2	0	1 (5.6%)	1 (1.4%)	0	0	0
Oesophageal varices	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Varices oesophageal	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Oral dryness and saliva altered	0	0	0	0	2 (18.2%)	2 (4.4%)
Grade 1	0	0	0	0	1 (9.1%)	1 (2.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Dental and periodontal infections and inflammations	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Dental caries	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Oesophageal varices	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 2	0	0	0	0	1 (5.3%)	1 (3.6%)
Varices oesophageal	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 2	0	0	0	0	1 (5.3%)	1 (3.6%)
Oral dryness and saliva altered	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
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Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Oral dryness and saliva altered (cont) (cont)						
Grade 2	0	0	0	0	1 (9.1%)	1 (2.2%)
Dry mouth	0	0	0	0	2 (18.2%)	2 (4.4%)
Grade 1	0	0	0	0	1 (9.1%)	1 (2.2%)
Grade 2	0	0	0	0	1 (9.1%)	1 (2.2%)
Oral soft tissue pain and paraesthesia	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (5.6%)	1 (1.4%)	0	0	0
Odynophagia	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (5.6%)	1 (1.4%)	0	0	0
Umbilical hernias	0	0	0	1 (2.9%)	0	1 (2.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Oral dryness and saliva altered (cont) (cont)						
Grade 2	0	1 (4.8%)	1 (2.9%)	0	0	0
Dry mouth	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (4.8%)	1 (2.9%)	0	0	0
Oral soft tissue pain and paraesthesia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Odynophagia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Umbilical hernias	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Umbilical hernias (cont)						
(cont)						
Grade 1	0	0	0	1 (2.9%)	0	1 (2.2%)
Umbilical hernia	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 1	0	0	0	1 (2.9%)	0	1 (2.2%)
Infections and infestations	25 (48.1%)	7 (38.9%)	32 (45.7%)	11 (32.4%)	5 (45.5%)	16 (35.6%)
Grade 1	6 (11.5%)	2 (11.1%)	8 (11.4%)	2 (5.9%)	2 (18.2%)	4 (8.9%)
Grade 2	10 (19.2%)	2 (11.1%)	12 (17.1%)	6 (17.6%)	2 (18.2%)	8 (17.8%)
Grade 3	6 (11.5%)	1 (5.6%)	7 (10.0%)	1 (2.9%)	1 (9.1%)	2 (4.4%)
Grade 4	2 (3.8%)	0	2 (2.9%)	2 (5.9%)	0	2 (4.4%)
Grade 5	1 (1.9%)	2 (11.1%)	3 (4.3%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Gastrointestinal disorders (cont)						
Umbilical hernias (cont)						
(cont)						
Grade 1	0	0	0	0	0	0
Umbilical hernia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Infections and infestations	9 (64.3%)	9 (42.9%)	18 (51.4%)	7 (77.8%)	9 (47.4%)	16 (57.1%)
Grade 1	4 (28.6%)	1 (4.8%)	5 (14.3%)	0	3 (15.8%)	3 (10.7%)
Grade 2	5 (35.7%)	7 (33.3%)	12 (34.3%)	6 (66.7%)	5 (26.3%)	11 (39.3%)
Grade 3	0	1 (4.8%)	1 (2.9%)	1 (11.1%)	0	1 (3.6%)
Grade 4	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 5	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Upper respiratory tract infections	10 (19.2%)	2 (11.1%)	12 (17.1%)	4 (11.8%)	2 (18.2%)	6 (13.3%)
Grade 1	4 (7.7%)	2 (11.1%)	6 (8.6%)	1 (2.9%)	1 (9.1%)	2 (4.4%)
Grade 2	5 (9.6%)	0	5 (7.1%)	3 (8.8%)	1 (9.1%)	4 (8.9%)
Grade 4	1 (1.9%)	0	1 (1.4%)	0	0	0
Upper respiratory tract infection	7 (13.5%)	1 (5.6%)	8 (11.4%)	1 (2.9%)	1 (9.1%)	2 (4.4%)
Grade 1	3 (5.8%)	1 (5.6%)	4 (5.7%)	0	0	0
Grade 2	3 (5.8%)	0	3 (4.3%)	1 (2.9%)	1 (9.1%)	2 (4.4%)
Grade 4	1 (1.9%)	0	1 (1.4%)	0	0	0
Nasopharyngitis	1 (1.9%)	0	1 (1.4%)	2 (5.9%)	1 (9.1%)	3 (6.7%)
Grade 1	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	1 (9.1%)	2 (4.4%)
Grade 2	0	0	0	1 (2.9%)	0	1 (2.2%)
Sinusitis	2 (3.8%)	0	2 (2.9%)	1 (2.9%)	0	1 (2.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Upper respiratory tract infections	1 (7.1%)	3 (14.3%)	4 (11.4%)	4 (44.4%)	3 (15.8%)	7 (25.0%)
Grade 1	1 (7.1%)	1 (4.8%)	2 (5.7%)	1 (11.1%)	3 (15.8%)	4 (14.3%)
Grade 2	0	2 (9.5%)	2 (5.7%)	3 (33.3%)	0	3 (10.7%)
Grade 4	0	0	0	0	0	0
Upper respiratory tract infection	0	2 (9.5%)	2 (5.7%)	2 (22.2%)	2 (10.5%)	4 (14.3%)
Grade 1	0	0	0	1 (11.1%)	2 (10.5%)	3 (10.7%)
Grade 2	0	2 (9.5%)	2 (5.7%)	1 (11.1%)	0	1 (3.6%)
Grade 4	0	0	0	0	0	0
Nasopharyngitis	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	1 (5.3%)	1 (3.6%)
Grade 1	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	1 (5.3%)	1 (3.6%)
Grade 2	0	0	0	0	0	0
Sinusitis	0	0	0	2 (22.2%)	0	2 (7.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Upper respiratory tract infections (cont)						
Sinusitis (cont)						
Grade 2	2 (3.8%)	0	2 (2.9%)	1 (2.9%)	0	1 (2.2%)
Rhinitis	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (5.6%)	1 (1.4%)	0	0	0
Urinary tract infections	4 (7.7%)	2 (11.1%)	6 (8.6%)	1 (2.9%)	0	1 (2.2%)
Grade 1	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 2	2 (3.8%)	1 (5.6%)	3 (4.3%)	0	0	0
Grade 3	2 (3.8%)	0	2 (2.9%)	1 (2.9%)	0	1 (2.2%)
Urinary tract infection	4 (7.7%)	1 (5.6%)	5 (7.1%)	1 (2.9%)	0	1 (2.2%)
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Upper respiratory tract infections (cont)						
Sinusitis (cont)						
Grade 2	0	0	0	2 (22.2%)	0	2 (7.1%)
Rhinitis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Urinary tract infections	4 (28.6%)	2 (9.5%)	6 (17.1%)	3 (33.3%)	3 (15.8%)	6 (21.4%)
Grade 1	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 2	3 (21.4%)	2 (9.5%)	5 (14.3%)	3 (33.3%)	3 (15.8%)	6 (21.4%)
Grade 3	0	0	0	0	0	0
Urinary tract infection	2 (14.3%)	2 (9.5%)	4 (11.4%)	2 (22.2%)	3 (15.8%)	5 (17.9%)
Grade 1	1 (7.1%)	0	1 (2.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Urinary tract infections (cont)						
Urinary tract infection (cont)						
Grade 2	2 (3.8%)	1 (5.6%)	3 (4.3%)	0	0	0
Grade 3	2 (3.8%)	0	2 (2.9%)	1 (2.9%)	0	1 (2.2%)
Cystitis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Kidney infection	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (5.6%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Urinary tract infections (cont)						
Urinary tract infection (cont)						
Grade 2	1 (7.1%)	2 (9.5%)	3 (8.6%)	2 (22.2%)	3 (15.8%)	5 (17.9%)
Grade 3	0	0	0	0	0	0
Cystitis	2 (14.3%)	0	2 (5.7%)	1 (11.1%)	0	1 (3.6%)
Grade 2	2 (14.3%)	0	2 (5.7%)	1 (11.1%)	0	1 (3.6%)
Kidney infection	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Lower respiratory tract and lung infections	5 (9.6%)	3 (16.7%)	8 (11.4%)	5 (14.7%)	2 (18.2%)	7 (15.6%)
Grade 1	0	0	0	1 (2.9%)	1 (9.1%)	2 (4.4%)
Grade 2	3 (5.8%)	1 (5.6%)	4 (5.7%)	2 (5.9%)	0	2 (4.4%)
Grade 3	1 (1.9%)	2 (11.1%)	3 (4.3%)	2 (5.9%)	1 (9.1%)	3 (6.7%)
Grade 4	1 (1.9%)	0	1 (1.4%)	0	0	0
Pneumonia	3 (5.8%)	1 (5.6%)	4 (5.7%)	2 (5.9%)	1 (9.1%)	3 (6.7%)
Grade 2	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Grade 3	1 (1.9%)	1 (5.6%)	2 (2.9%)	1 (2.9%)	1 (9.1%)	2 (4.4%)
Grade 4	1 (1.9%)	0	1 (1.4%)	0	0	0
Bronchitis	0	0	0	1 (2.9%)	1 (9.1%)	2 (4.4%)
Grade 1	0	0	0	0	1 (9.1%)	1 (2.2%)
Grade 2	0	0	0	1 (2.9%)	0	1 (2.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Lower respiratory tract and lung infections	2 (14.3%)	0	2 (5.7%)	2 (22.2%)	1 (5.3%)	3 (10.7%)
Grade 1	0	0	0	0	0	0
Grade 2	2 (14.3%)	0	2 (5.7%)	1 (11.1%)	1 (5.3%)	2 (7.1%)
Grade 3	0	0	0	1 (11.1%)	0	1 (3.6%)
Grade 4	0	0	0	0	0	0
Pneumonia	0	0	0	2 (22.2%)	0	2 (7.1%)
Grade 2	0	0	0	1 (11.1%)	0	1 (3.6%)
Grade 3	0	0	0	1 (11.1%)	0	1 (3.6%)
Grade 4	0	0	0	0	0	0
Bronchitis	2 (14.3%)	0	2 (5.7%)	2 (22.2%)	1 (5.3%)	3 (10.7%)
Grade 1	0	0	0	0	0	0
Grade 2	2 (14.3%)	0	2 (5.7%)	2 (22.2%)	1 (5.3%)	3 (10.7%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Lower respiratory tract and lung infections (cont)						
Lung infection	2 (3.8%)	0	2 (2.9%)	1 (2.9%)	0	1 (2.2%)
Grade 2	2 (3.8%)	0	2 (2.9%)	0	0	0
Grade 3	0	0	0	1 (2.9%)	0	1 (2.2%)
Atypical pneumonia	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 1	0	0	0	1 (2.9%)	0	1 (2.2%)
Lower respiratory tract infection	0	2 (11.1%)	2 (2.9%)	0	0	0
Grade 2	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 3	0	1 (5.6%)	1 (1.4%)	0	0	0
Herpes viral infections	4 (7.7%)	0	4 (5.7%)	1 (2.9%)	2 (18.2%)	3 (6.7%)
Grade 1	2 (3.8%)	0	2 (2.9%)	1 (2.9%)	0	1 (2.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Lower respiratory tract and lung infections (cont)						
Lung infection	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Atypical pneumonia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Lower respiratory tract infection	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Herpes viral infections	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	0	0
Grade 1	1 (7.1%)	0	1 (2.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Herpes viral infections (cont)						
(cont)						
Grade 2	1 (1.9%)	0	1 (1.4%)	0	2 (18.2%)	2 (4.4%)
Grade 3	1 (1.9%)	0	1 (1.4%)	0	0	0
Oral herpes	3 (5.8%)	0	3 (4.3%)	1 (2.9%)	1 (9.1%)	2 (4.4%)
Grade 1	2 (3.8%)	0	2 (2.9%)	1 (2.9%)	0	1 (2.2%)
Grade 2	1 (1.9%)	0	1 (1.4%)	0	1 (9.1%)	1 (2.2%)
Herpes zoster	1 (1.9%)	0	1 (1.4%)	0	1 (9.1%)	1 (2.2%)
Grade 2	1 (1.9%)	0	1 (1.4%)	0	1 (9.1%)	1 (2.2%)
Grade 3	0	0	0	0	0	0
Ophthalmic herpes zoster	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 3	1 (1.9%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Herpes viral infections (cont)						
(cont)						
Grade 2	0	0	0	0	0	0
Grade 3	0	1 (4.8%)	1 (2.9%)	0	0	0
Oral herpes	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 1	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Herpes zoster	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	1 (4.8%)	1 (2.9%)	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Herpes viral infections (cont)						
Herpes simplex	0	0	0	0	1 (9.1%)	1 (2.2%)
Grade 2	0	0	0	0	1 (9.1%)	1 (2.2%)
Bacterial infections NEC	4 (7.7%)	0	4 (5.7%)	2 (5.9%)	0	2 (4.4%)
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 3	2 (3.8%)	0	2 (2.9%)	2 (5.9%)	0	2 (4.4%)
Grade 5	1 (1.9%)	0	1 (1.4%)	0	0	0
Bacterial sepsis	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 5	1 (1.9%)	0	1 (1.4%)	0	0	0
Cellulitis	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Grade 3	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Herpes viral infections (cont)						
Herpes simplex	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Bacterial infections NEC	0	0	0	1 (11.1%)	0	1 (3.6%)
Grade 2	0	0	0	1 (11.1%)	0	1 (3.6%)
Grade 3	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Cellulitis	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Bacterial infections NEC (cont)						
Peritonitis bacterial	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 3	1 (1.9%)	0	1 (1.4%)	0	0	0
Propionibacterium infection	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Citrobacter infection	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 3	0	0	0	1 (2.9%)	0	1 (2.2%)
Urinary tract infection bacterial	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Candida infections	2 (3.8%)	0	2 (2.9%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Bacterial infections NEC (cont)						
Peritonitis bacterial	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Propionibacterium infection	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Citrobacter infection	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Urinary tract infection bacterial	0	0	0	1 (11.1%)	0	1 (3.6%)
Grade 2	0	0	0	1 (11.1%)	0	1 (3.6%)
Candida infections	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	1 (5.3%)	1 (3.6%)
Grade 1	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Candida infections (cont)						
(cont)						
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 3	0	0	0	0	0	0
Oral candidiasis	2 (3.8%)	0	2 (2.9%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 3	0	0	0	0	0	0
Oropharyngeal candidiasis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Candida infections (cont)						
(cont)						
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	1 (5.3%)	1 (3.6%)
Oral candidiasis	0	1 (4.8%)	1 (2.9%)	0	1 (5.3%)	1 (3.6%)
Grade 1	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	1 (5.3%)	1 (3.6%)
Oropharyngeal candidiasis	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 1	1 (7.1%)	0	1 (2.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Sepsis, bacteraemia, viraemia and fungaemia NEC	3 (5.8%)	2 (11.1%)	5 (7.1%)	2 (5.9%)	0	2 (4.4%)
Grade 3	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 4	2 (3.8%)	0	2 (2.9%)	2 (5.9%)	0	2 (4.4%)
Grade 5	0	2 (11.1%)	2 (2.9%)	0	0	0
Sepsis	3 (5.8%)	2 (11.1%)	5 (7.1%)	2 (5.9%)	0	2 (4.4%)
Grade 3	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 4	2 (3.8%)	0	2 (2.9%)	2 (5.9%)	0	2 (4.4%)
Grade 5	0	2 (11.1%)	2 (2.9%)	0	0	0
Urosepsis	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Sepsis, bacteraemia, viraemia and fungaemia NEC	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 3	0	0	0	0	0	0
Grade 4	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 5	0	0	0	0	0	0
Sepsis	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 3	0	0	0	0	0	0
Grade 4	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 5	0	0	0	0	0	0
Urosepsis	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 3	0	0	0	0	1 (5.3%)	1 (3.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Skin structures and soft tissue infections	2 (3.8%)	0	2 (2.9%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Folliculitis	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Skin infection	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Rash pustular	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Skin structures and soft tissue infections	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (4.8%)	1 (2.9%)	0	0	0
Folliculitis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Skin infection	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Rash pustular	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 2	0	1 (4.8%)	1 (2.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Abdominal and gastrointestinal infections	1 (1.9%)	1 (5.6%)	2 (2.9%)	0	0	0
Grade 2	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 3	1 (1.9%)	0	1 (1.4%)	0	0	0
Diverticulitis	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	1 (1.9%)	0	1 (1.4%)	0	0	0
Gastroenteritis	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 2	0	1 (5.6%)	1 (1.4%)	0	0	0
Enterococcal infections	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Abdominal and gastrointestinal infections	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 2	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 3	0	0	0	0	0	0
Diverticulitis	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 2	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 3	0	0	0	0	0	0
Gastroenteritis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Enterococcal infections	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Enterococcal infections (cont)						
Urinary tract infection enterococcal	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Escherichia infections	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Grade 2	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 3	1 (1.9%)	0	1 (1.4%)	0	0	0
Escherichia urinary tract infection	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Grade 2	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 3	1 (1.9%)	0	1 (1.4%)	0	0	0
Eye and eyelid infections	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Enterococcal infections (cont)						
Urinary tract infection enterococcal	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Escherichia infections	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Escherichia urinary tract infection	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Eye and eyelid infections	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Eye and eyelid infections (cont)						
Conjunctivitis	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Infections NEC	1 (1.9%)	1 (5.6%)	2 (2.9%)	1 (2.9%)	0	1 (2.2%)
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	0	1 (5.6%)	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Respiratory tract infection	1 (1.9%)	1 (5.6%)	2 (2.9%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	0	1 (5.6%)	1 (1.4%)	0	0	0
Localised infection	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Eye and eyelid infections (cont)						
Conjunctivitis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Infections NEC	0	1 (4.8%)	1 (2.9%)	0	1 (5.3%)	1 (3.6%)
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (4.8%)	1 (2.9%)	0	1 (5.3%)	1 (3.6%)
Respiratory tract infection	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (4.8%)	1 (2.9%)	0	0	0
Localised infection	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 2	0	0	0	0	1 (5.3%)	1 (3.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Infections NEC (cont)						
Wound infection	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 2	0	0	0	1 (2.9%)	0	1 (2.2%)
Influenza viral infections	1 (1.9%)	0	1 (1.4%)	0	1 (9.1%)	1 (2.2%)
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	0	0	0	0	1 (9.1%)	1 (2.2%)
Influenza	1 (1.9%)	0	1 (1.4%)	0	1 (9.1%)	1 (2.2%)
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	0	0	0	0	1 (9.1%)	1 (2.2%)
Staphylococcal infections	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Infections NEC (cont)						
Wound infection	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Influenza viral infections	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Influenza	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Staphylococcal infections	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Staphylococcal infections (cont)						
Staphylococcal infection	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Streptococcal infections	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Erysipelas	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Clostridia infections	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 3	0	0	0	1 (2.9%)	0	1 (2.2%)
Clostridium difficile infection	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 3	0	0	0	1 (2.9%)	0	1 (2.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Staphylococcal infections (cont)						
Staphylococcal infection	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Streptococcal infections	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Erysipelas	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Clostridia infections	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Clostridium difficile infection	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Dental and oral soft tissue infections	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 2	0	0	0	1 (2.9%)	0	1 (2.2%)
Dental fistula	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 2	0	0	0	1 (2.9%)	0	1 (2.2%)
Viral infections NEC	0	0	0	0	1 (9.1%)	1 (2.2%)
Grade 1	0	0	0	0	1 (9.1%)	1 (2.2%)
Viral rash	0	0	0	0	1 (9.1%)	1 (2.2%)
Grade 1	0	0	0	0	1 (9.1%)	1 (2.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Infections and infestations (cont)						
Dental and oral soft tissue infections	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Dental fistula	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Viral infections NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Viral rash	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions	26 (50.0%)	8 (44.4%)	34 (48.6%)	10 (29.4%)	6 (54.5%)	16 (35.6%)
Grade 1	9 (17.3%)	4 (22.2%)	13 (18.6%)	6 (17.6%)	1 (9.1%)	7 (15.6%)
Grade 2	10 (19.2%)	3 (16.7%)	13 (18.6%)	3 (8.8%)	3 (27.3%)	6 (13.3%)
Grade 3	7 (13.5%)	1 (5.6%)	8 (11.4%)	1 (2.9%)	2 (18.2%)	3 (6.7%)
Asthenic conditions	17 (32.7%)	4 (22.2%)	21 (30.0%)	3 (8.8%)	4 (36.4%)	7 (15.6%)
Grade 1	5 (9.6%)	1 (5.6%)	6 (8.6%)	1 (2.9%)	1 (9.1%)	2 (4.4%)
Grade 2	9 (17.3%)	2 (11.1%)	11 (15.7%)	1 (2.9%)	2 (18.2%)	3 (6.7%)
Grade 3	3 (5.8%)	1 (5.6%)	4 (5.7%)	1 (2.9%)	1 (9.1%)	2 (4.4%)
Asthenia	10 (19.2%)	3 (16.7%)	13 (18.6%)	2 (5.9%)	3 (27.3%)	5 (11.1%)
Grade 1	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Grade 2	6 (11.5%)	2 (11.1%)	8 (11.4%)	0	2 (18.2%)	2 (4.4%)
Grade 3	3 (5.8%)	1 (5.6%)	4 (5.7%)	1 (2.9%)	1 (9.1%)	2 (4.4%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions	7 (50.0%)	12 (57.1%)	19 (54.3%)	3 (33.3%)	9 (47.4%)	12 (42.9%)
Grade 1	1 (7.1%)	1 (4.8%)	2 (5.7%)	1 (11.1%)	3 (15.8%)	4 (14.3%)
Grade 2	5 (35.7%)	11 (52.4%)	16 (45.7%)	1 (11.1%)	4 (21.1%)	5 (17.9%)
Grade 3	1 (7.1%)	0	1 (2.9%)	1 (11.1%)	2 (10.5%)	3 (10.7%)
Asthenic conditions	5 (35.7%)	10 (47.6%)	15 (42.9%)	1 (11.1%)	6 (31.6%)	7 (25.0%)
Grade 1	2 (14.3%)	1 (4.8%)	3 (8.6%)	0	2 (10.5%)	2 (7.1%)
Grade 2	2 (14.3%)	9 (42.9%)	11 (31.4%)	1 (11.1%)	2 (10.5%)	3 (10.7%)
Grade 3	1 (7.1%)	0	1 (2.9%)	0	2 (10.5%)	2 (7.1%)
Asthenia	3 (21.4%)	5 (23.8%)	8 (22.9%)	1 (11.1%)	5 (26.3%)	6 (21.4%)
Grade 1	2 (14.3%)	0	2 (5.7%)	0	2 (10.5%)	2 (7.1%)
Grade 2	0	5 (23.8%)	5 (14.3%)	1 (11.1%)	1 (5.3%)	2 (7.1%)
Grade 3	1 (7.1%)	0	1 (2.9%)	0	2 (10.5%)	2 (7.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Asthenic conditions (cont)						
Fatigue	7 (13.5%)	1 (5.6%)	8 (11.4%)	1 (2.9%)	1 (9.1%)	2 (4.4%)
Grade 1	4 (7.7%)	1 (5.6%)	5 (7.1%)	0	1 (9.1%)	1 (2.2%)
Grade 2	3 (5.8%)	0	3 (4.3%)	1 (2.9%)	0	1 (2.2%)
Grade 3	0	0	0	0	0	0
Febrile disorders	8 (15.4%)	1 (5.6%)	9 (12.9%)	4 (11.8%)	3 (27.3%)	7 (15.6%)
Grade 1	6 (11.5%)	1 (5.6%)	7 (10.0%)	3 (8.8%)	2 (18.2%)	5 (11.1%)
Grade 2	0	0	0	1 (2.9%)	1 (9.1%)	2 (4.4%)
Grade 3	2 (3.8%)	0	2 (2.9%)	0	0	0
Pyrexia	8 (15.4%)	1 (5.6%)	9 (12.9%)	4 (11.8%)	3 (27.3%)	7 (15.6%)
Grade 1	6 (11.5%)	1 (5.6%)	7 (10.0%)	3 (8.8%)	2 (18.2%)	5 (11.1%)
Grade 2	0	0	0	1 (2.9%)	1 (9.1%)	2 (4.4%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Asthenic conditions (cont)						
Fatigue	3 (21.4%)	6 (28.6%)	9 (25.7%)	0	2 (10.5%)	2 (7.1%)
Grade 1	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	0	0
Grade 2	2 (14.3%)	5 (23.8%)	7 (20.0%)	0	1 (5.3%)	1 (3.6%)
Grade 3	0	0	0	0	1 (5.3%)	1 (3.6%)
Febrile disorders	3 (21.4%)	2 (9.5%)	5 (14.3%)	3 (33.3%)	4 (21.1%)	7 (25.0%)
Grade 1	1 (7.1%)	1 (4.8%)	2 (5.7%)	1 (11.1%)	3 (15.8%)	4 (14.3%)
Grade 2	2 (14.3%)	1 (4.8%)	3 (8.6%)	1 (11.1%)	1 (5.3%)	2 (7.1%)
Grade 3	0	0	0	1 (11.1%)	0	1 (3.6%)
Pyrexia	3 (21.4%)	2 (9.5%)	5 (14.3%)	3 (33.3%)	4 (21.1%)	7 (25.0%)
Grade 1	1 (7.1%)	1 (4.8%)	2 (5.7%)	1 (11.1%)	3 (15.8%)	4 (14.3%)
Grade 2	2 (14.3%)	1 (4.8%)	3 (8.6%)	1 (11.1%)	1 (5.3%)	2 (7.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Febrile disorders (cont)						
Pyrexia (cont)						
Grade 3	2 (3.8%)	0	2 (2.9%)	0	0	0
Oedema NEC	8 (15.4%)	4 (22.2%)	12 (17.1%)	4 (11.8%)	1 (9.1%)	5 (11.1%)
Grade 1	4 (7.7%)	4 (22.2%)	8 (11.4%)	2 (5.9%)	0	2 (4.4%)
Grade 2	4 (7.7%)	0	4 (5.7%)	2 (5.9%)	0	2 (4.4%)
Grade 3	0	0	0	0	1 (9.1%)	1 (2.2%)
Oedema peripheral	8 (15.4%)	4 (22.2%)	12 (17.1%)	4 (11.8%)	1 (9.1%)	5 (11.1%)
Grade 1	4 (7.7%)	4 (22.2%)	8 (11.4%)	2 (5.9%)	0	2 (4.4%)
Grade 2	4 (7.7%)	0	4 (5.7%)	2 (5.9%)	0	2 (4.4%)
Grade 3	0	0	0	0	1 (9.1%)	1 (2.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Febrile disorders (cont)						
Pyrexia (cont)						
Grade 3	0	0	0	1 (11.1%)	0	1 (3.6%)
Oedema NEC	0	2 (9.5%)	2 (5.7%)	0	2 (10.5%)	2 (7.1%)
Grade 1	0	1 (4.8%)	1 (2.9%)	0	1 (5.3%)	1 (3.6%)
Grade 2	0	1 (4.8%)	1 (2.9%)	0	1 (5.3%)	1 (3.6%)
Grade 3	0	0	0	0	0	0
Oedema peripheral	0	1 (4.8%)	1 (2.9%)	0	2 (10.5%)	2 (7.1%)
Grade 1	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 2	0	1 (4.8%)	1 (2.9%)	0	1 (5.3%)	1 (3.6%)
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Oedema NEC (cont)						
Generalised oedema	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Feelings and sensations NEC	4 (7.7%)	2 (11.1%)	6 (8.6%)	3 (8.8%)	0	3 (6.7%)
Grade 1	3 (5.8%)	1 (5.6%)	4 (5.7%)	2 (5.9%)	0	2 (4.4%)
Grade 2	1 (1.9%)	1 (5.6%)	2 (2.9%)	1 (2.9%)	0	1 (2.2%)
Early satiety	2 (3.8%)	2 (11.1%)	4 (5.7%)	0	0	0
Grade 1	1 (1.9%)	1 (5.6%)	2 (2.9%)	0	0	0
Grade 2	1 (1.9%)	1 (5.6%)	2 (2.9%)	0	0	0
Chills	1 (1.9%)	0	1 (1.4%)	2 (5.9%)	0	2 (4.4%)
Grade 1	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Oedema NEC (cont)						
Generalised oedema	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 1	0	1 (4.8%)	1 (2.9%)	0	0	0
Feelings and sensations NEC	0	2 (9.5%)	2 (5.7%)	0	1 (5.3%)	1 (3.6%)
Grade 1	0	2 (9.5%)	2 (5.7%)	0	1 (5.3%)	1 (3.6%)
Grade 2	0	0	0	0	0	0
Early satiety	0	2 (9.5%)	2 (5.7%)	0	1 (5.3%)	1 (3.6%)
Grade 1	0	2 (9.5%)	2 (5.7%)	0	1 (5.3%)	1 (3.6%)
Grade 2	0	0	0	0	0	0
Chills	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Feelings and sensations NEC (cont)						
Chills (cont)						
Grade 2	0	0	0	1 (2.9%)	0	1 (2.2%)
Feeling hot	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Grade 1	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Pain and discomfort NEC	2 (3.8%)	0	2 (2.9%)	1 (2.9%)	0	1 (2.2%)
Grade 2	2 (3.8%)	0	2 (2.9%)	1 (2.9%)	0	1 (2.2%)
Chest pain	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 2	0	0	0	1 (2.9%)	0	1 (2.2%)
Non-cardiac chest pain	1 (1.9%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Feelings and sensations NEC (cont)						
Chills (cont)						
Grade 2	0	0	0	0	0	0
Feeling hot	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Pain and discomfort NEC	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 2	1 (7.1%)	0	1 (2.9%)	0	0	0
Chest pain	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 2	1 (7.1%)	0	1 (2.9%)	0	0	0
Non-cardiac chest pain	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Pain and discomfort NEC (cont)						
Non-cardiac chest pain (cont)						
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Pain	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Gait disturbances	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Gait disturbance	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Pain and discomfort NEC (cont)						
Non-cardiac chest pain (cont)						
Grade 2	0	0	0	0	0	0
Pain	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Gait disturbances	1 (7.1%)	1 (4.8%)	2 (5.7%)	1 (11.1%)	0	1 (3.6%)
Grade 1	0	1 (4.8%)	1 (2.9%)	1 (11.1%)	0	1 (3.6%)
Grade 2	1 (7.1%)	0	1 (2.9%)	0	0	0
Gait disturbance	1 (7.1%)	1 (4.8%)	2 (5.7%)	1 (11.1%)	0	1 (3.6%)
Grade 1	0	1 (4.8%)	1 (2.9%)	1 (11.1%)	0	1 (3.6%)
Grade 2	1 (7.1%)	0	1 (2.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
General signs and symptoms NEC	2 (3.8%)	1 (5.6%)	3 (4.3%)	0	0	0
Grade 1	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	2 (3.8%)	0	2 (2.9%)	0	0	0
Disease progression	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 3	1 (1.9%)	0	1 (1.4%)	0	0	0
General physical health deterioration	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	1 (1.9%)	0	1 (1.4%)	0	0	0
Influenza like illness	0	1 (5.6%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
General signs and symptoms NEC	0	2 (9.5%)	2 (5.7%)	0	0	0
Grade 1	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 2	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 3	0	0	0	0	0	0
Disease progression	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
General physical health deterioration	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 2	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 3	0	0	0	0	0	0
Influenza like illness	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
General signs and symptoms NEC (cont)						
Influenza like illness (cont)						
Grade 1	0	1 (5.6%)	1 (1.4%)	0	0	0
Peripheral swelling	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Injection site reactions	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Injection site pain	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Body temperature altered	0	1 (5.6%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
General signs and symptoms NEC (cont)						
Influenza like illness (cont)						
Grade 1	0	0	0	0	0	0
Peripheral swelling	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 1	0	1 (4.8%)	1 (2.9%)	0	0	0
Injection site reactions	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Injection site pain	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Body temperature altered	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Body temperature altered (cont)						
(cont)						
Grade 1	0	1 (5.6%)	1 (1.4%)	0	0	0
Temperature regulation disorder	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (5.6%)	1 (1.4%)	0	0	0
Nervous system disorders	26 (50.0%)	1 (5.6%)	27 (38.6%)	9 (26.5%)	7 (63.6%)	16 (35.6%)
Grade 1	17 (32.7%)	0	17 (24.3%)	8 (23.5%)	6 (54.5%)	14 (31.1%)
Grade 2	7 (13.5%)	1 (5.6%)	8 (11.4%)	0	1 (9.1%)	1 (2.2%)
Grade 3	2 (3.8%)	0	2 (2.9%)	1 (2.9%)	0	1 (2.2%)
Neurological signs and symptoms NEC	12 (23.1%)	1 (5.6%)	13 (18.6%)	5 (14.7%)	1 (9.1%)	6 (13.3%)
Grade 1	8 (15.4%)	1 (5.6%)	9 (12.9%)	4 (11.8%)	1 (9.1%)	5 (11.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
General disorders and administration site conditions (cont)						
Body temperature altered (cont)						
(cont)						
Grade 1	0	0	0	0	0	0
Temperature regulation disorder	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Nervous system disorders	6 (42.9%)	7 (33.3%)	13 (37.1%)	2 (22.2%)	7 (36.8%)	9 (32.1%)
Grade 1	5 (35.7%)	5 (23.8%)	10 (28.6%)	1 (11.1%)	4 (21.1%)	5 (17.9%)
Grade 2	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	2 (10.5%)	2 (7.1%)
Grade 3	0	1 (4.8%)	1 (2.9%)	1 (11.1%)	1 (5.3%)	2 (7.1%)
Neurological signs and symptoms NEC	2 (14.3%)	2 (9.5%)	4 (11.4%)	1 (11.1%)	1 (5.3%)	2 (7.1%)
Grade 1	2 (14.3%)	2 (9.5%)	4 (11.4%)	0	1 (5.3%)	1 (3.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Neurological signs and symptoms NEC (cont)						
(cont)						
Grade 2	3 (5.8%)	0	3 (4.3%)	0	0	0
Grade 3	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Dizziness	9 (17.3%)	1 (5.6%)	10 (14.3%)	5 (14.7%)	1 (9.1%)	6 (13.3%)
Grade 1	7 (13.5%)	1 (5.6%)	8 (11.4%)	4 (11.8%)	1 (9.1%)	5 (11.1%)
Grade 2	2 (3.8%)	0	2 (2.9%)	0	0	0
Grade 3	0	0	0	1 (2.9%)	0	1 (2.2%)
Presyncope	3 (5.8%)	0	3 (4.3%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 3	1 (1.9%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Neurological signs and symptoms NEC (cont)						
(cont)						
Grade 2	0	0	0	1 (11.1%)	0	1 (3.6%)
Grade 3	0	0	0	0	0	0
Dizziness	2 (14.3%)	2 (9.5%)	4 (11.4%)	0	1 (5.3%)	1 (3.6%)
Grade 1	2 (14.3%)	2 (9.5%)	4 (11.4%)	0	1 (5.3%)	1 (3.6%)
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Presyncope	0	0	0	1 (11.1%)	0	1 (3.6%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	1 (11.1%)	0	1 (3.6%)
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Neurological signs and symptoms NEC (cont)						
Dizziness exertional	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Dizziness postural	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Headaches NEC	7 (13.5%)	1 (5.6%)	8 (11.4%)	0	1 (9.1%)	1 (2.2%)
Grade 1	5 (9.6%)	0	5 (7.1%)	0	1 (9.1%)	1 (2.2%)
Grade 2	2 (3.8%)	1 (5.6%)	3 (4.3%)	0	0	0
Grade 3	0	0	0	0	0	0
Headache	7 (13.5%)	1 (5.6%)	8 (11.4%)	0	1 (9.1%)	1 (2.2%)
Grade 1	5 (9.6%)	0	5 (7.1%)	0	1 (9.1%)	1 (2.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Neurological signs and symptoms NEC (cont)						
Dizziness exertional	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dizziness postural	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Headaches NEC	1 (7.1%)	2 (9.5%)	3 (8.6%)	0	4 (21.1%)	4 (14.3%)
Grade 1	1 (7.1%)	0	1 (2.9%)	0	1 (5.3%)	1 (3.6%)
Grade 2	0	1 (4.8%)	1 (2.9%)	0	2 (10.5%)	2 (7.1%)
Grade 3	0	1 (4.8%)	1 (2.9%)	0	1 (5.3%)	1 (3.6%)
Headache	1 (7.1%)	2 (9.5%)	3 (8.6%)	0	4 (21.1%)	4 (14.3%)
Grade 1	1 (7.1%)	0	1 (2.9%)	0	1 (5.3%)	1 (3.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Headaches NEC (cont)						
Headache (cont)						
Grade 2	2 (3.8%)	1 (5.6%)	3 (4.3%)	0	0	0
Grade 3	0	0	0	0	0	0
Peripheral neuropathies NEC	5 (9.6%)	0	5 (7.1%)	0	2 (18.2%)	2 (4.4%)
Grade 1	4 (7.7%)	0	4 (5.7%)	0	2 (18.2%)	2 (4.4%)
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Peripheral sensory neuropathy	4 (7.7%)	0	4 (5.7%)	0	2 (18.2%)	2 (4.4%)
Grade 1	3 (5.8%)	0	3 (4.3%)	0	2 (18.2%)	2 (4.4%)
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Peripheral motor neuropathy	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Headaches NEC (cont)						
Headache (cont)						
Grade 2	0	1 (4.8%)	1 (2.9%)	0	2 (10.5%)	2 (7.1%)
Grade 3	0	1 (4.8%)	1 (2.9%)	0	1 (5.3%)	1 (3.6%)
Peripheral neuropathies NEC	2 (14.3%)	0	2 (5.7%)	1 (11.1%)	2 (10.5%)	3 (10.7%)
Grade 1	2 (14.3%)	0	2 (5.7%)	1 (11.1%)	2 (10.5%)	3 (10.7%)
Grade 2	0	0	0	0	0	0
Peripheral sensory neuropathy	2 (14.3%)	0	2 (5.7%)	1 (11.1%)	2 (10.5%)	3 (10.7%)
Grade 1	2 (14.3%)	0	2 (5.7%)	1 (11.1%)	2 (10.5%)	3 (10.7%)
Grade 2	0	0	0	0	0	0
Peripheral motor neuropathy	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Paraesthesias and dysaesthesias	3 (5.8%)	0	3 (4.3%)	2 (5.9%)	1 (9.1%)	3 (6.7%)
Grade 1	2 (3.8%)	0	2 (2.9%)	2 (5.9%)	1 (9.1%)	3 (6.7%)
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Paraesthesia	3 (5.8%)	0	3 (4.3%)	1 (2.9%)	1 (9.1%)	2 (4.4%)
Grade 1	2 (3.8%)	0	2 (2.9%)	1 (2.9%)	1 (9.1%)	2 (4.4%)
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Hypoaesthesia	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 1	0	0	0	1 (2.9%)	0	1 (2.2%)
Sensory abnormalities NEC	2 (3.8%)	0	2 (2.9%)	1 (2.9%)	1 (9.1%)	2 (4.4%)
Grade 1	2 (3.8%)	0	2 (2.9%)	1 (2.9%)	0	1 (2.2%)
Grade 2	0	0	0	0	1 (9.1%)	1 (2.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Paraesthesias and dysaesthesias	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	1 (5.3%)	1 (3.6%)
Grade 1	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	1 (5.3%)	1 (3.6%)
Grade 2	0	0	0	0	0	0
Paraesthesia	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	1 (5.3%)	1 (3.6%)
Grade 1	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	1 (5.3%)	1 (3.6%)
Grade 2	0	0	0	0	0	0
Hypoaesthesia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Sensory abnormalities NEC	2 (14.3%)	0	2 (5.7%)	0	0	0
Grade 1	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 2	1 (7.1%)	0	1 (2.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Sensory abnormalities NEC (cont)						
Restless legs syndrome	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	0	0	0	0	0	0
Neuralgia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Taste disorder	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Hypogeusia	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 1	0	0	0	1 (2.9%)	0	1 (2.2%)
Post herpetic neuralgia	0	0	0	0	1 (9.1%)	1 (2.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Sensory abnormalities NEC (cont)						
Restless legs syndrome	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	1 (7.1%)	0	1 (2.9%)	0	0	0
Neuralgia	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 1	1 (7.1%)	0	1 (2.9%)	0	0	0
Taste disorder	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hypogeusia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Post herpetic neuralgia	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Sensory abnormalities NEC (cont)						
Post herpetic neuralgia (cont)						
Grade 2	0	0	0	0	1 (9.1%)	1 (2.2%)
Disturbances in consciousness NEC	2 (3.8%)	0	2 (2.9%)	0	2 (18.2%)	2 (4.4%)
Grade 1	1 (1.9%)	0	1 (1.4%)	0	2 (18.2%)	2 (4.4%)
Grade 3	1 (1.9%)	0	1 (1.4%)	0	0	0
Loss of consciousness	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 3	1 (1.9%)	0	1 (1.4%)	0	0	0
Somnolence	1 (1.9%)	0	1 (1.4%)	0	2 (18.2%)	2 (4.4%)
Grade 1	1 (1.9%)	0	1 (1.4%)	0	2 (18.2%)	2 (4.4%)
Syncope	1 (1.9%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Sensory abnormalities NEC (cont)						
Post herpetic neuralgia (cont)						
Grade 2	0	0	0	0	0	0
Disturbances in consciousness NEC	0	1 (4.8%)	1 (2.9%)	1 (11.1%)	0	1 (3.6%)
Grade 1	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 3	0	0	0	1 (11.1%)	0	1 (3.6%)
Loss of consciousness	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Somnolence	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 1	0	1 (4.8%)	1 (2.9%)	0	0	0
Syncope	0	0	0	1 (11.1%)	0	1 (3.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Disturbances in consciousness NEC (cont)						
Syncope (cont)						
Grade 3	1 (1.9%)	0	1 (1.4%)	0	0	0
Tremor (excl congenital)	2 (3.8%)	0	2 (2.9%)	0	0	0
Grade 1	2 (3.8%)	0	2 (2.9%)	0	0	0
Tremor	2 (3.8%)	0	2 (2.9%)	0	0	0
Grade 1	2 (3.8%)	0	2 (2.9%)	0	0	0
Cervical spinal cord and nerve root disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Disturbances in consciousness NEC (cont)						
Syncope (cont)						
Grade 3	0	0	0	1 (11.1%)	0	1 (3.6%)
Tremor (excl congenital)	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Tremor	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Cervical spinal cord and nerve root disorders	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 1	1 (7.1%)	0	1 (2.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Cervical spinal cord and nerve root disorders (cont)						
Cervical radiculopathy	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Coordination and balance disturbances	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Balance disorder	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Memory loss (excl dementia)	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Memory impairment	1 (1.9%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Cervical spinal cord and nerve root disorders (cont)						
Cervical radiculopathy	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 1	1 (7.1%)	0	1 (2.9%)	0	0	0
Coordination and balance disturbances	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 1	1 (7.1%)	0	1 (2.9%)	0	0	0
Balance disorder	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 1	1 (7.1%)	0	1 (2.9%)	0	0	0
Memory loss (excl dementia)	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Memory impairment	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Memory loss (excl dementia) (cont)						
Memory impairment (cont)						
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Mental impairment (excl dementia and memory loss)	1 (1.9%)	0	1 (1.4%)	2 (5.9%)	1 (9.1%)	3 (6.7%)
Grade 1	1 (1.9%)	0	1 (1.4%)	2 (5.9%)	1 (9.1%)	3 (6.7%)
Disturbance in attention	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	1 (9.1%)	2 (4.4%)
Grade 1	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	1 (9.1%)	2 (4.4%)
Cognitive disorder	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 1	0	0	0	1 (2.9%)	0	1 (2.2%)
Mononeuropathies	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase	RT Phase	RT Phase	ET Phase (Week 24 - 48) Continuing	ET Phase (Week 24 - 48) Switch	ET Phase (Week 24 - 48)
	MMB (N=14)	BAT (N=21)	Total (N=35)	(MMB->MMB) (N=9)	(BAT->MMB) (N=19)	Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Memory loss (excl dementia) (cont)						
Memory impairment (cont)						
Grade 1	0	0	0	0	0	0
Mental impairment (excl dementia and memory loss)	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Disturbance in attention	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Cognitive disorder	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Mononeuropathies	1 (7.1%)	0	1 (2.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Mononeuropathies (cont)						
(cont)						
Grade 1	0	0	0	0	0	0
Nerve compression	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Neurologic visual problems NEC	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Visual field defect	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Olfactory nerve disorders	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Mononeuropathies (cont)						
(cont)						
Grade 1	1 (7.1%)	0	1 (2.9%)	0	0	0
Nerve compression	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 1	1 (7.1%)	0	1 (2.9%)	0	0	0
Neurologic visual problems NEC	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Visual field defect	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Olfactory nerve disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Olfactory nerve disorders (cont)						
Parosmia	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Speech and language abnormalities	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Speech disorder	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Central nervous system haemorrhages and cerebrovascular accidents	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Cerebral infarction	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Olfactory nerve disorders (cont)						
Parosmia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Speech and language abnormalities	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Speech disorder	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Central nervous system haemorrhages and cerebrovascular accidents	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 1	0	0	0	0	1 (5.3%)	1 (3.6%)
Cerebral infarction	0	0	0	0	1 (5.3%)	1 (3.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Central nervous system haemorrhages and cerebrovascular accidents (cont)						
Cerebral infarction (cont)						
Grade 1	0	0	0	0	0	0
Dementia (excl Alzheimer's type)	0	0	0	0	1 (9.1%)	1 (2.2%)
Grade 1	0	0	0	0	1 (9.1%)	1 (2.2%)
Dementia	0	0	0	0	1 (9.1%)	1 (2.2%)
Grade 1	0	0	0	0	1 (9.1%)	1 (2.2%)
Muscle tone abnormal	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hypertonia	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Central nervous system haemorrhages and cerebrovascular accidents (cont)						
Cerebral infarction (cont)						
Grade 1	0	0	0	0	1 (5.3%)	1 (3.6%)
Dementia (excl Alzheimer's type)	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dementia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Muscle tone abnormal	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 1	0	1 (4.8%)	1 (2.9%)	0	0	0
Hypertonia	0	1 (4.8%)	1 (2.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Muscle tone abnormal (cont)						
Hypertonia (cont)						
Grade 1	0	0	0	0	0	0
Nervous system cysts and polyps	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Arachnoid cyst	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Blood and lymphatic system disorders	18 (34.6%)	10 (55.6%)	28 (40.0%)	4 (11.8%)	7 (63.6%)	11 (24.4%)
Grade 1	3 (5.8%)	0	3 (4.3%)	0	0	0
Grade 2	3 (5.8%)	1 (5.6%)	4 (5.7%)	2 (5.9%)	1 (9.1%)	3 (6.7%)
Grade 3	9 (17.3%)	8 (44.4%)	17 (24.3%)	1 (2.9%)	5 (45.5%)	6 (13.3%)
Grade 4	3 (5.8%)	1 (5.6%)	4 (5.7%)	1 (2.9%)	1 (9.1%)	2 (4.4%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Nervous system disorders (cont)						
Muscle tone abnormal (cont)						
Hypertonia (cont)						
Grade 1	0	1 (4.8%)	1 (2.9%)	0	0	0
Nervous system cysts and polyps	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 1	0	0	0	0	1 (5.3%)	1 (3.6%)
Arachnoid cyst	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 1	0	0	0	0	1 (5.3%)	1 (3.6%)
Blood and lymphatic system disorders	8 (57.1%)	6 (28.6%)	14 (40.0%)	3 (33.3%)	8 (42.1%)	11 (39.3%)
Grade 1	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	1 (5.3%)	1 (3.6%)
Grade 2	1 (7.1%)	2 (9.5%)	3 (8.6%)	0	4 (21.1%)	4 (14.3%)
Grade 3	4 (28.6%)	3 (14.3%)	7 (20.0%)	3 (33.3%)	2 (10.5%)	5 (17.9%)
Grade 4	2 (14.3%)	0	2 (5.7%)	0	1 (5.3%)	1 (3.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Anaemias NEC	9 (17.3%)	8 (44.4%)	17 (24.3%)	1 (2.9%)	4 (36.4%)	5 (11.1%)
Grade 2	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 3	9 (17.3%)	7 (38.9%)	16 (22.9%)	1 (2.9%)	4 (36.4%)	5 (11.1%)
Grade 4	0	0	0	0	0	0
Anaemia	9 (17.3%)	8 (44.4%)	17 (24.3%)	1 (2.9%)	4 (36.4%)	5 (11.1%)
Grade 2	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 3	9 (17.3%)	7 (38.9%)	16 (22.9%)	1 (2.9%)	4 (36.4%)	5 (11.1%)
Grade 4	0	0	0	0	0	0
Thrombocytopenias	8 (15.4%)	3 (16.7%)	11 (15.7%)	2 (5.9%)	4 (36.4%)	6 (13.3%)
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	3 (5.8%)	1 (5.6%)	4 (5.7%)	2 (5.9%)	1 (9.1%)	3 (6.7%)
Grade 3	1 (1.9%)	2 (11.1%)	3 (4.3%)	0	2 (18.2%)	2 (4.4%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Anaemias NEC	4 (28.6%)	2 (9.5%)	6 (17.1%)	3 (33.3%)	1 (5.3%)	4 (14.3%)
Grade 2	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 3	2 (14.3%)	2 (9.5%)	4 (11.4%)	3 (33.3%)	1 (5.3%)	4 (14.3%)
Grade 4	1 (7.1%)	0	1 (2.9%)	0	0	0
Anaemia	4 (28.6%)	2 (9.5%)	6 (17.1%)	3 (33.3%)	1 (5.3%)	4 (14.3%)
Grade 2	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 3	2 (14.3%)	2 (9.5%)	4 (11.4%)	3 (33.3%)	1 (5.3%)	4 (14.3%)
Grade 4	1 (7.1%)	0	1 (2.9%)	0	0	0
Thrombocytopenias	3 (21.4%)	1 (4.8%)	4 (11.4%)	0	3 (15.8%)	3 (10.7%)
Grade 1	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 2	0	1 (4.8%)	1 (2.9%)	0	2 (10.5%)	2 (7.1%)
Grade 3	1 (7.1%)	0	1 (2.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Thrombocytopenias (cont) (cont)						
Grade 4	3 (5.8%)	0	3 (4.3%)	0	1 (9.1%)	1 (2.2%)
Thrombocytopenia	8 (15.4%)	3 (16.7%)	11 (15.7%)	2 (5.9%)	4 (36.4%)	6 (13.3%)
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	3 (5.8%)	1 (5.6%)	4 (5.7%)	2 (5.9%)	1 (9.1%)	3 (6.7%)
Grade 3	1 (1.9%)	2 (11.1%)	3 (4.3%)	0	2 (18.2%)	2 (4.4%)
Grade 4	3 (5.8%)	0	3 (4.3%)	0	1 (9.1%)	1 (2.2%)
Neutropenias	3 (5.8%)	1 (5.6%)	4 (5.7%)	1 (2.9%)	1 (9.1%)	2 (4.4%)
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	1 (1.9%)	0	1 (1.4%)	0	1 (9.1%)	1 (2.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Thrombocytopenias (cont) (cont)						
Grade 4	1 (7.1%)	0	1 (2.9%)	0	1 (5.3%)	1 (3.6%)
Thrombocytopenia	3 (21.4%)	1 (4.8%)	4 (11.4%)	0	3 (15.8%)	3 (10.7%)
Grade 1	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 2	0	1 (4.8%)	1 (2.9%)	0	2 (10.5%)	2 (7.1%)
Grade 3	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 4	1 (7.1%)	0	1 (2.9%)	0	1 (5.3%)	1 (3.6%)
Neutropenias	4 (28.6%)	0	4 (11.4%)	0	1 (5.3%)	1 (3.6%)
Grade 1	0	0	0	0	0	0
Grade 2	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 3	1 (7.1%)	0	1 (2.9%)	0	1 (5.3%)	1 (3.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Neutropenias (cont)						
(cont)						
Grade 4	1 (1.9%)	1 (5.6%)	2 (2.9%)	1 (2.9%)	0	1 (2.2%)
Neutropenia	3 (5.8%)	1 (5.6%)	4 (5.7%)	1 (2.9%)	1 (9.1%)	2 (4.4%)
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	1 (1.9%)	0	1 (1.4%)	0	1 (9.1%)	1 (2.2%)
Grade 4	1 (1.9%)	1 (5.6%)	2 (2.9%)	1 (2.9%)	0	1 (2.2%)
Spleen disorders	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Neutropenias (cont) (cont)						
Grade 4	2 (14.3%)	0	2 (5.7%)	0	0	0
Neutropenia	4 (28.6%)	0	4 (11.4%)	0	1 (5.3%)	1 (3.6%)
Grade 1	0	0	0	0	0	0
Grade 2	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 3	1 (7.1%)	0	1 (2.9%)	0	1 (5.3%)	1 (3.6%)
Grade 4	2 (14.3%)	0	2 (5.7%)	0	0	0
Spleen disorders	1 (7.1%)	2 (9.5%)	3 (8.6%)	0	2 (10.5%)	2 (7.1%)
Grade 1	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 2	0	1 (4.8%)	1 (2.9%)	0	2 (10.5%)	2 (7.1%)
Grade 3	1 (7.1%)	0	1 (2.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Spleen disorders (cont)						
Splenic infarction	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Splenomegaly	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Bleeding tendencies	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Increased tendency to bruise	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Spleen disorders (cont)						
Splenic infarction	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 2	0	0	0	0	1 (5.3%)	1 (3.6%)
Splenomegaly	1 (7.1%)	2 (9.5%)	3 (8.6%)	0	1 (5.3%)	1 (3.6%)
Grade 1	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 2	0	1 (4.8%)	1 (2.9%)	0	1 (5.3%)	1 (3.6%)
Grade 3	1 (7.1%)	0	1 (2.9%)	0	0	0
Bleeding tendencies	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 1	0	0	0	0	1 (5.3%)	1 (3.6%)
Increased tendency to bruise	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 1	0	0	0	0	1 (5.3%)	1 (3.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Coagulopathies	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Hyperfibrinogenaemia	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Leukocytoses NEC	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Neutrophilia	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Leukopenias NEC	0	0	0	0	1 (9.1%)	1 (2.2%)
Grade 3	0	0	0	0	1 (9.1%)	1 (2.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Coagulopathies	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hyperfibrinogenaemia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Leukocytoses NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Neutrophilia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Leukopenias NEC	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 3	1 (7.1%)	0	1 (2.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Leukopenias NEC (cont)						
Leukopenia	0	0	0	0	1 (9.1%)	1 (2.2%)
Grade 3	0	0	0	0	1 (9.1%)	1 (2.2%)
Lymphatic system disorders NEC	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	1 (5.6%)	1 (1.4%)	0	0	0
Lymphadenopathy	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	1 (5.6%)	1 (1.4%)	0	0	0
Anaemias haemolytic NEC	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Leukopenias NEC (cont)						
Leukopenia	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 3	1 (7.1%)	0	1 (2.9%)	0	0	0
Lymphatic system disorders NEC	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 1	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 3	0	0	0	0	0	0
Lymphadenopathy	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 1	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 3	0	0	0	0	0	0
Anaemias haemolytic NEC	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 3	0	1 (4.8%)	1 (2.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Anaemias haemolytic NEC (cont)						
Haemolytic anaemia	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Metabolism and nutrition disorders	21 (40.4%)	6 (33.3%)	27 (38.6%)	7 (20.6%)	2 (18.2%)	9 (20.0%)
Grade 1	13 (25.0%)	2 (11.1%)	15 (21.4%)	4 (11.8%)	1 (9.1%)	5 (11.1%)
Grade 2	3 (5.8%)	1 (5.6%)	4 (5.7%)	3 (8.8%)	0	3 (6.7%)
Grade 3	5 (9.6%)	2 (11.1%)	7 (10.0%)	0	1 (9.1%)	1 (2.2%)
Grade 4	0	1 (5.6%)	1 (1.4%)	0	0	0
Water soluble vitamin deficiencies	7 (13.5%)	1 (5.6%)	8 (11.4%)	3 (8.8%)	1 (9.1%)	4 (8.9%)
Grade 1	5 (9.6%)	1 (5.6%)	6 (8.6%)	2 (5.9%)	1 (9.1%)	3 (6.7%)
Grade 2	2 (3.8%)	0	2 (2.9%)	1 (2.9%)	0	1 (2.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Blood and lymphatic system disorders (cont)						
Anaemias haemolytic NEC (cont)						
Haemolytic anaemia	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 3	0	1 (4.8%)	1 (2.9%)	0	0	0
Metabolism and nutrition disorders	4 (28.6%)	2 (9.5%)	6 (17.1%)	1 (11.1%)	5 (26.3%)	6 (21.4%)
Grade 1	4 (28.6%)	0	4 (11.4%)	0	2 (10.5%)	2 (7.1%)
Grade 2	0	1 (4.8%)	1 (2.9%)	0	3 (15.8%)	3 (10.7%)
Grade 3	0	1 (4.8%)	1 (2.9%)	1 (11.1%)	0	1 (3.6%)
Grade 4	0	0	0	0	0	0
Water soluble vitamin deficiencies	2 (14.3%)	0	2 (5.7%)	0	0	0
Grade 1	2 (14.3%)	0	2 (5.7%)	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Water soluble vitamin deficiencies (cont)						
Vitamin B1 deficiency	5 (9.6%)	1 (5.6%)	6 (8.6%)	3 (8.8%)	1 (9.1%)	4 (8.9%)
Grade 1	3 (5.8%)	1 (5.6%)	4 (5.7%)	2 (5.9%)	1 (9.1%)	3 (6.7%)
Grade 2	2 (3.8%)	0	2 (2.9%)	1 (2.9%)	0	1 (2.2%)
Vitamin B complex deficiency	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Vitamin B6 deficiency	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Potassium imbalance	6 (11.5%)	0	6 (8.6%)	1 (2.9%)	1 (9.1%)	2 (4.4%)
Grade 1	4 (7.7%)	0	4 (5.7%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Water soluble vitamin deficiencies (cont)						
Vitamin B1 deficiency	2 (14.3%)	0	2 (5.7%)	0	0	0
Grade 1	2 (14.3%)	0	2 (5.7%)	0	0	0
Grade 2	0	0	0	0	0	0
Vitamin B complex deficiency	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Vitamin B6 deficiency	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Potassium imbalance	0	0	0	1 (11.1%)	2 (10.5%)	3 (10.7%)
Grade 1	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 2	0	0	0	0	1 (5.3%)	1 (3.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Potassium imbalance (cont)						
(cont)						
Grade 3	1 (1.9%)	0	1 (1.4%)	0	1 (9.1%)	1 (2.2%)
Hyperkalaemia	6 (11.5%)	0	6 (8.6%)	1 (2.9%)	0	1 (2.2%)
Grade 1	5 (9.6%)	0	5 (7.1%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Hypokalaemia	2 (3.8%)	0	2 (2.9%)	0	1 (9.1%)	1 (2.2%)
Grade 1	0	0	0	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 3	1 (1.9%)	0	1 (1.4%)	0	1 (9.1%)	1 (2.2%)
Appetite disorders	5 (9.6%)	2 (11.1%)	7 (10.0%)	1 (2.9%)	0	1 (2.2%)
Grade 1	4 (7.7%)	0	4 (5.7%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Potassium imbalance (cont)						
(cont)						
Grade 3	0	0	0	1 (11.1%)	0	1 (3.6%)
Hyperkalaemia	0	0	0	1 (11.1%)	1 (5.3%)	2 (7.1%)
Grade 1	0	0	0	1 (11.1%)	0	1 (3.6%)
Grade 2	0	0	0	0	1 (5.3%)	1 (3.6%)
Hypokalaemia	0	0	0	1 (11.1%)	1 (5.3%)	2 (7.1%)
Grade 1	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	1 (11.1%)	0	1 (3.6%)
Appetite disorders	0	0	0	0	2 (10.5%)	2 (7.1%)
Grade 1	0	0	0	0	1 (5.3%)	1 (3.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Appetite disorders (cont)						
(cont)						
Grade 2	1 (1.9%)	1 (5.6%)	2 (2.9%)	1 (2.9%)	0	1 (2.2%)
Grade 3	0	1 (5.6%)	1 (1.4%)	0	0	0
Decreased appetite	4 (7.7%)	2 (11.1%)	6 (8.6%)	1 (2.9%)	0	1 (2.2%)
Grade 1	3 (5.8%)	0	3 (4.3%)	0	0	0
Grade 2	1 (1.9%)	1 (5.6%)	2 (2.9%)	1 (2.9%)	0	1 (2.2%)
Grade 3	0	1 (5.6%)	1 (1.4%)	0	0	0
Appetite disorder	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Calcium metabolism disorders	3 (5.8%)	1 (5.6%)	4 (5.7%)	2 (5.9%)	1 (9.1%)	3 (6.7%)
Grade 1	3 (5.8%)	1 (5.6%)	4 (5.7%)	2 (5.9%)	0	2 (4.4%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Appetite disorders (cont)						
(cont)						
Grade 2	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 3	0	0	0	0	0	0
Decreased appetite	0	0	0	0	2 (10.5%)	2 (7.1%)
Grade 1	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 2	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 3	0	0	0	0	0	0
Appetite disorder	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Calcium metabolism disorders	1 (7.1%)	0	1 (2.9%)	0	1 (5.3%)	1 (3.6%)
Grade 1	1 (7.1%)	0	1 (2.9%)	0	1 (5.3%)	1 (3.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Calcium metabolism disorders (cont)						
(cont)						
Grade 3	0	0	0	0	1 (9.1%)	1 (2.2%)
Hypocalcaemia	3 (5.8%)	1 (5.6%)	4 (5.7%)	2 (5.9%)	1 (9.1%)	3 (6.7%)
Grade 1	3 (5.8%)	1 (5.6%)	4 (5.7%)	2 (5.9%)	0	2 (4.4%)
Grade 3	0	0	0	0	1 (9.1%)	1 (2.2%)
Disorders of purine metabolism	4 (7.7%)	1 (5.6%)	5 (7.1%)	1 (2.9%)	1 (9.1%)	2 (4.4%)
Grade 1	3 (5.8%)	0	3 (4.3%)	1 (2.9%)	0	1 (2.2%)
Grade 2	0	0	0	0	1 (9.1%)	1 (2.2%)
Grade 3	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 4	0	1 (5.6%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Calcium metabolism disorders (cont)						
(cont)						
Grade 3	0	0	0	0	0	0
Hypocalcaemia	1 (7.1%)	0	1 (2.9%)	0	1 (5.3%)	1 (3.6%)
Grade 1	1 (7.1%)	0	1 (2.9%)	0	1 (5.3%)	1 (3.6%)
Grade 3	0	0	0	0	0	0
Disorders of purine metabolism	0	2 (9.5%)	2 (5.7%)	0	0	0
Grade 1	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 2	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 3	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Disorders of purine metabolism (cont)						
Hyperuricaemia	4 (7.7%)	1 (5.6%)	5 (7.1%)	1 (2.9%)	1 (9.1%)	2 (4.4%)
Grade 1	3 (5.8%)	0	3 (4.3%)	1 (2.9%)	0	1 (2.2%)
Grade 2	0	0	0	0	1 (9.1%)	1 (2.2%)
Grade 3	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 4	0	1 (5.6%)	1 (1.4%)	0	0	0
Gout	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Hyperglycaemic conditions NEC	3 (5.8%)	0	3 (4.3%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	2 (3.8%)	0	2 (2.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Disorders of purine metabolism (cont)						
Hyperuricaemia	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 1	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Gout	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 2	0	1 (4.8%)	1 (2.9%)	0	0	0
Hyperglycaemic conditions NEC	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Hyperglycaemic conditions NEC (cont)						
Hyperglycaemia	3 (5.8%)	0	3 (4.3%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	2 (3.8%)	0	2 (2.9%)	0	0	0
Sodium imbalance	2 (3.8%)	0	2 (2.9%)	1 (2.9%)	0	1 (2.2%)
Grade 1	2 (3.8%)	0	2 (2.9%)	1 (2.9%)	0	1 (2.2%)
Hyponatraemia	2 (3.8%)	0	2 (2.9%)	1 (2.9%)	0	1 (2.2%)
Grade 1	2 (3.8%)	0	2 (2.9%)	1 (2.9%)	0	1 (2.2%)
Hypernatraemia	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Hyperglycaemic conditions NEC (cont)						
Hyperglycaemia	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 3	0	0	0	0	0	0
Sodium imbalance	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	1 (5.3%)	1 (3.6%)
Grade 1	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	1 (5.3%)	1 (3.6%)
Hyponatraemia	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	1 (5.3%)	1 (3.6%)
Grade 1	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	1 (5.3%)	1 (3.6%)
Hypernatraemia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Phosphorus metabolism disorders	2 (3.8%)	0	2 (2.9%)	1 (2.9%)	1 (9.1%)	2 (4.4%)
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Grade 3	0	0	0	0	1 (9.1%)	1 (2.2%)
Hyperphosphataemia	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Hypophosphataemia	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	1 (9.1%)	2 (4.4%)
Grade 2	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Grade 3	0	0	0	0	1 (9.1%)	1 (2.2%)
Total fluid volume decreased	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Phosphorus metabolism disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Hyperphosphataemia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hypophosphataemia	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Total fluid volume decreased	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 1	1 (7.1%)	0	1 (2.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Total fluid volume decreased (cont)						
Dehydration	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hypovolaemia	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Electrolyte imbalance NEC	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 3	1 (1.9%)	0	1 (1.4%)	0	0	0
Tumour lysis syndrome	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 3	1 (1.9%)	0	1 (1.4%)	0	0	0
Magnesium metabolism disorders	0	0	0	1 (2.9%)	1 (9.1%)	2 (4.4%)
Grade 1	0	0	0	1 (2.9%)	0	1 (2.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Total fluid volume decreased (cont)						
Dehydration	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 1	1 (7.1%)	0	1 (2.9%)	0	0	0
Hypovolaemia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Electrolyte imbalance NEC	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Magnesium metabolism disorders	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	0	0
Grade 1	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Magnesium metabolism disorders (cont) (cont)						
Grade 3	0	0	0	0	1 (9.1%)	1 (2.2%)
Hypomagnesaemia	0	0	0	1 (2.9%)	1 (9.1%)	2 (4.4%)
Grade 1	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 3	0	0	0	0	1 (9.1%)	1 (2.2%)
Protein metabolism disorders NEC	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Hypoalbuminaemia	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Magnesium metabolism disorders (cont)						
(cont)						
Grade 3	0	0	0	0	0	0
Hypomagnesaemia	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	0	0
Grade 1	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	0	0
Grade 3	0	0	0	0	0	0
Protein metabolism disorders NEC	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 1	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Hypoalbuminaemia	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 1	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Fat soluble vitamin deficiencies and disorders	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (5.6%)	1 (1.4%)	0	0	0
Vitamin D deficiency	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (5.6%)	1 (1.4%)	0	0	0
General nutritional disorders NEC	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Cachexia	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Iron excess	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 3	0	1 (5.6%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Fat soluble vitamin deficiencies and disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Vitamin D deficiency	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
General nutritional disorders NEC	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 2	0	1 (4.8%)	1 (2.9%)	0	0	0
Cachexia	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 2	0	1 (4.8%)	1 (2.9%)	0	0	0
Iron excess	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 3	0	1 (4.8%)	1 (2.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Iron excess (cont)						
Iron overload	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 3	0	1 (5.6%)	1 (1.4%)	0	0	0
Respiratory, thoracic and mediastinal disorders	20 (38.5%)	5 (27.8%)	25 (35.7%)	10 (29.4%)	5 (45.5%)	15 (33.3%)
Grade 1	8 (15.4%)	2 (11.1%)	10 (14.3%)	8 (23.5%)	2 (18.2%)	10 (22.2%)
Grade 2	7 (13.5%)	3 (16.7%)	10 (14.3%)	0	2 (18.2%)	2 (4.4%)
Grade 3	2 (3.8%)	0	2 (2.9%)	1 (2.9%)	0	1 (2.2%)
Grade 4	1 (1.9%)	0	1 (1.4%)	0	1 (9.1%)	1 (2.2%)
Grade 5	2 (3.8%)	0	2 (2.9%)	1 (2.9%)	0	1 (2.2%)
Coughing and associated symptoms	9 (17.3%)	3 (16.7%)	12 (17.1%)	7 (20.6%)	3 (27.3%)	10 (22.2%)
Grade 1	7 (13.5%)	2 (11.1%)	9 (12.9%)	5 (14.7%)	2 (18.2%)	7 (15.6%)
Grade 2	2 (3.8%)	1 (5.6%)	3 (4.3%)	1 (2.9%)	1 (9.1%)	2 (4.4%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Metabolism and nutrition disorders (cont)						
Iron excess (cont)						
Iron overload	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 3	0	1 (4.8%)	1 (2.9%)	0	0	0
Respiratory, thoracic and mediastinal disorders	4 (28.6%)	8 (38.1%)	12 (34.3%)	3 (33.3%)	7 (36.8%)	10 (35.7%)
Grade 1	2 (14.3%)	4 (19.0%)	6 (17.1%)	2 (22.2%)	3 (15.8%)	5 (17.9%)
Grade 2	2 (14.3%)	3 (14.3%)	5 (14.3%)	1 (11.1%)	2 (10.5%)	3 (10.7%)
Grade 3	0	1 (4.8%)	1 (2.9%)	0	2 (10.5%)	2 (7.1%)
Grade 4	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Coughing and associated symptoms	2 (14.3%)	1 (4.8%)	3 (8.6%)	3 (33.3%)	3 (15.8%)	6 (21.4%)
Grade 1	1 (7.1%)	1 (4.8%)	2 (5.7%)	2 (22.2%)	1 (5.3%)	3 (10.7%)
Grade 2	1 (7.1%)	0	1 (2.9%)	1 (11.1%)	1 (5.3%)	2 (7.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Coughing and associated symptoms (cont) (cont)						
Grade 3	0	0	0	1 (2.9%)	0	1 (2.2%)
Cough	7 (13.5%)	3 (16.7%)	10 (14.3%)	7 (20.6%)	3 (27.3%)	10 (22.2%)
Grade 1	6 (11.5%)	2 (11.1%)	8 (11.4%)	5 (14.7%)	2 (18.2%)	7 (15.6%)
Grade 2	1 (1.9%)	1 (5.6%)	2 (2.9%)	1 (2.9%)	1 (9.1%)	2 (4.4%)
Grade 3	0	0	0	1 (2.9%)	0	1 (2.2%)
Haemoptysis	2 (3.8%)	0	2 (2.9%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Productive cough	1 (1.9%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Coughing and associated symptoms (cont) (cont)						
Grade 3	0	0	0	0	1 (5.3%)	1 (3.6%)
Cough	2 (14.3%)	1 (4.8%)	3 (8.6%)	3 (33.3%)	3 (15.8%)	6 (21.4%)
Grade 1	1 (7.1%)	1 (4.8%)	2 (5.7%)	2 (22.2%)	1 (5.3%)	3 (10.7%)
Grade 2	1 (7.1%)	0	1 (2.9%)	1 (11.1%)	1 (5.3%)	2 (7.1%)
Grade 3	0	0	0	0	1 (5.3%)	1 (3.6%)
Haemoptysis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Productive cough	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Coughing and associated symptoms (cont)						
Productive cough (cont)						
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Sputum discoloured	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Breathing abnormalities	8 (15.4%)	4 (22.2%)	12 (17.1%)	3 (8.8%)	0	3 (6.7%)
Grade 1	2 (3.8%)	2 (11.1%)	4 (5.7%)	2 (5.9%)	0	2 (4.4%)
Grade 2	4 (7.7%)	2 (11.1%)	6 (8.6%)	0	0	0
Grade 3	2 (3.8%)	0	2 (2.9%)	0	0	0
Grade 5	0	0	0	1 (2.9%)	0	1 (2.2%)
Dyspnoea	7 (13.5%)	3 (16.7%)	10 (14.3%)	1 (2.9%)	0	1 (2.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Coughing and associated symptoms (cont)						
Productive cough (cont)						
Grade 1	0	0	0	0	0	0
Sputum discoloured	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 2	0	0	0	0	1 (5.3%)	1 (3.6%)
Breathing abnormalities	1 (7.1%)	3 (14.3%)	4 (11.4%)	0	3 (15.8%)	3 (10.7%)
Grade 1	1 (7.1%)	2 (9.5%)	3 (8.6%)	0	2 (10.5%)	2 (7.1%)
Grade 2	0	1 (4.8%)	1 (2.9%)	0	1 (5.3%)	1 (3.6%)
Grade 3	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Dyspnoea	1 (7.1%)	3 (14.3%)	4 (11.4%)	0	3 (15.8%)	3 (10.7%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Breathing abnormalities (cont)						
Dyspnoea (cont)						
Grade 1	1 (1.9%)	1 (5.6%)	2 (2.9%)	1 (2.9%)	0	1 (2.2%)
Grade 2	4 (7.7%)	2 (11.1%)	6 (8.6%)	0	0	0
Grade 3	2 (3.8%)	0	2 (2.9%)	0	0	0
Dyspnoea exertional	1 (1.9%)	1 (5.6%)	2 (2.9%)	1 (2.9%)	0	1 (2.2%)
Grade 1	1 (1.9%)	1 (5.6%)	2 (2.9%)	1 (2.9%)	0	1 (2.2%)
Respiratory distress	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 5	0	0	0	1 (2.9%)	0	1 (2.2%)
Nasal disorders NEC	4 (7.7%)	1 (5.6%)	5 (7.1%)	1 (2.9%)	1 (9.1%)	2 (4.4%)
Grade 1	2 (3.8%)	1 (5.6%)	3 (4.3%)	1 (2.9%)	0	1 (2.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Breathing abnormalities (cont)						
Dyspnoea (cont)						
Grade 1	1 (7.1%)	2 (9.5%)	3 (8.6%)	0	2 (10.5%)	2 (7.1%)
Grade 2	0	1 (4.8%)	1 (2.9%)	0	1 (5.3%)	1 (3.6%)
Grade 3	0	0	0	0	0	0
Dyspnoea exertional	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Respiratory distress	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Nasal disorders NEC	2 (14.3%)	4 (19.0%)	6 (17.1%)	0	1 (5.3%)	1 (3.6%)
Grade 1	2 (14.3%)	2 (9.5%)	4 (11.4%)	0	1 (5.3%)	1 (3.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Nasal disorders NEC (cont) (cont)						
Grade 2	2 (3.8%)	0	2 (2.9%)	0	1 (9.1%)	1 (2.2%)
Epistaxis	4 (7.7%)	1 (5.6%)	5 (7.1%)	0	1 (9.1%)	1 (2.2%)
Grade 1	2 (3.8%)	1 (5.6%)	3 (4.3%)	0	0	0
Grade 2	2 (3.8%)	0	2 (2.9%)	0	1 (9.1%)	1 (2.2%)
Nasal septum ulceration	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 1	0	0	0	1 (2.9%)	0	1 (2.2%)
Upper respiratory tract signs and symptoms	2 (3.8%)	0	2 (2.9%)	2 (5.9%)	0	2 (4.4%)
Grade 1	2 (3.8%)	0	2 (2.9%)	2 (5.9%)	0	2 (4.4%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Nasal disorders NEC (cont) (cont)						
Grade 2	0	2 (9.5%)	2 (5.7%)	0	0	0
Epistaxis	2 (14.3%)	4 (19.0%)	6 (17.1%)	0	1 (5.3%)	1 (3.6%)
Grade 1	2 (14.3%)	2 (9.5%)	4 (11.4%)	0	1 (5.3%)	1 (3.6%)
Grade 2	0	2 (9.5%)	2 (5.7%)	0	0	0
Nasal septum ulceration	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Upper respiratory tract signs and symptoms	1 (7.1%)	0	1 (2.9%)	1 (11.1%)	0	1 (3.6%)
Grade 1	1 (7.1%)	0	1 (2.9%)	1 (11.1%)	0	1 (3.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Upper respiratory tract signs and symptoms (cont)						
Dysphonia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Oropharyngeal pain	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Grade 1	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Rhinorrhoea	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Grade 1	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Upper-airway cough syndrome	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Upper respiratory tract signs and symptoms (cont)						
Dysphonia	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 1	1 (7.1%)	0	1 (2.9%)	0	0	0
Oropharyngeal pain	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Rhinorrhoea	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Upper-airway cough syndrome	0	0	0	1 (11.1%)	0	1 (3.6%)
Grade 1	0	0	0	1 (11.1%)	0	1 (3.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Pulmonary hypertensions	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	1 (1.9%)	0	1 (1.4%)	0	0	0
Pulmonary hypertension	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	1 (1.9%)	0	1 (1.4%)	0	0	0
Respiratory failures (excl neonatal)	2 (3.8%)	0	2 (2.9%)	0	0	0
Grade 5	2 (3.8%)	0	2 (2.9%)	0	0	0
Respiratory failure	2 (3.8%)	0	2 (2.9%)	0	0	0
Grade 5	2 (3.8%)	0	2 (2.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Pulmonary hypertensions	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	0	0
Grade 2	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	0	0
Grade 3	0	0	0	0	0	0
Pulmonary hypertension	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	0	0
Grade 2	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	0	0
Grade 3	0	0	0	0	0	0
Respiratory failures (excl neonatal)	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Respiratory failure	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Parenchymal lung disorders NEC	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 3	0	0	0	0	0	0
Atelectasis	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Interstitial lung disease	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Pneumothorax and pleural effusions NEC	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 3	1 (1.9%)	0	1 (1.4%)	0	0	0
Pleural effusion	1 (1.9%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Parenchymal lung disorders NEC	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	1 (5.3%)	1 (3.6%)
Atelectasis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Interstitial lung disease	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 3	0	0	0	0	1 (5.3%)	1 (3.6%)
Pneumothorax and pleural effusions NEC	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Pleural effusion	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Pneumothorax and pleural effusions NEC (cont)						
Pleural effusion (cont)						
Grade 3	1 (1.9%)	0	1 (1.4%)	0	0	0
Pulmonary oedemas	1 (1.9%)	0	1 (1.4%)	0	1 (9.1%)	1 (2.2%)
Grade 3	0	0	0	0	1 (9.1%)	1 (2.2%)
Grade 4	1 (1.9%)	0	1 (1.4%)	0	0	0
Acute respiratory distress syndrome	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 4	1 (1.9%)	0	1 (1.4%)	0	0	0
Pulmonary congestion	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Pneumothorax and pleural effusions NEC (cont)						
Pleural effusion (cont)						
Grade 3	0	0	0	0	0	0
Pulmonary oedemas	0	1 (4.8%)	1 (2.9%)	0	1 (5.3%)	1 (3.6%)
Grade 3	0	1 (4.8%)	1 (2.9%)	0	1 (5.3%)	1 (3.6%)
Grade 4	0	0	0	0	0	0
Acute respiratory distress syndrome	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Pulmonary congestion	0	1 (4.8%)	1 (2.9%)	0	1 (5.3%)	1 (3.6%)
Grade 3	0	1 (4.8%)	1 (2.9%)	0	1 (5.3%)	1 (3.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Pulmonary oedemas (cont)						
Pulmonary oedema	0	0	0	0	1 (9.1%)	1 (2.2%)
Grade 3	0	0	0	0	1 (9.1%)	1 (2.2%)
Conditions associated with abnormal gas exchange	0	0	0	0	1 (9.1%)	1 (2.2%)
Grade 4	0	0	0	0	1 (9.1%)	1 (2.2%)
Hypoxia	0	0	0	0	1 (9.1%)	1 (2.2%)
Grade 4	0	0	0	0	1 (9.1%)	1 (2.2%)
Lower respiratory tract inflammatory and immunologic conditions	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 2	0	0	0	1 (2.9%)	0	1 (2.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Pulmonary oedemas (cont)						
Pulmonary oedema	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Conditions associated with abnormal gas exchange	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Hypoxia	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Lower respiratory tract inflammatory and immunologic conditions	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Lower respiratory tract inflammatory and immunologic conditions (cont)						
Pneumonitis	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 2	0	0	0	1 (2.9%)	0	1 (2.2%)
Nasal congestion and inflammations	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Rhinitis allergic	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Paranasal sinus disorders (excl infections and neoplasms)	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Lower respiratory tract inflammatory and immunologic conditions (cont)						
Pneumonitis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Nasal congestion and inflammations	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 1	0	1 (4.8%)	1 (2.9%)	0	0	0
Rhinitis allergic	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 1	0	1 (4.8%)	1 (2.9%)	0	0	0
Paranasal sinus disorders (excl infections and neoplasms)	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 1	0	1 (4.8%)	1 (2.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Paranasal sinus disorders (excl infections and neoplasms) (cont)						
Sinus congestion	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Skin and subcutaneous tissue disorders	19 (36.5%)	4 (22.2%)	23 (32.9%)	9 (26.5%)	2 (18.2%)	11 (24.4%)
Grade 1	15 (28.8%)	2 (11.1%)	17 (24.3%)	7 (20.6%)	0	7 (15.6%)
Grade 2	4 (7.7%)	2 (11.1%)	6 (8.6%)	2 (5.9%)	1 (9.1%)	3 (6.7%)
Grade 3	0	0	0	0	1 (9.1%)	1 (2.2%)
Pruritus NEC	12 (23.1%)	0	12 (17.1%)	2 (5.9%)	1 (9.1%)	3 (6.7%)
Grade 1	8 (15.4%)	0	8 (11.4%)	2 (5.9%)	0	2 (4.4%)
Grade 2	4 (7.7%)	0	4 (5.7%)	0	1 (9.1%)	1 (2.2%)
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Respiratory, thoracic and mediastinal disorders (cont)						
Paranasal sinus disorders (excl infections and neoplasms) (cont)						
Sinus congestion	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 1	0	1 (4.8%)	1 (2.9%)	0	0	0
Skin and subcutaneous tissue disorders	3 (21.4%)	7 (33.3%)	10 (28.6%)	0	4 (21.1%)	4 (14.3%)
Grade 1	3 (21.4%)	5 (23.8%)	8 (22.9%)	0	3 (15.8%)	3 (10.7%)
Grade 2	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 3	0	1 (4.8%)	1 (2.9%)	0	1 (5.3%)	1 (3.6%)
Pruritus NEC	0	4 (19.0%)	4 (11.4%)	0	1 (5.3%)	1 (3.6%)
Grade 1	0	2 (9.5%)	2 (5.7%)	0	0	0
Grade 2	0	2 (9.5%)	2 (5.7%)	0	0	0
Grade 3	0	0	0	0	1 (5.3%)	1 (3.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Pruritus NEC (cont)						
Pruritus	10 (19.2%)	0	10 (14.3%)	2 (5.9%)	0	2 (4.4%)
Grade 1	7 (13.5%)	0	7 (10.0%)	2 (5.9%)	0	2 (4.4%)
Grade 2	3 (5.8%)	0	3 (4.3%)	0	0	0
Grade 3	0	0	0	0	0	0
Pruritus generalised	2 (3.8%)	0	2 (2.9%)	1 (2.9%)	1 (9.1%)	2 (4.4%)
Grade 1	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Grade 2	1 (1.9%)	0	1 (1.4%)	0	1 (9.1%)	1 (2.2%)
Apocrine and eccrine gland disorders	5 (9.6%)	3 (16.7%)	8 (11.4%)	3 (8.8%)	1 (9.1%)	4 (8.9%)
Grade 1	4 (7.7%)	2 (11.1%)	6 (8.6%)	1 (2.9%)	0	1 (2.2%)
Grade 2	1 (1.9%)	1 (5.6%)	2 (2.9%)	2 (5.9%)	0	2 (4.4%)
Grade 3	0	0	0	0	1 (9.1%)	1 (2.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Pruritus NEC (cont)						
Pruritus	0	3 (14.3%)	3 (8.6%)	0	1 (5.3%)	1 (3.6%)
Grade 1	0	2 (9.5%)	2 (5.7%)	0	0	0
Grade 2	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 3	0	0	0	0	1 (5.3%)	1 (3.6%)
Pruritus generalised	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (4.8%)	1 (2.9%)	0	0	0
Apocrine and eccrine gland disorders	1 (7.1%)	2 (9.5%)	3 (8.6%)	0	3 (15.8%)	3 (10.7%)
Grade 1	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	2 (10.5%)	2 (7.1%)
Grade 2	0	0	0	0	0	0
Grade 3	0	1 (4.8%)	1 (2.9%)	0	1 (5.3%)	1 (3.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Apocrine and eccrine gland disorders (cont)						
Night sweats	4 (7.7%)	1 (5.6%)	5 (7.1%)	2 (5.9%)	1 (9.1%)	3 (6.7%)
Grade 1	3 (5.8%)	1 (5.6%)	4 (5.7%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	2 (5.9%)	0	2 (4.4%)
Grade 3	0	0	0	0	1 (9.1%)	1 (2.2%)
Hyperhidrosis	2 (3.8%)	3 (16.7%)	5 (7.1%)	1 (2.9%)	0	1 (2.2%)
Grade 1	2 (3.8%)	2 (11.1%)	4 (5.7%)	1 (2.9%)	0	1 (2.2%)
Grade 2	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 3	0	0	0	0	0	0
Rashes, eruptions and exanthems NEC	2 (3.8%)	0	2 (2.9%)	2 (5.9%)	0	2 (4.4%)
Grade 1	2 (3.8%)	0	2 (2.9%)	2 (5.9%)	0	2 (4.4%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Apocrine and eccrine gland disorders (cont)						
Night sweats	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	1 (5.3%)	1 (3.6%)
Grade 1	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	1 (5.3%)	1 (3.6%)
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Hyperhidrosis	0	1 (4.8%)	1 (2.9%)	0	2 (10.5%)	2 (7.1%)
Grade 1	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 2	0	0	0	0	0	0
Grade 3	0	1 (4.8%)	1 (2.9%)	0	1 (5.3%)	1 (3.6%)
Rashes, eruptions and exanthems NEC	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	0	0
Grade 1	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Rashes, eruptions and exanthems NEC (cont)						
Rash	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Grade 1	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Rash generalised	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Rash maculo-papular	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Grade 1	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Purpura and related conditions	2 (3.8%)	1 (5.6%)	3 (4.3%)	1 (2.9%)	1 (9.1%)	2 (4.4%)
Grade 1	2 (3.8%)	1 (5.6%)	3 (4.3%)	1 (2.9%)	0	1 (2.2%)
Grade 2	0	0	0	0	1 (9.1%)	1 (2.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Rashes, eruptions and exanthems NEC (cont)						
Rash	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 1	0	1 (4.8%)	1 (2.9%)	0	0	0
Rash generalised	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 1	1 (7.1%)	0	1 (2.9%)	0	0	0
Rash maculo-papular	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Purpura and related conditions	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 1	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Purpura and related conditions (cont)						
Ecchymosis	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Purpura senile	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Petechiae	0	1 (5.6%)	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Grade 1	0	1 (5.6%)	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Purpura	0	0	0	0	1 (9.1%)	1 (2.2%)
Grade 2	0	0	0	0	1 (9.1%)	1 (2.2%)
Dermal and epidermal conditions NEC	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Purpura and related conditions (cont)						
Ecchymosis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Purpura senile	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Petechiae	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 1	0	0	0	0	1 (5.3%)	1 (3.6%)
Purpura	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Dermal and epidermal conditions NEC	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Dermal and epidermal conditions NEC (cont)						
(cont)						
Grade 1	0	0	0	0	0	0
Dry skin	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Skin lesion	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dermatitis ascribed to specific agent	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Dermal and epidermal conditions NEC (cont)						
(cont)						
Grade 1	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	0	0
Dry skin	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 1	1 (7.1%)	0	1 (2.9%)	0	0	0
Skin lesion	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 1	0	1 (4.8%)	1 (2.9%)	0	0	0
Dermatitis ascribed to specific agent	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Dermatitis ascribed to specific agent (cont)						
Palmar-plantar erythrodysaesthesia syndrome	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Alopecias	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 1	0	0	0	1 (2.9%)	0	1 (2.2%)
Alopecia	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 1	0	0	0	1 (2.9%)	0	1 (2.2%)
Angioedemas	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 1	0	0	0	1 (2.9%)	0	1 (2.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Dermatitis ascribed to specific agent (cont)						
Palmar-plantar erythrodysaesthesia syndrome	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Alopecias	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Alopecia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Angioedemas	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Angioedemas (cont)						
Swelling face	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 1	0	0	0	1 (2.9%)	0	1 (2.2%)
Erythemas	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 1	0	0	0	1 (2.9%)	0	1 (2.2%)
Erythema	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 1	0	0	0	1 (2.9%)	0	1 (2.2%)
Ichthyoses	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (5.6%)	1 (1.4%)	0	0	0
Xeroderma	0	1 (5.6%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Angioedemas (cont)						
Swelling face	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Erythemas	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Erythema	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Ichthyoses	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Xeroderma	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Ichthyoses (cont)						
Xeroderma (cont)						
Grade 1	0	1 (5.6%)	1 (1.4%)	0	0	0
Skin and subcutaneous tissue ulcerations	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 2	0	1 (5.6%)	1 (1.4%)	0	0	0
Skin ulcer	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 2	0	1 (5.6%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase	RT Phase	RT Phase	ET Phase (Week 24 - 48) Continuing	ET Phase (Week 24 - 48) Switch	ET Phase (Week 24 - 48)
	MMB (N=14)	BAT (N=21)	Total (N=35)	(MMB->MMB) (N=9)	(BAT->MMB) (N=19)	Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Skin and subcutaneous tissue disorders (cont)						
Ichthyoses (cont)						
Xeroderma (cont)						
Grade 1	0	0	0	0	0	0
Skin and subcutaneous tissue ulcerations	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Skin ulcer	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders	16 (30.8%)	5 (27.8%)	21 (30.0%)	8 (23.5%)	2 (18.2%)	10 (22.2%)
Grade 1	9 (17.3%)	3 (16.7%)	12 (17.1%)	4 (11.8%)	2 (18.2%)	6 (13.3%)
Grade 2	5 (9.6%)	2 (11.1%)	7 (10.0%)	4 (11.8%)	0	4 (8.9%)
Grade 3	2 (3.8%)	0	2 (2.9%)	0	0	0
Joint related signs and symptoms	3 (5.8%)	0	3 (4.3%)	0	0	0
Grade 1	3 (5.8%)	0	3 (4.3%)	0	0	0
Grade 2	0	0	0	0	0	0
Arthralgia	3 (5.8%)	0	3 (4.3%)	0	0	0
Grade 1	3 (5.8%)	0	3 (4.3%)	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders	5 (35.7%)	9 (42.9%)	14 (40.0%)	3 (33.3%)	3 (15.8%)	6 (21.4%)
Grade 1	4 (28.6%)	5 (23.8%)	9 (25.7%)	1 (11.1%)	1 (5.3%)	2 (7.1%)
Grade 2	1 (7.1%)	4 (19.0%)	5 (14.3%)	2 (22.2%)	2 (10.5%)	4 (14.3%)
Grade 3	0	0	0	0	0	0
Joint related signs and symptoms	5 (35.7%)	3 (14.3%)	8 (22.9%)	0	0	0
Grade 1	4 (28.6%)	3 (14.3%)	7 (20.0%)	0	0	0
Grade 2	1 (7.1%)	0	1 (2.9%)	0	0	0
Arthralgia	5 (35.7%)	3 (14.3%)	8 (22.9%)	0	0	0
Grade 1	4 (28.6%)	3 (14.3%)	7 (20.0%)	0	0	0
Grade 2	1 (7.1%)	0	1 (2.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Musculoskeletal and connective tissue pain and discomfort	5 (9.6%)	3 (16.7%)	8 (11.4%)	5 (14.7%)	2 (18.2%)	7 (15.6%)
Grade 1	4 (7.7%)	3 (16.7%)	7 (10.0%)	3 (8.8%)	2 (18.2%)	5 (11.1%)
Grade 2	1 (1.9%)	0	1 (1.4%)	2 (5.9%)	0	2 (4.4%)
Pain in extremity	2 (3.8%)	1 (5.6%)	3 (4.3%)	4 (11.8%)	0	4 (8.9%)
Grade 1	2 (3.8%)	1 (5.6%)	3 (4.3%)	2 (5.9%)	0	2 (4.4%)
Grade 2	0	0	0	2 (5.9%)	0	2 (4.4%)
Back pain	2 (3.8%)	0	2 (2.9%)	2 (5.9%)	1 (9.1%)	3 (6.7%)
Grade 1	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	1 (9.1%)	2 (4.4%)
Grade 2	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Limb discomfort	1 (1.9%)	1 (5.6%)	2 (2.9%)	0	1 (9.1%)	1 (2.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Musculoskeletal and connective tissue pain and discomfort	2 (14.3%)	5 (23.8%)	7 (20.0%)	3 (33.3%)	1 (5.3%)	4 (14.3%)
Grade 1	2 (14.3%)	4 (19.0%)	6 (17.1%)	1 (11.1%)	0	1 (3.6%)
Grade 2	0	1 (4.8%)	1 (2.9%)	2 (22.2%)	1 (5.3%)	3 (10.7%)
Pain in extremity	1 (7.1%)	3 (14.3%)	4 (11.4%)	1 (11.1%)	0	1 (3.6%)
Grade 1	1 (7.1%)	3 (14.3%)	4 (11.4%)	1 (11.1%)	0	1 (3.6%)
Grade 2	0	0	0	0	0	0
Back pain	0	2 (9.5%)	2 (5.7%)	1 (11.1%)	0	1 (3.6%)
Grade 1	0	2 (9.5%)	2 (5.7%)	0	0	0
Grade 2	0	0	0	1 (11.1%)	0	1 (3.6%)
Limb discomfort	1 (7.1%)	0	1 (2.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Musculoskeletal and connective tissue pain and discomfort (cont)						
Limb discomfort (cont)						
Grade 1	1 (1.9%)	1 (5.6%)	2 (2.9%)	0	1 (9.1%)	1 (2.2%)
Flank pain	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 2	0	0	0	0	0	0
Musculoskeletal chest pain	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Musculoskeletal pain	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Musculoskeletal and connective tissue pain and discomfort (cont)						
Limb discomfort (cont)						
Grade 1	1 (7.1%)	0	1 (2.9%)	0	0	0
Flank pain	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	0	0
Grade 1	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 2	0	1 (4.8%)	1 (2.9%)	0	0	0
Musculoskeletal chest pain	0	0	0	1 (11.1%)	0	1 (3.6%)
Grade 1	0	0	0	1 (11.1%)	0	1 (3.6%)
Musculoskeletal pain	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 2	0	0	0	0	1 (5.3%)	1 (3.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Musculoskeletal and connective tissue pain and discomfort (cont)						
Neck pain	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Bone related signs and symptoms	3 (5.8%)	1 (5.6%)	4 (5.7%)	2 (5.9%)	1 (9.1%)	3 (6.7%)
Grade 1	0	0	0	1 (2.9%)	1 (9.1%)	2 (4.4%)
Grade 2	3 (5.8%)	1 (5.6%)	4 (5.7%)	1 (2.9%)	0	1 (2.2%)
Bone pain	2 (3.8%)	1 (5.6%)	3 (4.3%)	1 (2.9%)	1 (9.1%)	2 (4.4%)
Grade 1	0	0	0	0	1 (9.1%)	1 (2.2%)
Grade 2	2 (3.8%)	1 (5.6%)	3 (4.3%)	1 (2.9%)	0	1 (2.2%)
Spinal pain	1 (1.9%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Musculoskeletal and connective tissue pain and discomfort (cont)						
Neck pain	0	0	0	1 (11.1%)	0	1 (3.6%)
Grade 2	0	0	0	1 (11.1%)	0	1 (3.6%)
Bone related signs and symptoms	0	3 (14.3%)	3 (8.6%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	3 (14.3%)	3 (8.6%)	0	0	0
Bone pain	0	3 (14.3%)	3 (8.6%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	3 (14.3%)	3 (8.6%)	0	0	0
Spinal pain	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Bone related signs and symptoms (cont)						
Spinal pain (cont)						
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Metatarsalgia	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 1	0	0	0	1 (2.9%)	0	1 (2.2%)
Muscle related signs and symptoms NEC	2 (3.8%)	1 (5.6%)	3 (4.3%)	1 (2.9%)	0	1 (2.2%)
Grade 1	2 (3.8%)	0	2 (2.9%)	1 (2.9%)	0	1 (2.2%)
Grade 2	0	1 (5.6%)	1 (1.4%)	0	0	0
Muscle spasms	2 (3.8%)	1 (5.6%)	3 (4.3%)	1 (2.9%)	0	1 (2.2%)
Grade 1	2 (3.8%)	0	2 (2.9%)	1 (2.9%)	0	1 (2.2%)
Grade 2	0	1 (5.6%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Bone related signs and symptoms (cont)						
Spinal pain (cont)						
Grade 2	0	0	0	0	0	0
Metatarsalgia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Muscle related signs and symptoms NEC	1 (7.1%)	0	1 (2.9%)	1 (11.1%)	1 (5.3%)	2 (7.1%)
Grade 1	1 (7.1%)	0	1 (2.9%)	0	1 (5.3%)	1 (3.6%)
Grade 2	0	0	0	1 (11.1%)	0	1 (3.6%)
Muscle spasms	1 (7.1%)	0	1 (2.9%)	1 (11.1%)	1 (5.3%)	2 (7.1%)
Grade 1	1 (7.1%)	0	1 (2.9%)	0	1 (5.3%)	1 (3.6%)
Grade 2	0	0	0	1 (11.1%)	0	1 (3.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Muscle pains	2 (3.8%)	0	2 (2.9%)	0	1 (9.1%)	1 (2.2%)
Grade 1	1 (1.9%)	0	1 (1.4%)	0	1 (9.1%)	1 (2.2%)
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Myalgia	2 (3.8%)	0	2 (2.9%)	0	1 (9.1%)	1 (2.2%)
Grade 1	1 (1.9%)	0	1 (1.4%)	0	1 (9.1%)	1 (2.2%)
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Crystal arthropathic disorders	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 3	1 (1.9%)	0	1 (1.4%)	0	0	0
Gouty arthritis	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 3	1 (1.9%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Muscle pains	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Myalgia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Crystal arthropathic disorders	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Gouty arthritis	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Soft tissue disorders NEC	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 3	1 (1.9%)	0	1 (1.4%)	0	0	0
Groin pain	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 3	1 (1.9%)	0	1 (1.4%)	0	0	0
Arthropathies NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Arthritis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Bone disorders NEC	0	1 (5.6%)	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Grade 1	0	1 (5.6%)	1 (1.4%)	1 (2.9%)	0	1 (2.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Soft tissue disorders NEC	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Groin pain	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Arthropathies NEC	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 1	0	1 (4.8%)	1 (2.9%)	0	0	0
Arthritis	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 1	0	1 (4.8%)	1 (2.9%)	0	0	0
Bone disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Bone disorders NEC (cont)						
Bone lesion	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (5.6%)	1 (1.4%)	0	0	0
Osteosis	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 1	0	0	0	1 (2.9%)	0	1 (2.2%)
Bursal disorders	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 2	0	0	0	1 (2.9%)	0	1 (2.2%)
Bursitis	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 2	0	0	0	1 (2.9%)	0	1 (2.2%)
Metabolic bone disorders	0	1 (5.6%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Bone disorders NEC (cont)						
Bone lesion	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Osteosis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Bursal disorders	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Bursitis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Metabolic bone disorders	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase	RT Phase	RT Phase	ET Phase (Week 24 - 48) Continuing	ET Phase (Week 24 - 48) Switch	ET Phase (Week 24 - 48)
	MMB (N=52)	BAT (N=18)	Total (N=70)	(MMB->MMB) (N=34)	(BAT->MMB) (N=11)	Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Metabolic bone disorders (cont) (cont)						
Grade 1	0	1 (5.6%)	1 (1.4%)	0	0	0
Osteoporosis	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (5.6%)	1 (1.4%)	0	0	0
Muscle weakness conditions	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Muscular weakness	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Osteoarthropathies	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Metabolic bone disorders (cont) (cont)						
Grade 1	0	0	0	0	0	0
Osteoporosis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Muscle weakness conditions	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 2	0	0	0	0	1 (5.3%)	1 (3.6%)
Muscular weakness	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 2	0	0	0	0	1 (5.3%)	1 (3.6%)
Osteoarthropathies	0	1 (4.8%)	1 (2.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Osteoarthropathies (cont) (cont)						
Grade 1	0	0	0	0	0	0
Osteoarthritis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Spine and neck deformities	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Scoliosis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Tendon disorders	0	0	0	1 (2.9%)	0	1 (2.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Osteoarthropathies (cont) (cont)						
Grade 1	0	1 (4.8%)	1 (2.9%)	0	0	0
Osteoarthritis	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 1	0	1 (4.8%)	1 (2.9%)	0	0	0
Spine and neck deformities	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 1	0	1 (4.8%)	1 (2.9%)	0	0	0
Scoliosis	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 1	0	1 (4.8%)	1 (2.9%)	0	0	0
Tendon disorders	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Tendon disorders (cont)						
(cont)						
Grade 1	0	0	0	1 (2.9%)	0	1 (2.2%)
Tendonitis	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 1	0	0	0	1 (2.9%)	0	1 (2.2%)
Investigations	16 (30.8%)	2 (11.1%)	18 (25.7%)	5 (14.7%)	2 (18.2%)	7 (15.6%)
Grade 1	11 (21.2%)	1 (5.6%)	12 (17.1%)	3 (8.8%)	1 (9.1%)	4 (8.9%)
Grade 2	3 (5.8%)	1 (5.6%)	4 (5.7%)	2 (5.9%)	1 (9.1%)	3 (6.7%)
Grade 3	2 (3.8%)	0	2 (2.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase	RT Phase	RT Phase	ET Phase (Week 24 - 48) Continuing	ET Phase (Week 24 - 48) Switch	ET Phase (Week 24 - 48)
	MMB (N=14)	BAT (N=21)	Total (N=35)	(MMB->MMB) (N=9)	(BAT->MMB) (N=19)	Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Musculoskeletal and connective tissue disorders (cont)						
Tendon disorders (cont)						
(cont)						
Grade 1	0	0	0	0	0	0
Tendonitis	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Investigations	1 (7.1%)	1 (4.8%)	2 (5.7%)	2 (22.2%)	4 (21.1%)	6 (21.4%)
Grade 1	1 (7.1%)	0	1 (2.9%)	2 (22.2%)	1 (5.3%)	3 (10.7%)
Grade 2	0	1 (4.8%)	1 (2.9%)	0	2 (10.5%)	2 (7.1%)
Grade 3	0	0	0	0	1 (5.3%)	1 (3.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Physical examination procedures and organ system status	8 (15.4%)	1 (5.6%)	9 (12.9%)	2 (5.9%)	1 (9.1%)	3 (6.7%)
Grade 1	6 (11.5%)	0	6 (8.6%)	2 (5.9%)	1 (9.1%)	3 (6.7%)
Grade 2	2 (3.8%)	1 (5.6%)	3 (4.3%)	0	0	0
Weight decreased	6 (11.5%)	1 (5.6%)	7 (10.0%)	0	1 (9.1%)	1 (2.2%)
Grade 1	4 (7.7%)	0	4 (5.7%)	0	1 (9.1%)	1 (2.2%)
Grade 2	2 (3.8%)	1 (5.6%)	3 (4.3%)	0	0	0
Body temperature increased	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Weight increased	1 (1.9%)	0	1 (1.4%)	2 (5.9%)	0	2 (4.4%)
Grade 1	1 (1.9%)	0	1 (1.4%)	2 (5.9%)	0	2 (4.4%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Physical examination procedures and organ system status	1 (7.1%)	0	1 (2.9%)	0	2 (10.5%)	2 (7.1%)
Grade 1	1 (7.1%)	0	1 (2.9%)	0	1 (5.3%)	1 (3.6%)
Grade 2	0	0	0	0	1 (5.3%)	1 (3.6%)
Weight decreased	1 (7.1%)	0	1 (2.9%)	0	2 (10.5%)	2 (7.1%)
Grade 1	1 (7.1%)	0	1 (2.9%)	0	1 (5.3%)	1 (3.6%)
Grade 2	0	0	0	0	1 (5.3%)	1 (3.6%)
Body temperature increased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Weight increased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Liver function analyses	5 (9.6%)	0	5 (7.1%)	0	0	0
Grade 1	2 (3.8%)	0	2 (2.9%)	0	0	0
Grade 2	2 (3.8%)	0	2 (2.9%)	0	0	0
Grade 3	1 (1.9%)	0	1 (1.4%)	0	0	0
Blood bilirubin increased	3 (5.8%)	0	3 (4.3%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	2 (3.8%)	0	2 (2.9%)	0	0	0
Alanine aminotransferase increased	2 (3.8%)	0	2 (2.9%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 3	1 (1.9%)	0	1 (1.4%)	0	0	0
Aspartate aminotransferase increased	2 (3.8%)	0	2 (2.9%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Liver function analyses	0	1 (4.8%)	1 (2.9%)	1 (11.1%)	1 (5.3%)	2 (7.1%)
Grade 1	0	0	0	1 (11.1%)	0	1 (3.6%)
Grade 2	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 3	0	0	0	0	1 (5.3%)	1 (3.6%)
Blood bilirubin increased	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (4.8%)	1 (2.9%)	0	0	0
Alanine aminotransferase increased	0	0	0	1 (11.1%)	0	1 (3.6%)
Grade 1	0	0	0	1 (11.1%)	0	1 (3.6%)
Grade 3	0	0	0	0	0	0
Aspartate aminotransferase increased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Liver function analyses (cont)						
Aspartate aminotransferase increased (cont)						
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Gamma-glutamyltransferase increased	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	1 (1.9%)	0	1 (1.4%)	0	0	0
Liver function test increased	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Renal function analyses	3 (5.8%)	0	3 (4.3%)	2 (5.9%)	1 (9.1%)	3 (6.7%)
Grade 1	2 (3.8%)	0	2 (2.9%)	0	0	0
Grade 2	0	0	0	2 (5.9%)	1 (9.1%)	3 (6.7%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Liver function analyses (cont)						
Aspartate aminotransferase increased (cont)						
Grade 2	0	0	0	0	0	0
Gamma-glutamyltransferase increased	0	0	0	1 (11.1%)	1 (5.3%)	2 (7.1%)
Grade 1	0	0	0	1 (11.1%)	0	1 (3.6%)
Grade 3	0	0	0	0	1 (5.3%)	1 (3.6%)
Liver function test increased	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 3	0	0	0	0	1 (5.3%)	1 (3.6%)
Renal function analyses	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Renal function analyses (cont)						
(cont)						
Grade 3	1 (1.9%)	0	1 (1.4%)	0	0	0
Blood creatinine increased	3 (5.8%)	0	3 (4.3%)	2 (5.9%)	1 (9.1%)	3 (6.7%)
Grade 1	2 (3.8%)	0	2 (2.9%)	0	0	0
Grade 2	0	0	0	2 (5.9%)	1 (9.1%)	3 (6.7%)
Grade 3	1 (1.9%)	0	1 (1.4%)	0	0	0
Tissue enzyme analyses NEC	3 (5.8%)	0	3 (4.3%)	0	0	0
Grade 1	2 (3.8%)	0	2 (2.9%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Blood alkaline phosphatase increased	2 (3.8%)	0	2 (2.9%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Renal function analyses (cont)						
(cont)						
Grade 3	0	0	0	0	0	0
Blood creatinine increased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Tissue enzyme analyses NEC	0	1 (4.8%)	1 (2.9%)	1 (11.1%)	0	1 (3.6%)
Grade 1	0	1 (4.8%)	1 (2.9%)	1 (11.1%)	0	1 (3.6%)
Grade 2	0	0	0	0	0	0
Blood alkaline phosphatase increased	0	1 (4.8%)	1 (2.9%)	1 (11.1%)	0	1 (3.6%)
Grade 1	0	1 (4.8%)	1 (2.9%)	1 (11.1%)	0	1 (3.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Tissue enzyme analyses NEC (cont)						
Blood alkaline phosphatase increased (cont)						
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Blood lactate dehydrogenase increased	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Cardiac auscultatory investigations	2 (3.8%)	0	2 (2.9%)	0	0	0
Grade 1	2 (3.8%)	0	2 (2.9%)	0	0	0
Cardiac murmur	2 (3.8%)	0	2 (2.9%)	0	0	0
Grade 1	2 (3.8%)	0	2 (2.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Tissue enzyme analyses NEC (cont)						
Blood alkaline phosphatase increased (cont)						
Grade 2	0	0	0	0	0	0
Blood lactate dehydrogenase increased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Cardiac auscultatory investigations	0	0	0	1 (11.1%)	0	1 (3.6%)
Grade 1	0	0	0	1 (11.1%)	0	1 (3.6%)
Cardiac murmur	0	0	0	1 (11.1%)	0	1 (3.6%)
Grade 1	0	0	0	1 (11.1%)	0	1 (3.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Coagulation and bleeding analyses	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Grade 1	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Grade 2	0	0	0	0	0	0
International normalised ratio increased	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Grade 1	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Grade 2	0	0	0	0	0	0
Cardiac function diagnostic procedures	0	0	0	0	1 (9.1%)	1 (2.2%)
Grade 2	0	0	0	0	1 (9.1%)	1 (2.2%)
Ejection fraction decreased	0	0	0	0	1 (9.1%)	1 (2.2%)
Grade 2	0	0	0	0	1 (9.1%)	1 (2.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Coagulation and bleeding analyses	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (5.3%)	1 (3.6%)
International normalised ratio increased	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (5.3%)	1 (3.6%)
Cardiac function diagnostic procedures	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Ejection fraction decreased	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Mineral and electrolyte analyses	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 1	0	0	0	1 (2.9%)	0	1 (2.2%)
Blood bicarbonate decreased	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 1	0	0	0	1 (2.9%)	0	1 (2.2%)
Vascular tests NEC (incl blood pressure)	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (5.6%)	1 (1.4%)	0	0	0
Blood pressure increased	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (5.6%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Investigations (cont)						
Mineral and electrolyte analyses	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Blood bicarbonate decreased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Vascular tests NEC (incl blood pressure)	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Blood pressure increased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders	6 (11.5%)	1 (5.6%)	7 (10.0%)	4 (11.8%)	3 (27.3%)	7 (15.6%)
Grade 1	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	2 (18.2%)	3 (6.7%)
Grade 2	2 (3.8%)	0	2 (2.9%)	1 (2.9%)	1 (9.1%)	2 (4.4%)
Grade 3	2 (3.8%)	1 (5.6%)	3 (4.3%)	2 (5.9%)	0	2 (4.4%)
Grade 4	1 (1.9%)	0	1 (1.4%)	0	0	0
Vascular hypertensive disorders NEC	4 (7.7%)	0	4 (5.7%)	2 (5.9%)	0	2 (4.4%)
Grade 2	2 (3.8%)	0	2 (2.9%)	1 (2.9%)	0	1 (2.2%)
Grade 3	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Grade 4	1 (1.9%)	0	1 (1.4%)	0	0	0
Hypertension	4 (7.7%)	0	4 (5.7%)	2 (5.9%)	0	2 (4.4%)
Grade 2	2 (3.8%)	0	2 (2.9%)	1 (2.9%)	0	1 (2.2%)
Grade 3	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Grade 4	1 (1.9%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders	3 (21.4%)	1 (4.8%)	4 (11.4%)	0	3 (15.8%)	3 (10.7%)
Grade 1	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 2	2 (14.3%)	1 (4.8%)	3 (8.6%)	0	2 (10.5%)	2 (7.1%)
Grade 3	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 4	0	0	0	0	0	0
Vascular hypertensive disorders NEC	2 (14.3%)	0	2 (5.7%)	0	1 (5.3%)	1 (3.6%)
Grade 2	2 (14.3%)	0	2 (5.7%)	0	1 (5.3%)	1 (3.6%)
Grade 3	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Hypertension	2 (14.3%)	0	2 (5.7%)	0	1 (5.3%)	1 (3.6%)
Grade 2	2 (14.3%)	0	2 (5.7%)	0	1 (5.3%)	1 (3.6%)
Grade 3	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Vascular hypotensive disorders	1 (1.9%)	0	1 (1.4%)	0	2 (18.2%)	2 (4.4%)
Grade 1	1 (1.9%)	0	1 (1.4%)	0	1 (9.1%)	1 (2.2%)
Grade 2	0	0	0	0	1 (9.1%)	1 (2.2%)
Hypotension	0	0	0	0	2 (18.2%)	2 (4.4%)
Grade 1	0	0	0	0	1 (9.1%)	1 (2.2%)
Grade 2	0	0	0	0	1 (9.1%)	1 (2.2%)
Orthostatic hypotension	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Aortic necrosis and vascular insufficiency	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 3	1 (1.9%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Vascular hypotensive disorders	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 1	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Hypotension	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 1	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Orthostatic hypotension	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Aortic necrosis and vascular insufficiency	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Aortic necrosis and vascular insufficiency (cont)						
Aortic stenosis	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 3	1 (1.9%)	0	1 (1.4%)	0	0	0
Peripheral vascular disorders NEC	0	0	0	0	1 (9.1%)	1 (2.2%)
Grade 1	0	0	0	0	1 (9.1%)	1 (2.2%)
Hot flush	0	0	0	0	1 (9.1%)	1 (2.2%)
Grade 1	0	0	0	0	1 (9.1%)	1 (2.2%)
Haemorrhages NEC	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Haematoma	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Aortic necrosis and vascular insufficiency (cont)						
Aortic stenosis	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Peripheral vascular disorders NEC	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 1	1 (7.1%)	0	1 (2.9%)	0	0	0
Hot flush	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 1	1 (7.1%)	0	1 (2.9%)	0	0	0
Haemorrhages NEC	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 3	0	0	0	0	1 (5.3%)	1 (3.6%)
Haematoma	0	0	0	0	1 (5.3%)	1 (3.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Haemorrhages NEC (cont)						
Haematoma (cont)						
Grade 3	0	0	0	0	0	0
Non-site specific embolism and thrombosis	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 3	0	0	0	1 (2.9%)	0	1 (2.2%)
Embolism	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 3	0	0	0	1 (2.9%)	0	1 (2.2%)
Non-site specific necrosis and vascular insufficiency NEC	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Haemorrhages NEC (cont)						
Haematoma (cont)						
Grade 3	0	0	0	0	1 (5.3%)	1 (3.6%)
Non-site specific embolism and thrombosis	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Embolism	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Non-site specific necrosis and vascular insufficiency NEC	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 2	0	1 (4.8%)	1 (2.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Non-site specific necrosis and vascular insufficiency NEC (cont)						
Peripheral venous disease	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Non-site specific vascular disorders NEC	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 3	0	1 (5.6%)	1 (1.4%)	0	0	0
Arterial disorder	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 3	0	1 (5.6%)	1 (1.4%)	0	0	0
Peripheral embolism and thrombosis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Non-site specific necrosis and vascular insufficiency NEC (cont)						
Peripheral venous disease	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 2	0	1 (4.8%)	1 (2.9%)	0	0	0
Non-site specific vascular disorders NEC	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Arterial disorder	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Peripheral embolism and thrombosis	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 2	0	0	0	0	1 (5.3%)	1 (3.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Peripheral embolism and thrombosis (cont)						
Thrombophlebitis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Peripheral vasoconstriction, necrosis and vascular insufficiency	0	1 (5.6%)	1 (1.4%)	0	1 (9.1%)	1 (2.2%)
Grade 1	0	0	0	0	1 (9.1%)	1 (2.2%)
Grade 3	0	1 (5.6%)	1 (1.4%)	0	0	0
Diabetic vascular disorder	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 3	0	1 (5.6%)	1 (1.4%)	0	0	0
Peripheral coldness	0	0	0	0	1 (9.1%)	1 (2.2%)
Grade 1	0	0	0	0	1 (9.1%)	1 (2.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Peripheral embolism and thrombosis (cont)						
Thrombophlebitis	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 2	0	0	0	0	1 (5.3%)	1 (3.6%)
Peripheral vasoconstriction, necrosis and vascular insufficiency	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Diabetic vascular disorder	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Peripheral coldness	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Site specific vascular disorders NEC	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 1	0	0	0	1 (2.9%)	0	1 (2.2%)
Jugular vein distension	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 1	0	0	0	1 (2.9%)	0	1 (2.2%)
Cardiac disorders	6 (11.5%)	2 (11.1%)	8 (11.4%)	3 (8.8%)	1 (9.1%)	4 (8.9%)
Grade 1	0	0	0	0	0	0
Grade 2	1 (1.9%)	1 (5.6%)	2 (2.9%)	2 (5.9%)	0	2 (4.4%)
Grade 3	5 (9.6%)	1 (5.6%)	6 (8.6%)	0	1 (9.1%)	1 (2.2%)
Grade 4	0	0	0	1 (2.9%)	0	1 (2.2%)
Heart failures NEC	3 (5.8%)	0	3 (4.3%)	1 (2.9%)	1 (9.1%)	2 (4.4%)
Grade 2	0	0	0	0	0	0
Grade 3	3 (5.8%)	0	3 (4.3%)	1 (2.9%)	1 (9.1%)	2 (4.4%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Vascular disorders (cont)						
Site specific vascular disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Jugular vein distension	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Cardiac disorders	2 (14.3%)	3 (14.3%)	5 (14.3%)	1 (11.1%)	3 (15.8%)	4 (14.3%)
Grade 1	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	0	0
Grade 2	0	1 (4.8%)	1 (2.9%)	0	3 (15.8%)	3 (10.7%)
Grade 3	1 (7.1%)	1 (4.8%)	2 (5.7%)	1 (11.1%)	0	1 (3.6%)
Grade 4	0	0	0	0	0	0
Heart failures NEC	1 (7.1%)	1 (4.8%)	2 (5.7%)	1 (11.1%)	0	1 (3.6%)
Grade 2	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 3	1 (7.1%)	0	1 (2.9%)	1 (11.1%)	0	1 (3.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Heart failures NEC (cont)						
Cardiac failure	2 (3.8%)	0	2 (2.9%)	0	1 (9.1%)	1 (2.2%)
Grade 3	2 (3.8%)	0	2 (2.9%)	0	1 (9.1%)	1 (2.2%)
Cardiac failure congestive	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Grade 2	0	0	0	0	0	0
Grade 3	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Supraventricular arrhythmias	4 (7.7%)	1 (5.6%)	5 (7.1%)	3 (8.8%)	0	3 (6.7%)
Grade 2	1 (1.9%)	1 (5.6%)	2 (2.9%)	2 (5.9%)	0	2 (4.4%)
Grade 3	3 (5.8%)	0	3 (4.3%)	0	0	0
Grade 4	0	0	0	1 (2.9%)	0	1 (2.2%)
Atrial fibrillation	2 (3.8%)	1 (5.6%)	3 (4.3%)	1 (2.9%)	0	1 (2.2%)
Grade 2	1 (1.9%)	1 (5.6%)	2 (2.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Heart failures NEC (cont)						
Cardiac failure	1 (7.1%)	0	1 (2.9%)	1 (11.1%)	0	1 (3.6%)
Grade 3	1 (7.1%)	0	1 (2.9%)	1 (11.1%)	0	1 (3.6%)
Cardiac failure congestive	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 2	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 3	0	0	0	0	0	0
Supraventricular arrhythmias	0	1 (4.8%)	1 (2.9%)	0	1 (5.3%)	1 (3.6%)
Grade 2	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 3	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 4	0	0	0	0	0	0
Atrial fibrillation	0	1 (4.8%)	1 (2.9%)	0	1 (5.3%)	1 (3.6%)
Grade 2	0	0	0	0	1 (5.3%)	1 (3.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Supraventricular arrhythmias (cont)						
Atrial fibrillation (cont)						
Grade 3	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 4	0	0	0	1 (2.9%)	0	1 (2.2%)
Sinus tachycardia	1 (1.9%)	0	1 (1.4%)	2 (5.9%)	0	2 (4.4%)
Grade 2	0	0	0	2 (5.9%)	0	2 (4.4%)
Grade 3	1 (1.9%)	0	1 (1.4%)	0	0	0
Supraventricular tachycardia	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 3	1 (1.9%)	0	1 (1.4%)	0	0	0
Cardiac signs and symptoms NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Supraventricular arrhythmias (cont)						
Atrial fibrillation (cont)						
Grade 3	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 4	0	0	0	0	0	0
Sinus tachycardia	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Supraventricular tachycardia	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Cardiac signs and symptoms NEC	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	0	0
Grade 1	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Cardiac signs and symptoms NEC (cont)						
Palpitations	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Ischaemic coronary artery disorders	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Myocardial ischaemia	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Left ventricular failures	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Left ventricular failure	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Cardiac signs and symptoms NEC (cont)						
Palpitations	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	0	0
Grade 1	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	0	0
Ischaemic coronary artery disorders	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 2	0	0	0	0	1 (5.3%)	1 (3.6%)
Myocardial ischaemia	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 2	0	0	0	0	1 (5.3%)	1 (3.6%)
Left ventricular failures	0	0	0	1 (11.1%)	0	1 (3.6%)
Grade 2	0	0	0	1 (11.1%)	0	1 (3.6%)
Left ventricular failure	0	0	0	1 (11.1%)	0	1 (3.6%)
Grade 2	0	0	0	1 (11.1%)	0	1 (3.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Pericardial disorders NEC	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Pericardial effusion	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Rate and rhythm disorders NEC	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 3	0	1 (5.6%)	1 (1.4%)	0	0	0
Tachycardia	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 3	0	1 (5.6%)	1 (1.4%)	0	0	0
Psychiatric disorders	5 (9.6%)	2 (11.1%)	7 (10.0%)	3 (8.8%)	1 (9.1%)	4 (8.9%)
Grade 1	2 (3.8%)	2 (11.1%)	4 (5.7%)	1 (2.9%)	0	1 (2.2%)
Grade 2	3 (5.8%)	0	3 (4.3%)	2 (5.9%)	1 (9.1%)	3 (6.7%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Cardiac disorders (cont)						
Pericardial disorders NEC	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 2	0	0	0	0	1 (5.3%)	1 (3.6%)
Pericardial effusion	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 2	0	0	0	0	1 (5.3%)	1 (3.6%)
Rate and rhythm disorders NEC	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Tachycardia	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Psychiatric disorders	3 (21.4%)	3 (14.3%)	6 (17.1%)	0	4 (21.1%)	4 (14.3%)
Grade 1	2 (14.3%)	2 (9.5%)	4 (11.4%)	0	2 (10.5%)	2 (7.1%)
Grade 2	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	2 (10.5%)	2 (7.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Anxiety symptoms	3 (5.8%)	0	3 (4.3%)	1 (2.9%)	0	1 (2.2%)
Grade 1	3 (5.8%)	0	3 (4.3%)	0	0	0
Grade 2	0	0	0	1 (2.9%)	0	1 (2.2%)
Agitation	2 (3.8%)	0	2 (2.9%)	0	0	0
Grade 1	2 (3.8%)	0	2 (2.9%)	0	0	0
Anxiety	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	0	0	0	1 (2.9%)	0	1 (2.2%)
Depressive disorders	1 (1.9%)	1 (5.6%)	2 (2.9%)	0	0	0
Grade 1	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Anxiety symptoms	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (4.8%)	1 (2.9%)	0	0	0
Agitation	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Anxiety	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	1 (4.8%)	1 (2.9%)	0	0	0
Depressive disorders	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	1 (7.1%)	0	1 (2.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Depressive disorders (cont)						
Depression	1 (1.9%)	1 (5.6%)	2 (2.9%)	0	0	0
Grade 1	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Disturbances in initiating and maintaining sleep	1 (1.9%)	2 (11.1%)	3 (4.3%)	1 (2.9%)	0	1 (2.2%)
Grade 1	0	2 (11.1%)	2 (2.9%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Insomnia	1 (1.9%)	2 (11.1%)	3 (4.3%)	1 (2.9%)	0	1 (2.2%)
Grade 1	0	2 (11.1%)	2 (2.9%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Confusion and disorientation	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Depressive disorders (cont)						
Depression	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	1 (7.1%)	0	1 (2.9%)	0	0	0
Disturbances in initiating and maintaining sleep	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	2 (10.5%)	2 (7.1%)
Grade 1	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	1 (5.3%)	1 (3.6%)
Grade 2	0	0	0	0	1 (5.3%)	1 (3.6%)
Insomnia	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	2 (10.5%)	2 (7.1%)
Grade 1	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	1 (5.3%)	1 (3.6%)
Grade 2	0	0	0	0	1 (5.3%)	1 (3.6%)
Confusion and disorientation	0	1 (4.8%)	1 (2.9%)	0	2 (10.5%)	2 (7.1%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Confusion and disorientation (cont)						
(cont)						
Grade 1	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Confusional state	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Grade 1	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Emotional and mood disturbances NEC	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Irritability	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Confusion and disorientation (cont)						
(cont)						
Grade 1	0	1 (4.8%)	1 (2.9%)	0	1 (5.3%)	1 (3.6%)
Grade 2	0	0	0	0	1 (5.3%)	1 (3.6%)
Confusional state	0	1 (4.8%)	1 (2.9%)	0	2 (10.5%)	2 (7.1%)
Grade 1	0	1 (4.8%)	1 (2.9%)	0	1 (5.3%)	1 (3.6%)
Grade 2	0	0	0	0	1 (5.3%)	1 (3.6%)
Emotional and mood disturbances NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Irritability	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Increased physical activity levels	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Restlessness	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Deliria	0	0	0	0	1 (9.1%)	1 (2.2%)
Grade 2	0	0	0	0	1 (9.1%)	1 (2.2%)
Delirium	0	0	0	0	1 (9.1%)	1 (2.2%)
Grade 2	0	0	0	0	1 (9.1%)	1 (2.2%)
Mood alterations with depressive symptoms	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (5.6%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Increased physical activity levels	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	0	0
Grade 1	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	0	0
Restlessness	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	0	0
Grade 1	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	0	0
Deliria	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Delirium	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Mood alterations with depressive symptoms	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Mood alterations with depressive symptoms (cont) (cont)						
Grade 2	0	0	0	0	0	0
Depressed mood	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 2	0	0	0	0	0	0
Eye disorders	6 (11.5%)	2 (11.1%)	8 (11.4%)	0	1 (9.1%)	1 (2.2%)
Grade 1	3 (5.8%)	2 (11.1%)	5 (7.1%)	0	0	0
Grade 2	3 (5.8%)	0	3 (4.3%)	0	1 (9.1%)	1 (2.2%)
Cataract conditions	3 (5.8%)	0	3 (4.3%)	0	0	0
Grade 1	2 (3.8%)	0	2 (2.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Psychiatric disorders (cont)						
Mood alterations with depressive symptoms (cont)						
(cont)						
Grade 2	0	0	0	0	1 (5.3%)	1 (3.6%)
Depressed mood	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (5.3%)	1 (3.6%)
Eye disorders	1 (7.1%)	2 (9.5%)	3 (8.6%)	1 (11.1%)	1 (5.3%)	2 (7.1%)
Grade 1	1 (7.1%)	2 (9.5%)	3 (8.6%)	1 (11.1%)	1 (5.3%)	2 (7.1%)
Grade 2	0	0	0	0	0	0
Cataract conditions	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Cataract conditions (cont)						
(cont)						
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Cataract	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Cataract nuclear	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Cataract subcapsular	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase	RT Phase	RT Phase	ET Phase (Week 24 - 48) Continuing	ET Phase (Week 24 - 48) Switch	ET Phase (Week 24 - 48)
	MMB (N=14)	BAT (N=21)	Total (N=35)	(MMB->MMB) (N=9)	(BAT->MMB) (N=19)	Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Cataract conditions (cont)						
(cont)						
Grade 2	0	0	0	0	0	0
Cataract	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Cataract nuclear	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Cataract subcapsular	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Conjunctival and corneal bleeding and vascular disorders	1 (1.9%)	1 (5.6%)	2 (2.9%)	0	0	0
Grade 1	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Conjunctival haemorrhage	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Corneal bleeding	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (5.6%)	1 (1.4%)	0	0	0
Visual disorders NEC	2 (3.8%)	0	2 (2.9%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Conjunctival and corneal bleeding and vascular disorders	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	0	0
Grade 1	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	0	0
Grade 2	0	0	0	0	0	0
Conjunctival haemorrhage	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	0	0
Grade 1	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	0	0
Grade 2	0	0	0	0	0	0
Corneal bleeding	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Visual disorders NEC	0	0	0	1 (11.1%)	1 (5.3%)	2 (7.1%)
Grade 1	0	0	0	1 (11.1%)	1 (5.3%)	2 (7.1%)
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Visual disorders NEC (cont)						
Vision blurred	2 (3.8%)	0	2 (2.9%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Photopsia	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Lacrimation disorders	1 (1.9%)	0	1 (1.4%)	0	1 (9.1%)	1 (2.2%)
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	0	0	0	0	1 (9.1%)	1 (2.2%)
Lacrimation increased	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Visual disorders NEC (cont)						
Vision blurred	0	0	0	1 (11.1%)	0	1 (3.6%)
Grade 1	0	0	0	1 (11.1%)	0	1 (3.6%)
Grade 2	0	0	0	0	0	0
Photopsia	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 1	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 2	0	0	0	0	0	0
Lacrimation disorders	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 1	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 2	0	0	0	0	0	0
Lacrimation increased	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Lacrimation disorders (cont)						
Dry eye	0	0	0	0	1 (9.1%)	1 (2.2%)
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (9.1%)	1 (2.2%)
Ocular infections, inflammations and associated manifestations	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (5.6%)	1 (1.4%)	0	0	0
Ocular hyperaemia	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (5.6%)	1 (1.4%)	0	0	0
Retinal structural change, deposit and degeneration	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (5.6%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Lacrimation disorders (cont)						
Dry eye	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 1	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 2	0	0	0	0	0	0
Ocular infections, inflammations and associated manifestations	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Ocular hyperaemia	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Retinal structural change, deposit and degeneration	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Retinal structural change, deposit and degeneration (cont)						
Myopic chorioretinal degeneration	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (5.6%)	1 (1.4%)	0	0	0
Visual impairment and blindness (excl colour blindness)	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Visual acuity reduced	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Eye disorders (cont)						
Retinal structural change, deposit and degeneration (cont)						
Myopic chorioretinal degeneration	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Visual impairment and blindness (excl colour blindness)	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 1	0	1 (4.8%)	1 (2.9%)	0	0	0
Visual acuity reduced	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 1	0	1 (4.8%)	1 (2.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications	3 (5.8%)	1 (5.6%)	4 (5.7%)	1 (2.9%)	2 (18.2%)	3 (6.7%)
Grade 1	2 (3.8%)	0	2 (2.9%)	1 (2.9%)	1 (9.1%)	2 (4.4%)
Grade 2	1 (1.9%)	1 (5.6%)	2 (2.9%)	0	1 (9.1%)	1 (2.2%)
Grade 3	0	0	0	0	0	0
Skin injuries NEC	2 (3.8%)	0	2 (2.9%)	0	1 (9.1%)	1 (2.2%)
Grade 1	2 (3.8%)	0	2 (2.9%)	0	1 (9.1%)	1 (2.2%)
Grade 2	0	0	0	0	0	0
Contusion	2 (3.8%)	0	2 (2.9%)	0	1 (9.1%)	1 (2.2%)
Grade 1	2 (3.8%)	0	2 (2.9%)	0	1 (9.1%)	1 (2.2%)
Grade 2	0	0	0	0	0	0
Limb fractures and dislocations	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications	4 (28.6%)	3 (14.3%)	7 (20.0%)	1 (11.1%)	0	1 (3.6%)
Grade 1	3 (21.4%)	2 (9.5%)	5 (14.3%)	1 (11.1%)	0	1 (3.6%)
Grade 2	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 3	1 (7.1%)	0	1 (2.9%)	0	0	0
Skin injuries NEC	3 (21.4%)	3 (14.3%)	6 (17.1%)	0	0	0
Grade 1	3 (21.4%)	2 (9.5%)	5 (14.3%)	0	0	0
Grade 2	0	1 (4.8%)	1 (2.9%)	0	0	0
Contusion	3 (21.4%)	3 (14.3%)	6 (17.1%)	0	0	0
Grade 1	3 (21.4%)	2 (9.5%)	5 (14.3%)	0	0	0
Grade 2	0	1 (4.8%)	1 (2.9%)	0	0	0
Limb fractures and dislocations	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Limb fractures and dislocations (cont) (cont)						
Grade 3	0	0	0	0	0	0
Femur fracture	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Radius fracture	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Non-site specific injuries NEC	1 (1.9%)	1 (5.6%)	2 (2.9%)	1 (2.9%)	0	1 (2.2%)
Grade 1	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 2	1 (1.9%)	1 (5.6%)	2 (2.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Limb fractures and dislocations (cont) (cont)						
Grade 3	1 (7.1%)	0	1 (2.9%)	0	0	0
Femur fracture	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 3	1 (7.1%)	0	1 (2.9%)	0	0	0
Radius fracture	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Non-site specific injuries NEC	0	2 (9.5%)	2 (5.7%)	1 (11.1%)	0	1 (3.6%)
Grade 1	0	2 (9.5%)	2 (5.7%)	1 (11.1%)	0	1 (3.6%)
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Non-site specific injuries NEC (cont)						
Fall	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Grade 1	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Post-traumatic pain	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 2	0	1 (5.6%)	1 (1.4%)	0	0	0
Muscle, tendon and ligament injuries	0	0	0	0	1 (9.1%)	1 (2.2%)
Grade 2	0	0	0	0	1 (9.1%)	1 (2.2%)
Muscle rupture	0	0	0	0	1 (9.1%)	1 (2.2%)
Grade 2	0	0	0	0	1 (9.1%)	1 (2.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase	RT Phase	RT Phase	ET Phase (Week 24 - 48) Continuing	ET Phase (Week 24 - 48) Switch	ET Phase (Week 24 - 48)
	MMB (N=14)	BAT (N=21)	Total (N=35)	(MMB->MMB) (N=9)	(BAT->MMB) (N=19)	Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Non-site specific injuries NEC (cont)						
Fall	0	2 (9.5%)	2 (5.7%)	1 (11.1%)	0	1 (3.6%)
Grade 1	0	2 (9.5%)	2 (5.7%)	1 (11.1%)	0	1 (3.6%)
Grade 2	0	0	0	0	0	0
Post-traumatic pain	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Muscle, tendon and ligament injuries	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Muscle rupture	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Non-site specific procedural complications	0	0	0	0	1 (9.1%)	1 (2.2%)
Grade 1	0	0	0	0	1 (9.1%)	1 (2.2%)
Procedural pain	0	0	0	0	1 (9.1%)	1 (2.2%)
Grade 1	0	0	0	0	1 (9.1%)	1 (2.2%)
Site specific injuries NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Limb injury	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Injury, poisoning and procedural complications (cont)						
Non-site specific procedural complications	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Procedural pain	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Site specific injuries NEC	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 1	0	1 (4.8%)	1 (2.9%)	0	0	0
Limb injury	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 1	0	1 (4.8%)	1 (2.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (5.8%)	3 (16.7%)	6 (8.6%)	3 (8.8%)	0	3 (6.7%)
Grade 1	0	0	0	0	0	0
Grade 2	2 (3.8%)	1 (5.6%)	3 (4.3%)	2 (5.9%)	0	2 (4.4%)
Grade 3	0	1 (5.6%)	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Grade 4	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 5	0	1 (5.6%)	1 (1.4%)	0	0	0
Skin neoplasms malignant and unspecified (excl melanoma)	0	1 (5.6%)	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Grade 2	0	1 (5.6%)	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Basal cell carcinoma	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Bowen's disease	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4 (28.6%)	1 (4.8%)	5 (14.3%)	0	0	0
Grade 1	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 2	2 (14.3%)	0	2 (5.7%)	0	0	0
Grade 3	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Grade 5	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	0	0
Skin neoplasms malignant and unspecified (excl melanoma)	2 (14.3%)	0	2 (5.7%)	0	0	0
Grade 2	2 (14.3%)	0	2 (5.7%)	0	0	0
Basal cell carcinoma	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 2	1 (7.1%)	0	1 (2.9%)	0	0	0
Bowen's disease	1 (7.1%)	0	1 (2.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Skin neoplasms malignant and unspecified (excl melanoma) (cont)						
Bowen's disease (cont)						
Grade 2	0	0	0	0	0	0
Carcinoma in situ of skin	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Squamous cell carcinoma of skin	0	1 (5.6%)	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Grade 2	0	1 (5.6%)	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Bladder neoplasms malignant	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase	RT Phase	RT Phase	ET Phase (Week 24 - 48) Continuing	ET Phase (Week 24 - 48) Switch	ET Phase (Week 24 - 48)
	MMB (N=14)	BAT (N=21)	Total (N=35)	(MMB->MMB) (N=9)	(BAT->MMB) (N=19)	Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Skin neoplasms malignant and unspecified (excl melanoma) (cont)						
Bowen's disease (cont)						
Grade 2	1 (7.1%)	0	1 (2.9%)	0	0	0
Carcinoma in situ of skin	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 2	1 (7.1%)	0	1 (2.9%)	0	0	0
Squamous cell carcinoma of skin	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 2	1 (7.1%)	0	1 (2.9%)	0	0	0
Bladder neoplasms malignant	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Bladder neoplasms malignant (cont)						
Bladder cancer	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Leukaemias NEC	1 (1.9%)	1 (5.6%)	2 (2.9%)	1 (2.9%)	0	1 (2.2%)
Grade 3	0	1 (5.6%)	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Grade 4	1 (1.9%)	0	1 (1.4%)	0	0	0
Leukaemia	1 (1.9%)	1 (5.6%)	2 (2.9%)	1 (2.9%)	0	1 (2.2%)
Grade 3	0	1 (5.6%)	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Grade 4	1 (1.9%)	0	1 (1.4%)	0	0	0
Leukaemias acute myeloid	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Bladder neoplasms malignant (cont)						
Bladder cancer	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Leukaemias NEC	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Leukaemia	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0
Leukaemias acute myeloid	1 (7.1%)	0	1 (2.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cists and polyps) (cont)						
Leukaemias acute myeloid (cont) (cont)						
Grade 5	0	0	0	0	0	0
Acute myeloid leukaemia	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Upper gastrointestinal neoplasms benign	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Oesophageal papilloma	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cts and polyps) (cont)						
Leukaemias acute myeloid (cont)						
(cont)						
Grade 5	1 (7.1%)	0	1 (2.9%)	0	0	0
Acute myeloid leukaemia	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 5	1 (7.1%)	0	1 (2.9%)	0	0	0
Upper gastrointestinal neoplasms benign	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 1	1 (7.1%)	0	1 (2.9%)	0	0	0
Oesophageal papilloma	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 1	1 (7.1%)	0	1 (2.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Urinary tract neoplasms malignant NEC	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Transitional cell carcinoma	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Myeloproliferative disorders (excl leukaemias)	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Myelofibrosis	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Urinary tract neoplasms malignant NEC	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Transitional cell carcinoma	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Myeloproliferative disorders (excl leukaemias)	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 5	0	1 (4.8%)	1 (2.9%)	0	0	0
Myelofibrosis	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 5	0	1 (4.8%)	1 (2.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Non-small cell neoplasms malignant of the respiratory tract cell type specified	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 5	0	1 (5.6%)	1 (1.4%)	0	0	0
Lung adenocarcinoma	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 5	0	1 (5.6%)	1 (1.4%)	0	0	0
Urinary tract neoplasms unspecified malignancy NEC	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 2	0	0	0	1 (2.9%)	0	1 (2.2%)
Bladder neoplasm	0	0	0	1 (2.9%)	0	1 (2.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Non-small cell neoplasms malignant of the respiratory tract cell type specified	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Lung adenocarcinoma	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Urinary tract neoplasms unspecified malignancy NEC	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Bladder neoplasm	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Urinary tract neoplasms unspecified malignancy NEC (cont)						
Bladder neoplasm (cont)						
Grade 2	0	0	0	1 (2.9%)	0	1 (2.2%)
Renal and urinary disorders	5 (9.6%)	1 (5.6%)	6 (8.6%)	5 (14.7%)	2 (18.2%)	7 (15.6%)
Grade 1	2 (3.8%)	0	2 (2.9%)	0	0	0
Grade 2	2 (3.8%)	0	2 (2.9%)	4 (11.8%)	1 (9.1%)	5 (11.1%)
Grade 3	1 (1.9%)	1 (5.6%)	2 (2.9%)	1 (2.9%)	1 (9.1%)	2 (4.4%)
Renal failure and impairment	3 (5.8%)	1 (5.6%)	4 (5.7%)	3 (8.8%)	2 (18.2%)	5 (11.1%)
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	2 (3.8%)	0	2 (2.9%)	3 (8.8%)	1 (9.1%)	4 (8.9%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)						
Urinary tract neoplasms unspecified malignancy NEC (cont)						
Bladder neoplasm (cont)						
Grade 2	0	0	0	0	0	0
Renal and urinary disorders	0	2 (9.5%)	2 (5.7%)	2 (22.2%)	3 (15.8%)	5 (17.9%)
Grade 1	0	1 (4.8%)	1 (2.9%)	1 (11.1%)	3 (15.8%)	4 (14.3%)
Grade 2	0	1 (4.8%)	1 (2.9%)	1 (11.1%)	0	1 (3.6%)
Grade 3	0	0	0	0	0	0
Renal failure and impairment	0	1 (4.8%)	1 (2.9%)	0	2 (10.5%)	2 (7.1%)
Grade 1	0	0	0	0	2 (10.5%)	2 (7.1%)
Grade 2	0	1 (4.8%)	1 (2.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Renal failure and impairment (cont)						
(cont)						
Grade 3	0	1 (5.6%)	1 (1.4%)	0	1 (9.1%)	1 (2.2%)
Acute kidney injury	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Grade 1	0	0	0	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Renal failure	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	1 (9.1%)	2 (4.4%)
Grade 1	0	0	0	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	1 (9.1%)	2 (4.4%)
Renal impairment	1 (1.9%)	1 (5.6%)	2 (2.9%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 3	0	1 (5.6%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Renal failure and impairment (cont)						
(cont)						
Grade 3	0	0	0	0	0	0
Acute kidney injury	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 1	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 2	0	0	0	0	0	0
Renal failure	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 1	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 2	0	0	0	0	0	0
Renal impairment	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Renal failure and impairment (cont)						
Chronic kidney disease	0	0	0	1 (2.9%)	1 (9.1%)	2 (4.4%)
Grade 2	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 3	0	0	0	0	1 (9.1%)	1 (2.2%)
Bladder and urethral symptoms	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	0	0	0	0	0	0
Micturition urgency	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Dysuria	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Renal failure and impairment (cont)						
Chronic kidney disease	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 2	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 3	0	0	0	0	0	0
Bladder and urethral symptoms	0	1 (4.8%)	1 (2.9%)	2 (22.2%)	1 (5.3%)	3 (10.7%)
Grade 1	0	1 (4.8%)	1 (2.9%)	1 (11.1%)	1 (5.3%)	2 (7.1%)
Grade 2	0	0	0	1 (11.1%)	0	1 (3.6%)
Micturition urgency	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Dysuria	0	0	0	2 (22.2%)	0	2 (7.1%)
Grade 1	0	0	0	1 (11.1%)	0	1 (3.6%)
Grade 2	0	0	0	1 (11.1%)	0	1 (3.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Bladder and urethral symptoms (cont)						
Pollakiuria	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Urinary incontinence	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Renal lithiasis	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Grade 2	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 3	1 (1.9%)	0	1 (1.4%)	0	0	0
Nephrolithiasis	1 (1.9%)	0	1 (1.4%)	1 (2.9%)	0	1 (2.2%)
Grade 2	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 3	1 (1.9%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Bladder and urethral symptoms (cont)						
Pollakiuria	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 1	0	1 (4.8%)	1 (2.9%)	0	0	0
Urinary incontinence	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 1	0	0	0	0	1 (5.3%)	1 (3.6%)
Renal lithiasis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Nephrolithiasis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Urinary abnormalities	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Haematuria	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Urinary tract signs and symptoms NEC	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Renal colic	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Renal neoplasms	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 1	0	0	0	1 (2.9%)	0	1 (2.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Urinary abnormalities	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Haematuria	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Urinary tract signs and symptoms NEC	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Renal colic	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Renal neoplasms	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Renal neoplasms (cont)						
Renal cyst	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 1	0	0	0	1 (2.9%)	0	1 (2.2%)
Urinary tract lithiasis (excl renal)	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 3	0	0	0	1 (2.9%)	0	1 (2.2%)
Ureterolithiasis	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 3	0	0	0	1 (2.9%)	0	1 (2.2%)
Ear and labyrinth disorders	1 (1.9%)	1 (5.6%)	2 (2.9%)	1 (2.9%)	0	1 (2.2%)
Grade 1	1 (1.9%)	1 (5.6%)	2 (2.9%)	0	0	0
Grade 2	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 3	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Renal and urinary disorders (cont)						
Renal neoplasms (cont)						
Renal cyst	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Urinary tract lithiasis (excl renal)	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Ureterolithiasis	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Ear and labyrinth disorders	2 (14.3%)	1 (4.8%)	3 (8.6%)	1 (11.1%)	2 (10.5%)	3 (10.7%)
Grade 1	1 (7.1%)	0	1 (2.9%)	0	2 (10.5%)	2 (7.1%)
Grade 2	1 (7.1%)	0	1 (2.9%)	1 (11.1%)	0	1 (3.6%)
Grade 3	0	1 (4.8%)	1 (2.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Ear and labyrinth disorders (cont)						
Inner ear signs and symptoms	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0
Tinnitus	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Vertigo	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 3	0	0	0	0	0	0
Ear disorders NEC	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (5.6%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Ear and labyrinth disorders (cont)						
Inner ear signs and symptoms	2 (14.3%)	1 (4.8%)	3 (8.6%)	0	1 (5.3%)	1 (3.6%)
Grade 1	1 (7.1%)	0	1 (2.9%)	0	1 (5.3%)	1 (3.6%)
Grade 2	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 3	0	1 (4.8%)	1 (2.9%)	0	0	0
Tinnitus	2 (14.3%)	0	2 (5.7%)	0	0	0
Grade 1	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 2	1 (7.1%)	0	1 (2.9%)	0	0	0
Vertigo	0	1 (4.8%)	1 (2.9%)	0	1 (5.3%)	1 (3.6%)
Grade 1	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 3	0	1 (4.8%)	1 (2.9%)	0	0	0
Ear disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Ear and labyrinth disorders (cont)						
Ear disorders NEC (cont)						
Ear discomfort	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (5.6%)	1 (1.4%)	0	0	0
Hearing losses	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Deafness bilateral	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hypoacusis	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Inner ear disorders NEC	0	0	0	1 (2.9%)	0	1 (2.2%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Ear and labyrinth disorders (cont)						
Ear disorders NEC (cont)						
Ear discomfort	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hearing losses	0	0	0	1 (11.1%)	1 (5.3%)	2 (7.1%)
Grade 1	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 2	0	0	0	1 (11.1%)	0	1 (3.6%)
Deafness bilateral	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 1	0	0	0	0	1 (5.3%)	1 (3.6%)
Hypoacusis	0	0	0	1 (11.1%)	0	1 (3.6%)
Grade 2	0	0	0	1 (11.1%)	0	1 (3.6%)
Inner ear disorders NEC	0	1 (4.8%)	1 (2.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Ear and labyrinth disorders (cont)						
Inner ear disorders NEC (cont)						
(cont)						
Grade 2	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 3	0	0	0	0	0	0
Vestibular disorder	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 2	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 3	0	0	0	0	0	0
Reproductive system and breast disorders	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Breast signs and symptoms	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Ear and labyrinth disorders (cont)						
Inner ear disorders NEC (cont)						
(cont)						
Grade 2	0	0	0	0	0	0
Grade 3	0	1 (4.8%)	1 (2.9%)	0	0	0
Vestibular disorder	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 2	0	0	0	0	0	0
Grade 3	0	1 (4.8%)	1 (2.9%)	0	0	0
Reproductive system and breast disorders	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	0	0
Grade 1	1 (7.1%)	1 (4.8%)	2 (5.7%)	0	0	0
Grade 2	0	0	0	0	0	0
Breast signs and symptoms	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 1	1 (7.1%)	0	1 (2.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Reproductive system and breast disorders (cont)						
Breast signs and symptoms (cont)						
Breast pain	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Prostatic neoplasms and hypertrophy	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Benign prostatic hyperplasia	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 2	1 (1.9%)	0	1 (1.4%)	0	0	0
Vulvovaginal disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Vaginal haemorrhage	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Reproductive system and breast disorders (cont)						
Breast signs and symptoms (cont)						
Breast pain	1 (7.1%)	0	1 (2.9%)	0	0	0
Grade 1	1 (7.1%)	0	1 (2.9%)	0	0	0
Prostatic neoplasms and hypertrophy	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Benign prostatic hyperplasia	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Vulvovaginal disorders NEC	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 1	0	1 (4.8%)	1 (2.9%)	0	0	0
Vaginal haemorrhage	0	1 (4.8%)	1 (2.9%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Reproductive system and breast disorders (cont)						
Vulvovaginal disorders NEC (cont)						
Vaginal haemorrhage (cont)						
Grade 1	0	0	0	0	0	0
Endocrine disorders	1 (1.9%)	0	1 (1.4%)	2 (5.9%)	1 (9.1%)	3 (6.7%)
Grade 1	0	0	0	0	1 (9.1%)	1 (2.2%)
Grade 2	1 (1.9%)	0	1 (1.4%)	2 (5.9%)	0	2 (4.4%)
Thyroid hypofunction disorders	1 (1.9%)	0	1 (1.4%)	2 (5.9%)	0	2 (4.4%)
Grade 2	1 (1.9%)	0	1 (1.4%)	2 (5.9%)	0	2 (4.4%)
Hypothyroidism	1 (1.9%)	0	1 (1.4%)	2 (5.9%)	0	2 (4.4%)
Grade 2	1 (1.9%)	0	1 (1.4%)	2 (5.9%)	0	2 (4.4%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Reproductive system and breast disorders (cont)						
Vulvovaginal disorders NEC (cont)						
Vaginal haemorrhage (cont)						
Grade 1	0	1 (4.8%)	1 (2.9%)	0	0	0
Endocrine disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Thyroid hypofunction disorders	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0
Hypothyroidism	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Endocrine disorders (cont)						
Thyroid disorders NEC	0	0	0	0	1 (9.1%)	1 (2.2%)
Grade 1	0	0	0	0	1 (9.1%)	1 (2.2%)
Thyroid mass	0	0	0	0	1 (9.1%)	1 (2.2%)
Grade 1	0	0	0	0	1 (9.1%)	1 (2.2%)
Hepatobiliary disorders	1 (1.9%)	1 (5.6%)	2 (2.9%)	1 (2.9%)	0	1 (2.2%)
Grade 1	1 (1.9%)	1 (5.6%)	2 (2.9%)	0	0	0
Grade 5	0	0	0	1 (2.9%)	0	1 (2.2%)
Hepatic vascular disorders	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0
Portal hypertension	1 (1.9%)	0	1 (1.4%)	0	0	0
Grade 1	1 (1.9%)	0	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Endocrine disorders (cont)						
Thyroid disorders NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Thyroid mass	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hepatobiliary disorders	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 1	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 5	0	0	0	0	0	0
Hepatic vascular disorders	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Portal hypertension	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Hepatobiliary disorders (cont)						
Cholestasis and jaundice	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Ocular icterus	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Hepatic failure and associated disorders	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 5	0	0	0	1 (2.9%)	0	1 (2.2%)
Hepatic failure	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 5	0	0	0	1 (2.9%)	0	1 (2.2%)
Hepatobiliary signs and symptoms	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (5.6%)	1 (1.4%)	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Hepatobiliary disorders (cont)						
Cholestasis and jaundice	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 1	0	1 (4.8%)	1 (2.9%)	0	0	0
Ocular icterus	0	1 (4.8%)	1 (2.9%)	0	0	0
Grade 1	0	1 (4.8%)	1 (2.9%)	0	0	0
Hepatic failure and associated disorders	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Hepatic failure	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0
Hepatobiliary signs and symptoms	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Hepatobiliary disorders (cont)						
Hepatobiliary signs and symptoms (cont)						
Hepatomegaly	0	1 (5.6%)	1 (1.4%)	0	0	0
Grade 1	0	1 (5.6%)	1 (1.4%)	0	0	0
Immune system disorders	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 1	0	0	0	1 (2.9%)	0	1 (2.2%)
Allergic conditions NEC	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 1	0	0	0	1 (2.9%)	0	1 (2.2%)
Allergic oedema	0	0	0	1 (2.9%)	0	1 (2.2%)
Grade 1	0	0	0	1 (2.9%)	0	1 (2.2%)
Allergies to foods, food additives, drugs and other chemicals	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019
Source: /mnt/code/SSAP/G-BA/prod/tfls/t-ae-hlt-tox.sas V.03.05 Output file: t-teae-sex-rt.pdf 24AUG2023:15:00

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Hepatobiliary disorders (cont)						
Hepatobiliary signs and symptoms (cont)						
Hepatomegaly	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Immune system disorders	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 1	0	0	0	0	1 (5.3%)	1 (3.6%)
Allergic conditions NEC	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Allergic oedema	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0
Allergies to foods, food additives, drugs and other chemicals	0	0	0	0	1 (5.3%)	1 (3.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

	Male					
	RT Phase MMB (N=52)	RT Phase BAT (N=18)	RT Phase Total (N=70)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=34)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=11)	ET Phase (Week 24 - 48) Total (N=45)
Number of Subjects with Any Treatment-Emergent AE	52 (100.0%)	16 (88.9%)	68 (97.1%)	32 (94.1%)	11 (100.0%)	43 (95.6%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Immune system disorders (cont)						
Allergies to foods, food additives, drugs and other chemicals (cont) (cont)						
Grade 1	0	0	0	0	0	0
Drug hypersensitivity	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019

Table 3.0401: TEAEs by SOC, HLT, PT and Severity by Gender
Randomized Treatment Phase, and First 24 Weeks in Extended Treatment Phase
SAF-Anemic Analysis Set

(Continued)	Female					
	RT Phase MMB (N=14)	RT Phase BAT (N=21)	RT Phase Total (N=35)	ET Phase (Week 24 - 48) Continuing (MMB->MMB) (N=9)	ET Phase (Week 24 - 48) Switch (BAT->MMB) (N=19)	ET Phase (Week 24 - 48) Total (N=28)
Number of Subjects with Any Treatment-Emergent AE	14 (100.0%)	19 (90.5%)	33 (94.3%)	8 (88.9%)	19 (100.0%)	27 (96.4%)
Number of Subjects with Treatment-Emergent AE, By System Organ Class, High Level Term, Preferred Term And Highest Grade						
Immune system disorders (cont)						
Allergies to foods, food additives, drugs and other chemicals (cont) (cont)						
Grade 1	0	0	0	0	1 (5.3%)	1 (3.6%)
Drug hypersensitivity	0	0	0	0	1 (5.3%)	1 (3.6%)
Grade 1	0	0	0	0	1 (5.3%)	1 (3.6%)

SAF-Anemic Analysis Set includes subjects in the Safety Population with Baseline Hemoglobin < 10 g/dL.
Adverse events were mapped according to MedDRA Version 22.0.
Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
SOCs, HLTs (within each SOC), PTs (within each SOC) were presented by descending order of frequency under "MMB" column.
TEAE = Treatment-Emergent Adverse Event; SOC = System Organ Class; HLT = High Level Term; PT = Preferred Term;

Data Extracted: CRF data: 25JUN2019